Note: This file consolidates the individual titles of the Public Health Service Act. The currency notes contained herein are specific to the titles in which they appear.

PUBLIC HEALTH SERVICE ACT

As Amended Through P.L. 112–240, Enacted January 2, 2013

TITLE I—SHORT TITLE AND DEFINITIONS

SHORT TITLE.

SECTION 1.[201 note] This Act may be cited as the "Public Health Service Act".

DEFINITIONS.

SEC. 2.[201] When used in this Act—

(a) The term "Service" means the Public Health Service;

(b) The term "Surgeon General" means the Surgeon General of the Public Health Service;

(c) Unless the context otherwise requires, the term "Secretary" means the Secretary of Health and Human Services;

(d) The term "regulations", except when otherwise specified, means rules and regulations made by the Surgeon General with the approval of the Secretary;

(e) The term "executive department" means any executive department, agency, or independent establishment of the United States or any corporation wholly owned by the United States;

(f) Except as provided in sections 314(g)(4)(B), 318(c)(1), 331(h)(3), 335(5), 361(d), 701(9), 1002(c), 1401(13), 1531(1), and 1633(1), the term "State" includes, in addition to the several States, only the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, American Samoa, and the Trust Territory of the Pacific Islands.

(g) The term "possession" includes, among other possessions, Puerto Rico and the Virgin Islands;

(h)

(i) The term "vessel" includes every description of watercraft or other artificial contrivance used, or capable of being used, as a means of transportation on water, exclusive of aircraft and amphibious contrivances;

(j) The term "habit-forming narcotic drug" or "narcotic" means opium and coca leaves and the several alkaloids derived therefrom, the best known of these alkaloids being morphia, heroin, and codeine, obtained from opium, and cocaine derived from the coca plant; all compounds, salts, preparations, or other derivatives obtained either from the raw material or from the various alkaloids; Indian hemp and its various derivatives, compounds, and preparations, and peyote in its various forms; isonipecaine and its derivatives, compounds, salts and preparations; opiates (as defined in section 3228(f) of the Internal Revenue Code);

(k) The term "addict" means any person who habitually uses any habit-forming narcotic drugs so as to endanger the public morals, health, safety, or welfare, or who is or has been so far addicted to the use of such habit-forming narcotic drugs as to have lost the power of self-control with reference to his addiction;

(l) The term "psychiatric disorders" includes diseases of the nervous system which affect mental health;

(m) The term "State mental health authority" means the State health authority, except that, in the case of any State in which there is a single State agency, other than the State health authority, charged with responsibility for administering the mental health program of the State, it means such other State agency;

(n) The term "heart diseases" means diseases of the heart and circulation;

(o) The term "dental diseases and conditions" means diseases and conditions affecting teeth and their supporting structures, and other related diseases of the mouth;

(p) The term "uniformed service" means the Army, Navy, Air Force, Marine Corps, Coast Guard, Public Health Service, or Coast and Geodetic Survey; and

(q) The term "drug dependent person" means a person who is using a controlled substance (as defined in section 102 of the Controlled Substances Act) and who is in a state of psychic or physical dependence, or both, arising from the use of that substance on a continuous basis. Drug dependence is characterized by behavioral and other responses which include a strong compulsion to take the substance on a continuous basis in order to experience its psychic effects or to avoid the discomfort caused by its absence.

PUBLIC HEALTH SERVICE ACT

As Amended Through P.L. 112–240, Enacted January 2, 2013

TITLE II—ADMINISTRATION AND MISCELLANEOUS PROVISIONS

PART A—ADMINISTRATION

PUBLIC HEALTH SERVICE.

SEC. 201.[202] The Public Health Service in the Department of Health and Human Services shall be administered by the Assistant Secretary for Health under the supervision and direction of the Secretary.

ORGANIZATION.

SEC. 202.[1][203] The Service shall consist of (1) the Office of the Surgeon General, (2) the National Institutes of Health, (3) the Bureau of Medical Services, and (4) the Bureau of State Services, and the Agency for Health Care Policy and Research.[2] The Secretary is authorized and directed to assign to the Office of the Secretary, to the National Institutes of Health, to the Bureau of Medical Services, and to the Bureau of State Services, respectively, the several functions of the Service, and to establish within them such divisions, sections and other units as he may find necessary; and from time to time, abolish, transfer, and consolidate divisions, sections, and other units and assign their functions and personnel in such manner as he may find necessary for efficient operation of the Service. No division shall be established, abolished, or transferred, and no divisions shall be consolidated, except with the approval of the Secretary. The National Institutes of Health shall be administered as a part of the field service. The Secretary may delegate to any officer or employee of the Service such of his powers and duties

[1] The organizational units specified in this section, other than the Agency for Health Care Policy and Research, were all abolished as *statutory* entities by Reorganization Plan No. 3 of 1966. Although the Reorganization Plan abolished the National Institutes of Health as an agency, it did not abolish the individual research institutes.

In 1985, Public Law 99–158 added title IV of this Act, which provides that the National Institutes of Health is an agency of the Public Health Service. See section 401(a).

Other laws have established additional agencies within the Service. Section 501(a) of this Act provides that the Substance Abuse and Mental Health Services Administration is an agency of the Service. Section 901(a) establishes the Agency for Healthcare Research and Quality within the Service (formerly designated as the Agency for Health Care Policy and Research).

Although not established in this Act, the Centers for Disease Control and Prevention, the Health Resources and Services Administration, and the Agency for Toxic Substances and Disease Registry are agencies of the Service.

The Food and Drug Administration is also an agency of the Service.

[2] So in law. See section 2008(g)(2) of Public Law 103–43 (107 Stat. 212). The term "the Agency" probably should be preceded by "(5)", and the "and" before "(4)" probably should be struck. Further, Public Law 106–129 redesignated the Agency for Health Care Policy and Research as the Agency for Healthcare Research and Quality (see 113 Stat. 1653).

under this Act, except the making of regulations, as he may deem necessary or expedient.

SEC. 203.[204] COMMISSIONED CORPS AND READY RESERVE CORPS.

(a) ESTABLISHMENT.—

(1) IN GENERAL.—There shall be in the Service a commissioned Regular Corps and a Ready Reserve Corps for service in time of national emergency.

(2) REQUIREMENT.—All commissioned officers shall be citizens of the United States and shall be appointed without regard to the civil-service laws and compensated without regard to the Classification Act of 1923,[3] as amended.

(3) APPOINTMENT.—Commissioned officers of the Ready Reserve Corps shall be appointed by the President and commissioned officers of the Regular Corps shall be appointed by the President.

(4) ACTIVE DUTY.—Commissioned officers of the Ready Reserve Corps shall at all times be subject to call to active duty by the Surgeon General, including active duty for the purpose of training.

(5) WARRANT OFFICERS.—Warrant officers may be appointed to the Service for the purpose of providing support to the health and delivery systems maintained by the Service and any warrant officer appointed to the Service shall be considered for purposes of this Act and title 37, United States Code, to be a commissioned officer within the Commissioned Corps of the Service.

(b) ASSIMILATING RESERVE CORP OFFICERS INTO THE REGULAR CORPS.—Effective on the date of enactment of the Patient Protection and Affordable Care Act, all individuals classified as officers in the Reserve Corps under this section (as such section existed on the day before the date of enactment of such Act) and serving on active duty shall be deemed to be commissioned officers of the Regular Corps.

(c) PURPOSE AND USE OF READY RESEARCH.—

(1) PURPOSE.—The purpose of the Ready Reserve Corps is to fulfill the need to have additional Commissioned Corps personnel available on short notice (similar to the uniformed service's reserve program) to assist regular Commissioned Corps personnel to meet both routine public health and emergency response missions.

(2) USES.—The Ready Reserve Corps shall—

(A) participate in routine training to meet the general and specific needs of the Commissioned Corps;

(B) be available and ready for involuntary calls to active duty during national emergencies and public health crises, similar to the uniformed service reserve personnel;

(C) be available for backfilling critical positions left vacant during deployment of active duty Commissioned Corps members, as well as for deployment to respond to public health emergencies, both foreign and domestic; and

[3] Civil service and classification laws are now codified to title 5, United States Code.

(D) be available for service assignment in isolated, hardship, and medically underserved communities (as defined in section 799B) to improve access to health services.

(d) FUNDING.—For the purpose of carrying out the duties and responsibilities of the Commissioned Corps under this section, there are authorized to be appropriated $5,000,000 for each of fiscal years 2010 through 2014 for recruitment and training and $12,500,000 for each of fiscal years 2010 through 2014 for the Ready Reserve Corps.

SEC. 203A.[204a] DEPLOYMENT READINESS.

(a) READINESS REQUIREMENTS FOR COMMISSIONED CORPS OFFICERS.—

(1) IN GENERAL.—The Secretary, with respect to members of the following Corps components, shall establish requirements, including training and medical examinations, to ensure the readiness of such components to respond to urgent or emergency public health care needs that cannot otherwise be met at the Federal, State, and local levels:

(A) Active duty Regular Corps.

(B) Active Reserves.

(2) ANNUAL ASSESSMENT OF MEMBERS.—The Secretary shall annually determine whether each member of the Corps meets the applicable readiness requirements established under paragraph (1).

(3) FAILURE TO MEET REQUIREMENTS.—A member of the Corps who fails to meet or maintain the readiness requirements established under paragraph (1) or who fails to comply with orders to respond to an urgent or emergency public health care need shall, except as provided in paragraph (4), in accordance with procedures established by the Secretary, be subject to disciplinary action as prescribed by the Secretary.

(4) WAIVER OF REQUIREMENTS.—

(A) IN GENERAL.—The Secretary may waive one or more of the requirements established under paragraph (1) for an individual who is not able to meet such requirements because of—

(i) a disability;

(ii) a temporary medical condition; or

(iii) any other extraordinary limitation as determined by the Secretary.

(B) REGULATIONS.—The Secretary shall promulgate regulations under which a waiver described in subparagraph (A) may be granted.

(5) URGENT OR EMERGENCY PUBLIC HEALTH CARE NEED.—For purposes of this section and section 214, the term "urgent or emergency public health care need" means a health care need, as determined by the Secretary, arising as the result of—

(A) a national emergency declared by the President under the National Emergencies Act (50 U.S.C. 1601 et seq.);

(B) an emergency or major disaster declared by the President under the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121 et seq.);

(C) a public health emergency declared by the Secretary under section 319 of this Act; or

(D) any emergency that, in the judgment of the Secretary, is appropriate for the deployment of members of the Corps.

(b) CORPS MANAGEMENT FOR DEPLOYMENT.—The Secretary shall—

(1) organize members of the Corps into units for rapid deployment by the Secretary to respond to urgent or emergency public health care needs;

(2) establish appropriate procedures for the command and control of units or individual members of the Corps that are deployed at the direction of the President or the Secretary in response to an urgent or emergency public health care need of national, State or local significance;

(3) ensure that members of the Corps are trained, equipped and otherwise prepared to fulfill their public health and emergency response roles; and

(4) ensure that deployment planning takes into account—

(A) any deployment exemptions that may be granted by the Secretary based on the unique requirements of an agency and an individual's functional role in such agency; and

(B) the nature of the urgent or emergency public health care need.

(c) DEPLOYMENT OF DETAILED OR ASSIGNED OFFICERS.—For purposes of pay, allowances, and benefits of a Commissioned Corps officer who is detailed or assigned to a Federal entity, the deployment of such officer by the Secretary in response to an urgent or emergency public health care need shall be deemed to be an authorized activity of the Federal entity to which the officer is detailed or assigned.

SURGEON GENERAL.

SEC. 204.[205] The Surgeon General shall be appointed from the Regular Corps for a four-year term by the President by and with the advice and consent of the Senate. The Surgeon General shall be appointed from individuals who (1) are members of the Regular Corps, and (2) have specialized training or significant experience in public health programs. Upon the expiration of such term, the Surgeon General, unless reappointed, shall revert to the grade and number in the Regular or Reserve Corps that he would have occupied had he not served as Surgeon General.

DEPUTY SURGEON GENERAL AND ASSISTANT SURGEONS GENERAL.

SEC. 205.[206] (a) The Surgeon General shall assign one commissioned officer from the Regular Corps to administer the Office of the Surgeon General, to act as Surgeon General during the absence or disability of the Surgeon General or in the event of a vacancy in that office, and to perform such other duties as the Surgeon General may prescribe, and while so assigned he shall have the title of Deputy Surgeon General.

(b) The Surgeon General shall assign eight commissioned officers from the Regular Corps to be, respectively, the Director of the National Institutes of Health, the Chief of the Bureau of State Services, the Chief of the Bureau of Medical Services, the Chief Medical Officer of the United States Coast Guard, the Chief Dental Officer of the Service, the Chief Nurse Officer of the Service, the Chief Pharmacist Officer of the Service, and the Chief Sanitary Engineering Officer of the Service, and while so serving they shall each have the title of Assistant Surgeon General.

(c)(1) The Surgeon General, with the approval of the Secretary, is authorized to create special temporary positions in the grade of Assistant Surgeons General when necessary for the proper staffing of the Service. The Surgeon General may assign officers of either the Regular Corps or the Reserve Corps to any such temporary position, and while so serving they shall each have the title of Assistant Surgeon General.

(2) Except as provided in this paragraph, the number of special temporary positions created by the Surgeon General under paragraph (1) shall not on any day exceed 1 per centum of the highest number, during the ninety days preceding such day, of officers of the Regular Corps on active duty and officers of the Reserve Corps on active duty for more than thirty days. If on any day the number of such special temporary positions exceeds such 1 per centum limitations, for a period of not more than one year after such day, the number of such special temporary positions shall be reduced for purposes of complying with such 1 per centum limitation only by the resignation, retirement, death, or transfer to a position of a lower grade, of any officer holding any such temporary position.

(d) The Surgeon General shall designate the Assistant Surgeon General who shall serve as Surgeon General in case of absence or disability, or vacancy in the offices, of both the Surgeon General and the Deputy Surgeon General.

GRADES, RANKS, AND TITLES OF THE COMMISSIONED CORPS.

SEC. 206.[207] (a) The Surgeon General during the period of his appointment as such, shall be of the same grade as the Surgeon General of the army; the Deputy Surgeon General and the Chief Medical Officer of the United States Coast Guard, while assigned as such, shall have the grade corresponding with the grade of major general; and the Chief Dental Officer, while assigned as such, shall have the grade as is prescribed by law for the officer of the Dental Corps selected and appointed as Assistant Surgeon General of the Army. During the period of appointment to the position of Assistant Secretary for Health, a commissioned officer of the Public Health Service shall have the grade corresponding to the grade of General of the Army. Assistant Surgeons General, while assigned as such, shall have the grade corresponding with either the grade of brigadier general or the grade of major general, as may be determined by the Secretary after considering the importance of the duties to be performed: *Provided,* That the number of Assistant Surgeons General having a grade higher than that corresponding to the grade of brigadier general shall at no time exceed one-half of the number of positions created by subsection (b) of sec-

tion 205 or pursuant to subsection (c) of such section. The grades of commissioned officers of the Service shall correspond with grades of officers of the Army as follows:

(1) Officers of the director grade—colonel;

(2) Officers of the senior grade—lieutenant colonel;

(3) Officers of the full grade—major;

(4) Officers of the senior assistant grade—captain;

(5) Officers of the assistant grade—first lieutenant;

(6) Officers of the junior assistant grade—second lieutenant;

(7) Chief warrant officers of (W–4) grade—chief warrant officer (W–4);

(8) Chief warrant officers of (W–3) grade—chief warrant officer (W–3);

(9) Chief warrant officers of (W–2) grade—chief warrant officer (W–2); and

(10) Warrant officers of (W–1) grade—warrant officer (W–1).

(b) The titles of medical officers of the foregoing grades shall be respectively (1) medical director, (2) senior surgeon, (3) surgeon, (4) senior assistant surgeon, (5) assistant surgeon and (6) junior assistant surgeon.

(c) The President is authorized to prescribe titles, appropriate to the several grades, for commissioned officers of the Service other than medical officers. All titles of the officers of the Reserve Corps shall have the suffix "Reserve".

(d) Within the total number of officers of the Regular Corps authorized by the appropriation Act or Acts for each fiscal year to be on active duty, the Secretary shall by regulation prescribe the maximum number of officers authorized to be in each of the grades from the warrant officer (W–1) grade to the director grade, inclusive. Such numbers shall be determined after considering the anticipated needs of the Service during the fiscal year, the funds available, the number of officers in each grade at the beginning of the fiscal year, and the anticipated appointments, the anticipated promotions based on years of service, and the anticipated retirements during the fiscal year. The number so determined for any grade for a fiscal year may not exceed the number limitation (if any) contained in the appropriation Act or Acts for such year. Such regulations for each fiscal year shall be prescribed as promptly as possible after the appropriation Act fixing the authorized strength of the corps for that year, and shall be subject to amendment only if such authorized strength or such number limitation is thereafter changed. The maxima established by such regulations shall not require (apart from action pursuant to other provisions of this Act) any officer to be separated from the Service or reduced in grade.

(e) In computing the maximum number of commissioned officers of the Public Health Service authorized by law to hold a grade which corresponds to the grade of brigadier general or major general, there may be excluded from such computation not more than three officers who hold such a grade so long as such officers are assigned to duty and are serving in a policymaking position in the Department of Defense.

(f) In computing the maximum number of commissioned officers of the Public Health Service authorized by law or administrative determination to serve on active duty, there may be excluded from such computation officers who are assigned to duty in the Department of Defense.

APPOINTMENT OF PERSONNEL.

SEC. 207.[209] (a)(1) Except as provided in subsections (b) and (e) of this section, original appointments to the Regular Corps may be made only in the warrant officer (W–1), chief warrant officer (W–2), chief warrant officer (W–3), chief warrant officer (W–4), junior assistant, assistant, and senior assistant grades and original appointments to a grade above junior assistant shall be made only after passage of an examination, given in accordance with regulations of the President, in one or more of the several branches of medicine, dentistry, hygiene, sanitary engineering, pharmacy, psychology, nursing, or related scientific specialties in the field of public health.

(2) Original appointments to the Reserve Corps may be made to any grade up to and including the director grade but only after passage of an examination given in accordance with regulations of the President. Reserve commissions shall be for an indefinite period and may be terminated at any time, as the President may direct.

(3) No individual who has attained the age of forty-four shall be appointed to the Regular Corps, or called to active duty in the Reserve Corps for a period in excess of one year, unless (A) he has had a number of years of active service (as defined in section 211(d)) equal to the number of years by which his age exceeds forty-four, or (B) the Surgeon General determines that he possesses exceptional qualifications, not readily available elsewhere in the Commissioned Corps of the Public Health Service, for the performance of special duties with the Service, or (C) in the case of an officer of the Reserve Corps, the Commissioned Corps of the Service has been declared by the President to be a military service.

(b)(1) Not more than 10 per centum of the original appointments to the Regular Corps authorized to be made during any fiscal year may be made to grades above that of senior assistant, but no such appointment (other than an appointment under section 204) may be made to a grade above that of director. For the purpose of this subsection the number of original appointments authorized to be made during a fiscal year shall be (1) the excess of the number of officers of the Regular Corps authorized by the appropriation Act or Acts for such year over the number of officers on active duty in the Regular Corps on the first day of such year, plus (2) the number of such officers of the Regular Corps who, during such fiscal year, have been or will be retired upon attainment of age sixty-four or have for any other reason ceased to be on active duty. In determining the number of appointments authorized by this subsection an appointment shall be deemed to be made in the fiscal year in which the nomination is transmitted by the President to the Senate.

(2) In addition to the number of original appointments to the Regular Corps authorized by paragraph (1) to be made to grades above that of senior assistant, original appointments authorized to be made to the Regular Corps in any year may be made to grades above that of senior assistant, but not above that of director, in the case of any individual who—

(A)(i) was on active duty in the Regular Corps on July 1, 1960, (ii) was on such active duty continuously for not less than one year immediately prior to such date, and (iii) applies for appointment to the Regular Corps prior to July 1, 1962; or

(B) does not come within clause (A)(i) and (ii) but was on active duty in the Reserve Corps continuously for not less than one year immediately prior to his appointment to the Regular Corps and has not served on active duty continuously for a period, occurring after June 30, 1960, of more than three and one-half years prior to applying for such appointment.

(3) No person shall be appointed pursuant to this subsection unless he meets standards established in accordance with regulations of the President.

(c) Commissions evidencing the appointment by the President of officers of the Regular or Reserve Corps shall be issued by the Secretary under the seal of the Department of Health, Education, and Welfare.

(d)(1) For purposes of basic pay and for purposes of promotion, any person appointed under subsection (a) to the grade of senior assistant in the Regular Corps and any person appointed under subsection (b), shall, except as provided in paragraphs (2) and (3) of this subsection, be considered as having had on the date of appointment the following length of service: Three years if appointed to the senior assistant grade, ten years if appointed to the full grade, seventeen years if appointed to the senior grade, and eighteen years if appointed to the director grade.

(2) For purposes of basic pay, any person appointed under subsection (a) to the grade of senior assistant in the Regular Corps, and any person appointed under subsection (b), shall, in lieu of the credit provided in paragraph (1), be credited with the service for which he is entitled to credit under any other provision of law if such service exceeds that to which he would be entitled under such paragraph.

(3) For purposes of promotion, any person originally appointed in the Regular Corps to the senior assistant grade or above who has had active service in the Reserve Corps shall be considered as having had on the date of appointment the length of service provided for in paragraph (1), plus whichever of the following is greater: (A) The excess of his total active service in the Reserve Corps (above the grade of junior assistant) over the length of service provided in such paragraph, to the extent that such excess is on account of service in the Reserve Corps in or above the grade to which he is appointed in the Regular Corps or (B) his active service in the same or any higher grade in the Reserve Corps after the first day on which, under regulations in effect on the date of his appointment to the Regular Corps, he would have had the training and experience necessary for such appointment.

(4) For purposes of promotion, any person whose original appointment is to the assistant grade in the Regular Corps shall be considered as having had on the date of appointment service equal to his total active service in the Reserve Corps in and above the assistant grade.

(e)(1) A former officer of the Regular Corps may, if application for appointment is made within two years after the date of the termination of his prior commission in the Regular Corps, be reappointed to the Regular Corps without examination, except as the Surgeon General may otherwise prescribe, and without regard to the numerical limitations of subsection (b).

(2) Reappointments pursuant to this subsection may be made to the permanent grade held by the former officer at the time of the termination of his prior commission, or to the next higher grade if such officer meets the eligibility requirements prescribed by regulation for original appointment to such higher grade. For purposes of pay, promotion, and seniority in grade, such reappointed officer shall receive the credits for service to which he would be entitled if such appointment were an original appointment, but in no event less than the credits he held at the time his prior commission was terminated, except that if such officer is reappointed to the next higher grade he shall receive no credit for seniority in grade.

(3) No former officer shall be reappointed pursuant to this subsection unless he shall meet such standards as the Secretary may prescribe.

(f) In accordance with regulations, special consultants may be employed to assist and advise in the operations of the Service. Such consultants may be appointed without regard to the civil-service laws and their compensation may be fixed without regard to the Classification Act of 1923, as amended.[4]

(g) In accordance with regulations, individual scientists, other than commissioned officers of the Service, may be designated by the Surgeon General to receive fellowships, appointed for duty with the Service without regard to the civil-service laws and compensated without regard to the Classification Act of 1923, as amended, may hold their fellowships under conditions prescribed therein, and may be assigned for studies or investigations either in this country or abroad during the terms of their fellowships.

(h) Persons who are not citizens may be employed as consultants pursuant to subsection (e) and may be appointed to fellowships pursuant to subsection (f). Unless otherwise specifically provided, any prohibition in any other Act against the employment of aliens, or against the payment of compensation to them, shall not be applicable in the case of persons employed or appointed pursuant to such subsections.

(i) The appointment of any officer or employee of the Service made in accordance with the civil-service laws shall be made by the Secretary, and may be made effective as of the date on which such officer or employee enters upon duty.

[4] See footnote for the second sentence of section 203.

PAY AND ALLOWANCES.

SEC. 208.[210] (a)(1) Commissioned officers of the Regular and Reserve Corps shall be entitled to receive such pay and allowances as are now or may hereafter be authorized by law.

(2) For provisions relating to the receipt of special pay by commissioned officers of the Regular and Reserve Corps while on active duty, see section 303a(b) of title 37, United States Code.

(b) Commissioned officers on active duty, and retired officers entitled to retired pay pursuant to section 210(g)(3), section 211 or section 221(a), shall be permitted to purchase supplies from the Army, Navy, Air Force, and Marine Corps at the same price as is charged officers thereof.

(c) Members of the National Advisory Health Council and members of other national advisory or review councils or committees established under this Act, including members of the Technical Electronic Product Radiation Safety Standards Committee and the Board of Regents of the National Library of Medicine, but excluding ex officio members, while attending conferences or meetings of their respective councils or committees or while otherwise serving at the request of the Secretary shall be entitled to receive compensation at rates to be fixed by the Secretary, but at rates not exceeding the daily equivalent of the rate specified at the time of such service for grade GS–18 of the General Schedule, including traveltime; and while away from their homes or regular places of business they may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5 of the United States Code for persons in the Government service employed intermittently.

(d) Field employees of the Service, except those employed on a per diem or fee basis, who render part-time duty and are also subject to call at any time for services not contemplated in their regular part-time employment, may be paid annual compensation for such part-time duty and, in addition, such fees for such other services as the Surgeon General may determine; but in no case shall the total paid to any such employee for any fiscal year exceed the amount of the minimum annual salary rate of the classification grade of the employee.

(e) Any civilian employee of the Service who is employed at the Gillis W. Long Hansen's Disease Center on the date of the enactment of the Consolidated Omnibus Budget Reconciliation Act of 1985 shall be entitled to receive, in addition to any compensation to which the employee may otherwise be entitled and for so long as the employee remains employed at the Center, an amount equal to one-fourth of such compensation.

(f) Individuals appointed under subsection (g) shall have included in their fellowships such stipends or allowances, including travel and subsistence expenses, as the Surgeon General may deem necessary to procure qualified fellows.

(g) The Secretary is authorized to establish and fix the compensation for, within the Public Health Service, not more than one hundred and seventy-nine positions, of which not less than one hundred and fifteen shall be for the National Institutes of Health, not less than five shall be for the National Institute on Alcohol

Abuse and Alcoholism for individuals engaged in research on alcohol and alcoholism, not less than ten shall be for the National Center for Health Services Research, not less than twelve shall be for the National Center for Health Statistics, and not less than seven shall be for the National Center for Health Care Technology, in the professional, scientific, and executive service, each such position being established to effectuate those research and development activities of the Public Health Service which require the services of specially qualified scientific, professional, and administrative personnel: *Provided,* That the rates of compensation for positions established pursuant to the provisions of this subsection shall not be less than the minimum rate of grade 16 of the General Schedule of the Classification Act of 1949, as amended,[5] nor more than (1) the highest rate of grade 18 of the General Schedule of such Act, or (2) in the case of two such positions, the rate specified, at the time the service in the position is performed, for level II of the Executive Schedule (5 U.S.C. 5313); and such rates of compensation for all positions included in this proviso shall be subject to the approval of the Civil Service Commission. Positions created pursuant to this subsection shall be included in the classified civil service of the United States, but appointments to such positions shall be made without competitive examination upon approval of the proposed appointee's qualifications by the Civil Service Commission or such officers or agents as it may designate for this purpose.

PROFESSIONAL CATEGORIES.

SEC. 209.[210b] (a) For the purpose of establishing eligibility of officers of the Regular Corps for promotions, the Surgeon General shall by regulation divide the corps into professional categories. Each category shall, as far as practicable, be based upon one of the subjects of examination set forth in section 207(a)(1) or upon a subdivision of such subject, and the categories shall be designed to group officers by fields of training in such manner that officers in any one grade in any one category will be available for similar duty in the discharge of the several functions of the Service.

(b) Each officer of the Regular Corps on active duty shall, on the basis of his training and experience, be assigned by the Surgeon General to one of the categories established by regulations under subsection (a). Except upon amendment of such regulations, no assignment so made shall be changed unless the Surgeon General finds (1) that the original assignment was erroneous, or (2) that the officer is equally well qualified to serve in another category to which he has requested to be transferred, and that such transfer is in the interests of the Service.

(c) Within the limits fixed by the Secretary in regulations under section 206(d) for any fiscal year, the Surgeon General shall determine for each category in the Regular Corps the maximum number of officers authorized to be in each of the grades from the warrant officer (W–1) grade to the director grade, inclusive.

(d) The excess of the number so fixed for any grade in any category over the number of officers of the Regular Corps on active

[5] See footnote for the second sentence of section 203.

duty in such grade in such category (including, in the case of the director grade, officers holding such grade in accordance with section 206(c)) shall for the purpose of promotions constitute vacancies in such grade in such category. For purposes of this subsection, an officer who has been temporarily promoted or who is temporarily holding the grade of director in accordance with section 206(c) shall be deemed to hold the grade to which so promoted or which he is temporarily holding; but while he holds such promotion or grade, and while any officer is temporarily assigned to a position pursuant to section 205(c), the number fixed under subsection (c) of this section for the grade of his permanent rank shall be reduced by one.

(e) The absence of a vacancy in a grade in a category shall not prevent an appointment to such grade pursuant to section 207, a permanent length of service promotion, or the recall of a retired officer to active duty; but the making of such an appointment, promotion, or recall shall be deemed to fill a vacancy if one exists.

(f) Whenever a vacancy exists in any grade in a category the Surgeon General may increase by one the number fixed by him under subsection (c) for the next lower grade in the same category, without regard to the numbers fixed in regulations under section 206(d); and in that event the vacancy in the higher grade shall not be filled except by a permanent promotion, and upon the making of such promotion the number for the next lower grade shall be reduced by one.

PROMOTIONS AND SEPARATION OF COMMISSIONED OFFICERS IN THE REGULAR CORPS.

SEC. 210.[211] (a) Promotions of officers of the Regular Corps to any grade up to and including the director grade shall be either permanent promotions based on length of service, other permanent promotions to fill vacancies, or temporary promotions. Permanent promotions shall be made by the President, and temporary promotions shall be made by the President. Each permanent promotion shall be to the next higher grade, and shall be made only after examination given in accordance with regulations of the President.

(b) The President may by regulation provide that in a specified professional category permanent promotions to the senior grade, or to both the full grade and the senior grade, shall be made only if there are vacancies in such grade. A grade in any category with respect to which such regulations have been issued is referred to in this section as a "restricted grade".

(c) Examinations to determine qualification for permanent promotions may be either noncompetitive or competitive, as the Surgeon General shall in each case determine; except that examinations for promotions to the assistant or senior assistant grade shall in all cases be noncompetitive. The officers to be examined shall be selected by the Surgeon General from the professional category, and in the order of seniority in the grade, from which promotion is to be recommended. In the case of a competitive examination the Surgeon General shall determine in advance of the examination the number (which may be one or more) of officers who, after passing the examination, will be recommended to the President for pro-

motion; but if the examination is one for promotions based on length of service, or is one for promotions to fill vacancies other than vacancies in the director grade or in a restricted grade, such number shall not be less than 80 per centum of the number of officers to be examined.

(d) Officers of the Regular Corps, found pursuant to subsection (c) to be qualified, shall be given permanent promotions based on length of service, as follows:

(1) Officers in the warrant officer (W–1) grade, chief warrant officer (W–2) grade, chief warrant officer (W–3) grade, chief warrant officer (W–4) grade, and junior assistant grade shall be promoted at such times as may be prescribed in regulations of the President.

(2) Officers with permanent rank in the assistant grade, the senior assistant grade, and the full grade shall (except as provided in regulations under subsection (b)) be promoted after completion of three, ten, and seventeen years, respectively, of service in grades above the junior assistant grade; and such promotions, when made, shall be effective, for purposes of pay and seniority in grade, as of the day following the completion of such years of service. An officer with permanent rank in the assistant, senior assistant, or full grade who has not completed such years of service shall be promoted at the same time, and his promotion shall be effective as of the same day, as any officer junior to him in the same grade in the same professional category who is promoted under this paragraph.

(e) Officers in a professional category of the Regular Corps, found pursuant to subsection (c) to be qualified may be given permanent promotions to fill any or all vacancies in such category in the senior assistant grade, the full grade, the senior grade, or the director grade; but no officer who has not had one year of service with permanent or temporary rank in the next lower grade shall be promoted to any restricted grade or to the director grade.

(f) If an officer who has completed the years of service required for promotion to a grade under paragraph (2) of subsection (d) fails to receive such promotion, he shall (unless he has already been twice examined for promotion to such grade) be once reexamined for promotion to such grade. If he is thereupon promoted (otherwise than under subsection (e)), the effective date of such promotion shall be one year later than it would have been but for such failure. Upon the effective date of any permanent promotion of such officer to such grade, he shall be considered as having had only the length of service required for such promotion which he previously failed to receive.

(g) If, for reasons other than physical disability, an officer of the Regular Corps in the warrant officer (W–1) grade or junior assistant grade is found pursuant to subsection (c) not to be qualified for promotion he shall be separated from the Service. If, for reasons other than physical disability, an officer of the Regular Corps in the chief warrant officer (W–2), chief warrant officer (W–3), assistant, senior assistant, or full grade, after having been twice examined for promotion (other than promotion to a restricted grade), fails to be promoted—

(1) if in the chief warrant officer (W–2) or assistant grade he shall be separated from the Service and paid six months' basic pay and allowances;

(2) if in the chief warrant officer (W–3) or senior assistant grade he shall be separated from the Service and paid one year's basic pay and allowances;

(3) if in the full grade he shall be considered as not in line for promotion and shall, at such time thereafter as the Surgeon General may determine, be retired from the Service with retired pay (unless he is entitled to a greater amount by reason of another provision of law)—

(A) in the case of an officer who first became a member of a uniformed service before September 8, 1980, at the rate of 2½ percent of the retired pay base determined under section 1406(h) of title 10, United States Code, for each year, not in excess of 30, of his active commissioned service in the Service; or

(B) in the case of an officer who first became a member of a uniformed service on or after September 8, 1980, at the rate determined by multiplying—

(i) the retired pay base determined under section 1407 of title 10, United States Code; by

(ii) the retired pay multiplier determined under section 1409 of such title for the number of years of his active commissioned service in the Service.

(h) If an officer of the Regular Corps, eligible to take an examination for promotion, refuses to take such examination, he may be separated from the Service in accordance with regulations of the President.

(i) At the end of his first three years of service, the record of each officer of the Regular Corps, originally appointed to the senior assistant grade or above, shall be reviewed in accordance with regulations of the President and, if found not qualified for further service, he shall be separated from the Service and paid six months' pay and allowances.

(j)(1) The order of seniority of officers in a grade in the Regular Corps shall be determined, subject to the provisions of paragraph (2), by the relative length of time spent in active service after the effective date of each such officer's original appointment or permanent promotion in that grade. When permanent promotions of two or more officers to the same grade are effective on the same day, their relative seniority shall be the same as it was in the grade from which promoted. In all other cases of original appointments or permanent promotions (or both) to the same grade effective on the same day, relative seniority shall be determined in accordance with regulations of the President.

(2) In the case of an officer originally appointed in the Regular Corps to the grade of assistant or above, his seniority in the grade to which appointed shall be determined after inclusion, as service in such grade, of any active service in such grade or in any higher grade in the Reserve Corps, but (if the appointment is to the grade of senior assistant or above) only to the extent of whichever of the following is greater: (A) His active service in such grade or any higher grade in the Reserve Corps after the first day on which,

under regulations in effect on the date of his appointment to the Regular Corps, he had the training and experience necessary for such appointment, or (B) the excess of his total active service in the Reserve Corps (above the grade of junior assistant) over three years if his appointment in the Regular Corps is to the senior assistant grade, over ten years if the appointment is to the full grade, or over seventeen years if the appointment is to the senior grade.

(k) Any commissioned officer of the Regular Corps in any grade in any professional category may be recommended to the President for temporary promotion to fill a vacancy in any higher grade in such category, up to and including the director grade. In time of war, or of national emergency proclaimed by the President, any commissioned officer of the Regular Corps in any grade in any professional category may be recommended to the President for promotion to any higher grade in such category, up to and including the director grade, whether or not a vacancy exists in such grade. The selection of officers to be recommended for temporary promotions shall be made in accordance with regulations of the President. Promotion of an officer recommended pursuant to this subsection may be made without regard to length of service, without examination, and without vacating his permanent appointment, and shall carry with it the pay and allowances of the grade to which promoted. Such promotions may be terminated at any time, as may be directed by the President.

(l) Whenever the number of officers of the Regular Corps on active duty, plus the number of officers of the Reserve Corps who have been on active duty for thirty days or more, exceeds the authorized strength of the Regular Corps, the Secretary shall determine the requirements of the Service in each grade in each category, based upon the total number of officers so serving on active duty and the tasks being performed by the Service; and the Surgeon General shall thereupon assign each officer of the Reserve Corps on active duty to a professional category. If the Secretary finds that the number of officers fixed under section 209(c) for any grade and category (or the number of officers, including officers of the Reserve Corps, on active duty in such grade in such category, if such number is greater than the number fixed under section 209(c)) is insufficient to meet such requirements of the Service, officers of either the Regular Corps or the Reserve Corps may be recommended for temporary promotion to such grade in such category. Any such promotion may be terminated at any time, as may be directed by the President.

(m) Any officer of the Regular Corps, or any officer of the Reserve Corps on active duty, who is promoted to a higher grade shall, unless he expressly declines such promotion, be deemed for all purposes to have accepted such promotion; and shall not be required to renew his oath of office, or to execute a new affidavit as required by the Act of December 11, 1926, as amended (5 U.S.C. 21a).[6]

[6] That Act has been codified to section 3332 of title 5, United States Code.

RETIREMENT OF COMMISSIONED OFFICERS.

SEC. 211.[212] (a)(1) A commissioned officer of the Service shall, if he applies for retirement, be retired on or after the first day of the month following the month in which he attains the age of sixty-four years. This paragraph does not permit or require the involuntary retirement of any individual because of the age of the individual.

(2) A commissioned officer of the Service may be retired by the Secretary, and shall be retired if he applies for retirement, on the first day of any month after completion of thirty years of active service.

(3) Any commissioned officer of the Service who has had less than thirty years of active service may be retired by the Secretary, with or without application by the officer, on the first day of any month after completion of twenty or more years of active service of which not less than ten are years of active commissioned service in any of the uniformed services.

(4) Except as provided in paragraph (6), a commissioned officer retired pursuant to paragraph (1), (2), or (3) who was (in the case of an officer in the Reserve Corps) on active duty with the Service on the day preceding such retirement shall be entitled to receive retired pay at the rate of 2½ per centum of the basic pay of the highest grade held by him as such officer and in which, in the case of a temporary promotion to such grade, he has performed active duty for not less than six months, (A) for each year of active service, or (B) if it results in higher retired pay, for each of the following years:

(i) his years of active service (determined without regard to subsection (d)) as a member of a uniformed service; plus

(ii) in the case of a medical or dental officer, four years and, in the case of a medical officer, who has completed one year of medical internship or the equivalent thereof, one additional year, the four years and the one year to be reduced by the period of active service performed during such officer's attendance at medical school or dental school or during his medical internship; plus

(iii) the number of years of service with which he was entitled to be credited for purposes of basic pay on May 31, 1958, or (if higher) on any date prior thereto, reduced by any such year included under clause (i) and further reduced by any such year with which he was entitled to be credited under paragraphs (7) and (8) of section 205(a) of title 37, United States Code, on any date before June 1, 1958;

except that (C) in the case of any officer whose retired pay, so computed, is less than 50 per centum of such basic pay, who retires pursuant to paragraph (1) of this subsection, who has not less than twelve whole years of active service (computed without the application of subsection (e)), and who does not use, for purposes of a retirement annuity under the Civil Service Retirement Act,[7] any service which is also creditable in computing his retired pay from the Service, it shall, instead, be 50 per centum of such pay, and (D)

[7] The Civil Service Retirement Act has been codified to chapter 83 of title 5, United States Code.

the retired pay of an officer shall in no case be more than 75 per centum of such basic pay.

(5) With the approval of the President, a commissioned officer whose service as Surgeon General, Deputy Surgeon General, or Assistant Surgeon General has totaled four years or more and who has had not less than twenty-five years of active service in the Service may retire voluntarily at any time; and except as provided in paragraph (6), his retired pay shall be at the rate of 75 per centum of the basic pay of the highest grade held by him as such officer.

(6) The retired pay of a commissioned officer retired under this subsection who first became a member of a uniformed service after September 7, 1980, is determined by multiplying—

(A) the retired pay base determined under section 1407 of title 10, United States Code; by

(B) the retired pay multiplier determined under section 1409 of such title for the number of years of service credited to the officer under paragraph (4).

(7) Retired pay computed under section 210(g)(3) or under paragraph (4) or (5) of this subsection, if not a multiple of $1, shall be rounded to the next lower multiple of $1.

(b) For purposes of subsection (a), the basic pay of the highest grade to which a commissioned officer has received a temporary promotion means the basic pay to which he would be entitled if serving on active duty in such grade on the date of his retirement.

(c) A commissioned officer, retired for reasons other than for failure of promotion to the senior grade, may (1) if an officer of the Regular Corps or an officer of the Reserve Corps entitled to retired pay under subsection (a), be involuntarily recalled to active duty during such times as the Commissioned Corps constitutes a branch of the land or naval forces of the United States, and (2) if an officer of either the Regular or Reserve Corps, be recalled to active duty at any time with his consent.

(d) The term "active service", as used in subsection (a), includes:

(1) all active service in any of the uniformed services;

(2) active service with the Public Health Service, other than as a commissioned officer, which the Surgeon General determines is comparable to service performed by commissioned officers of the Service, except that, if there are more than five years of such service only the last five years thereof may be included;

(3) all active service (other than service included under the preceding provisions of this subsection) which is creditable for retirement purposes under laws governing the retirement of members of any of the uniformed services; and

(4) service performed as a member of the Senior Biomedical Research Service established by section 228, except that, if there are more than 5 years of such service, only the last 5 years thereof may be included.

(e) For the purpose of determining the number of years by which a percentage of the basic pay of an officer is to be multiplied in computing the amount of his retired pay pursuant to section 210(g)(3) or paragraph (4) of subsection (a) of this section, each full

month of service that is in addition to the number of full years of service credited to an officer is counted as one-twelfth of a year and any remaining fractional part of a month is disregarded.

(f) For purposes of retirement or separation for physical disability under chapter 61 of title 10, United States Code, a commissioned officer of the Service shall be credited, in addition to the service described in section 1208(a)(2) of that title, with active service with the Public Health Service, other than as a commissioned officer, which the Surgeon General determines is comparable to service performed by commissioned officers of the Service, except that, if there are more than five years of such service, only the last five years thereof may be so credited. For such purposes, such section 1208(a)(2) shall be applicable to officers of the Regular or Reserve Corps of the Service.

MILITARY BENEFITS.

SEC. 212.[213] (a) Except as provided in subsection (b), commissioned officers of the Service and their surviving beneficiaries shall, with respect to active service performed by such officers—

(1) in time of war;

(2) on detail for duty with the Army, Navy, Air Force, Marine Corps, or Coast Guard; or

(3) while the Service is part of the military forces of the United States pursuant to Executive order of the President;

be entitled to all rights, privileges, immunities, and benefits now or hereafter provided under any law of the United States in the case of commissioned officers of the Army or their surviving beneficiaries on account of active military service, except retired pay and uniform allowances.

(b) The President may prescribe the conditions under which commissioned officers of the Service may be awarded military ribbons, medals, and decorations.

(c) The authority vested by law in the Department of the Army, the Secretary of the Army, or other officers of the Department of the Army with respect to rights, privileges, immunities, and benefits referred to in subsection (a) shall be exercised, with respect to commissioned officers of the Service, by the Surgeon General.

(d) Active service of commissioned officers of the Service shall be deemed to be active military service in the Armed Forces of the United States for the purposes of all laws administered by the Secretary of Veterans Affairs (except the Servicemen's Indemnity Act of 1951) and section 217 of the Social Security Act.

(e) Active service of commissioned officers of the Service shall be deemed to be active military service in the Armed Forces of the United States for the purposes of all rights, privileges, immunities, and benefits now or hereafter provided under the Servicemembers Civil Relief Act (50 App. U.S.C. 501 et seq.).

(f) Active service of commissioned officers of the Service shall be deemed to be active military service in the Armed Forces of the United States for purposes of all laws related to discrimination on the basis of race, color, sex, ethnicity, age, religion, and disability.

PRESENTATION OF UNITED STATES FLAG UPON RETIREMENT.

SEC. 213.[214] (a) PRESENTATION OF FLAG.—Upon the release of an officer of the commissioned corps of the Service from active commissioned service for retirement, the Secretary of Health and Human Services shall present a United States flag to the officer.

(b) MULTIPLE PRESENTATIONS NOT AUTHORIZED.—An officer is not eligible for presentation of a flag under subsection (a) if the officer has previously been presented a flag under this section or any other provision of law providing for the presentation of a United States flag incident to release from active service for retirement.

(c) NO COST TO RECIPIENT.—The presentation of a flag under this section shall be at no cost to the recipient.

DETAIL OF PERSONNEL.

SEC. 214.[8][215] (a) The Secretary is authorized, upon the request of the head of an executive department, to detail officers or employees of the Service to such department for duty as agreed upon by the Secretary and the head of such department in order to cooperate in, or conduct work related to, the functions of such department or of the Service. When officers or employees are so detailed their salaries and allowances may be paid from working funds established as provided by law or may be paid by the Service from applicable appropriation and reimbursement may be made as agreed upon by the Secretary and the head of the executive department concerned. Officers detailed for duty with the Army, Navy, or Coast Guard shall be subject to the laws for the government of the service to which detailed.

(b) Upon the request of any State health authority or, in the case of work relating to mental health, any State mental health authority, personnel of the Service may be detailed by the Surgeon General for the purpose of assisting such State or political subdivision thereof in work related to the functions of the Service.

(c) The Surgeon General may detail personnel of the Service to any appropriate committee of the Congress or to nonprofit educational research or other institutions engaged in health activities for special studies of scientific problems and for the dissemination of information relating to public health.

(d) Personnel detailed under subsections (b) and (c) shall be paid from applicable appropriations of the Service except that, in accordance with regulations such personnel may be placed on leave without pay and paid by the State, subdivision, or institution to which they are detailed. In the case of detail of personnel under subsections (b) or (c) to be paid from applicable Service appropriations, the Secretary may condition such detail on an agreement by the State, subdivision, or institution concerned that such State, subdivision, or institution concerned shall reimburse the United States for the amount of such payments made by the Service. The services of personnel while detailed pursuant to this section shall be considered as having been performed in the Service for purposes

[8] Former section 213 was repealed by section 14 of Public Law 87–649 (76 Stat. 499). Section 415(c) of title 37, United States Code, now applies to the matter with which former section 213 was concerned.

of the computation of basic pay, promotion, retirement, compensation for injury or death, and the benefits provided by section 212.

(e) Except with respect to the United States Coast Guard and the Department of Defense, and except as provided in agreements negotiated with officials at agencies where officers of the Commissioned Corps may be assigned, the Secretary shall have the sole authority to deploy any Commissioned Corps officer assigned under this section to an entity outside of the Department of Health and Human Services for service under the Secretary's direction in response to an urgent or emergency public health care need (as defined in section 203A(a)(5)).

REGULATIONS.

SEC. 215.[216] (a) The President shall from time to time prescribe regulations with respect to the appointment, promotion, retirement, termination of commission, title, pay, uniforms, allowances (including increased allowances for foreign service), and discipline of the commissioned corps of the Service.

(b) The Surgeon General, with the approval of the Secretary, unless specifically otherwise provided, shall promulgate all other regulations necessary to the administration of the Service, including regulations with respect to uniforms for employees, and regulations with respect to the custody, use, and preservation of the records, papers, and property of the Service.

(c) No regulations relating to qualifications for appointment of medical officers or employees shall give preference to any school of medicine.

USE OF SERVICE IN TIME OF WAR OR EMERGENCY.

SEC. 216.[217] In time of war, or of emergency proclaimed by the President, he may utilize the Service to such extent and in such manner as shall in his judgment promote the public interest. In time of war, or of emergency involving the national defense proclaimed by the President, he may by Executive order declare the commissioned corps of the Service to be a military service. Upon such declaration, and during the period of such war or such emergency or such part thereof as the President shall prescribe, the commissioned corps (a) shall constitute a branch of the land and naval forces of the United States, (b) shall, to the extent prescribed by regulations of the President, be subject to the Uniform Code of Military Justice, and (c) shall continue to operate as part of the Service except to the extent that the President may direct as Commander in Chief.

NATIONAL ADVISORY COUNCILS.

SEC. 217.[218] (a) Within 120 days of the date of the enactment of this subsection, the Secretary shall appoint and organize a National Advisory Council on Migrant Health (hereinafter in this subsection referred to as the Council) which shall advise, consult with, and make recommendations to, the Secretary on matters concerning the organization, operation, selection, and funding of mi-

grant health centers and other entities under grants and contracts under section 329.[9]

(b) The Council shall consist of fifteen members, at least twelve of whom shall be members of the governing boards of migrant health centers or other entities assisted under section 329. Of such twelve members who are members of such governing boards, at least nine shall be chosen from among those members of such governing boards who are being served by such centers or grantees and who are familiar with the delivery of health care to migratory agricultural workers and seasonal agricultural workers. The remaining three Council members shall be individuals qualified by training and experience in the medical sciences or in the administration of health programs.

(c) Each member of the Council shall hold office for a term of four years, except that (1) any member appointed to fill a vacancy occurring prior to the expiration of the term for which his predecessor was appointed shall be appointed for the remainder of such term; and (2) the terms of the members first taking office after the date of enactment of this subsection shall expire as follows: four shall expire four years after such date, four shall expire three years after such date, four shall expire two years after such date, and three shall expire one year after such date, as designated by the Secretary at the time of appointment.

(d) Section 14(a) of the Federal Advisory Committee Act shall not apply to the Council.

TRAINING OF OFFICERS.

SEC. 218.[218a] (a) Appropriations available for the pay and allowances of commissioned officers of the Service shall also be available for the pay and allowances of any such officer on active duty while attending any Federal or non-Federal educational institution or training program and, subject to regulations of the President and to the limitation prescribed in such appropriations, for payment of his tuition, fees, and other necessary expenses incident to such attendance.

(b) Any officer whose tuition, fees, and other necessary expenses are paid pursuant to subsection (a) while attending an educational institution or training program for a period in excess of thirty days shall be obligated to pay to the Service an amount equal to two times the total amount of such tuition, fees, and other necessary expenses received by such officer during such period, and two times the total amount of any compensation received by, and any allowance paid to, such officer during such period, if after return to active service such officer voluntarily leaves the Service within (1) six months, or (2) twice the period of such attendance, whichever is greater. Such subsequent period of service shall commence upon the cessation of such attendance and of any further continuous period of training duty for which no tuition and fees are

[9] As a result of the amendments made by Public Law 104–299 (110 Stat. 3626), the Public Health Service Act no longer contained a section 329, 340, or 340A, and section 330 of such Act was substantially revised. Section 330 now includes provisions that relate to medically underserved populations, to migratory and seasonal agricultural workers, to homeless individuals, and to residents of public housing. Section 402 of Public Law 107–251 (116 Stat. 1655) added a new section 340 that relates to a healthy communities access program.

paid by the Service and which is part of the officer's prescribed formal training program, whether such further training is at Service facility or otherwise. The Surgeon General may waive, in whole or in part, any payment which may be required by this subsection upon a determination that such payment would be inequitable or would not be in public interest.

(c) A commissioned officer may be placed in leave without pay status while attending an educational institution or training program whenever the Secretary determines that such status is in the best interest of the Service. For purposes of computation of basic pay, promotion, retirement, compensation for injury or death, and the benefits provided by sections 212 and 224, an officer in such status pursuant to the preceding sentence shall be considered as performing service in the Service and shall have an active service obligation as set forth in subsection (b) of this section.

ANNUAL AND SICK LEAVE.

SEC. 219.[210–1] (a) In accordance with regulations of the President, commissioned officers of the Regular Corps and officers of the Reserve Corps on active duty may be granted annual leave and sick leave without any deductions from their pay and allowances: *Provided*, That such regulations shall not authorize annual leave to be accumulated in excess of sixty days.

(d)[10] For purposes of this section the term "accumulated annual leave" means unused accrued annual leave carried forward from one leave year into a succeeding leave year, and the term "accrued annual leave" means the annual leave accruing to an officer during one leave year.

PROMOTION CREDIT—ASSISTANT GRADE.

SEC. 220.[211c] Any medical officer of the Regular Corps of the Public Health Service who—

(1)(A) was appointed to the assistant grade in the Regular Corps and whose service in such Corps has been continuous from the date of appointment or (B) may hereafter be appointed to the assistant grade in the Regular Corps, and

(2) had or will have completed a medical internship on the date of such appointment,

shall be credited with one year for purposes of promotion and seniority in grade, except that no such credit shall be authorized if the officer has received or will receive similar credit for his internship under other provisions of law. In the case of an officer on active duty on the effective date of this section who is entitled to the credit authorized herein, the one year shall be added to the promotion and seniority-in-grade credits with which he is credited on such date.

[10] Former subsection (b) was repealed by section 14 of Public Law 87–649 (76 Stat. 499). Section 503(b) of title 37, United States Code, now applies to the matter with which former subsection (b) was concerned. Former subsection (c) was repealed by section 311 of Public Law 96–76 (93 Stat. 586).

RIGHTS, PRIVILEGES, ETC. OF OFFICERS AND SURVIVING BENEFICIARIES.

SEC. 221.[213a] (a) Commissioned officers of the Service or their surviving beneficiaries are entitled to all the rights, benefits, privileges, and immunities now or hereafter provided for commissioned officers of the Army or their surviving beneficiaries under the following provisions of title 10, United States Code:

(1) Section 1036, Escorts for dependents of members: transportation and travel allowances.

(2) Chapter 61, Retirement or Separation for Physical Disability, except that sections 1201, 1202, and 1203 do not apply to commissioned officers of the Public Health Service who have been ordered to active duty for training for a period of more than 30 days.

(3) Chapter 69, Retired Grade, except sections 1370, 1374, 1375, and 1376(a).

(4) Chapter 71, Computation of Retired Pay, except formula No. 3 of section 1401.

(5) Chapter 73, Retired Serviceman's Family Protection Plan, Survivor Benefit Plan.

(6) Chapter 75, Death Benefits.

(7) Section 2771, Final settlement of accounts: deceased members.

(8) Chapter 163, Military Claims, but only when commissioned officers of the Service are entitled to military benefits under section 212 of this Act.

(9) Section 2603, Acceptance of fellowships, scholarships, or grants.

(10) Section 2634 Motor vehicles: for members on permanent change of station.

(11) Section 1035, Deposit of savings.

(12) Section 1552, Correction of military records: claims incident thereto.

(13) Section 1553, Review of discharge or dismissal.

(14) Section 1554, Review of retirement or separation without pay for physical disability.

(15) Section 1124, Cash awards for suggestions, inventions, or scientific achievements.

(16) Section 1052, Reimbursement for adoption expenses.

(17) Section 1059, Transitional compensation and commissary and exchange benefits for dependents of members separated for dependent abuse.

(18) Section 1034, Protected Communications; Prohibition of Retaliatory Personnel Actions.

(b) The authority vested by title 10, United States Code, in the "military departments", "the Secretary concerned", or "the Secretary of Defense" with respect to the rights, privileges, immunities, and benefits referred to in subsection (a) shall be exercised, with respect to commissioned officers of the Service, by the Secretary of Health, Education, and Welfare or his designee. For purposes of paragraph (18) of subsection (a), the term "Inspector General" in section 1034 of such title 10 shall mean the Inspector General of the Department of Health and Human Services.

ADVISORY COUNCILS OR COMMITTEES.

SEC. 222.[217a] (a) The Secretary may, without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates, from time to time, appoint such advisory councils or committees (in addition to those authorized to be established under other provisions of law), for such periods of time, as he deems desirable with such period commencing on a date specified by the Secretary for the purpose of advising him in connection with any of his functions.

(b) Members of any advisory council or committee appointed under this section who are not regular full-time employees of the United States shall, while attending meetings or conferences of such council or committee or otherwise engaged on business of such council or committee receive compensation and allowances as provided in section 208(c) for members of national advisory councils established under this Act.

(c) Upon appointment of any such council or committee, the Secretary may delegate to such council or committee such advisory functions relating to grants-in-aid for research or training projects or programs, in the areas or fields with which such council or committee is concerned, as the Secretary determines to be appropriate.

VOLUNTEER SERVICES.

SEC. 223.[217b] Subject to regulations, volunteer and uncompensated services may be accepted by the Secretary, or by any other officer or employee of the Department of Health and Human Services designated by him, for use in the operation of any health care facility or in the provision of health care.

DEFENSE OF CERTAIN MALPRACTICE AND NEGLIGENCE SUITS.

SEC. 224.[233] (a) The remedy against the United States provided by sections 1346(b) and 2672 of title 28, or by alternative benefits provided by the United States where the availability of such benefits precludes a remedy under section 1346(b) of title 28, for damage for personal injury, including death, resulting from the performance of medical, surgical, dental, or related functions, including the conduct of clinical studies or investigation, by any commissioned officer or employee of the Public Health Service while acting within the scope of his office or employment, shall be exclusive of any other civil action or proceeding by reason of the same subject-matter against the officer or employee (or his estate) whose act or omission gave rise to the claim.

(b) The Attorney General shall defend any civil action or proceeding brought in any court against any person referred to in subsection (a) of this section (or his estate) for any such damage or injury. Any such person against whom such civil action or proceeding is brought shall deliver within such time after date of service or knowledge of service as determined by the Attorney General, all process served upon him or an attested true copy thereof to his immediate superior or to whomever was designated by the Secretary

to receive such papers and such persons shall promptly furnish copies of the pleading and process therein to the United States attorney for the district embracing the place wherein the proceeding is brought, to the Attorney General, and to the Secretary.

(c) Upon a certification by the Attorney General that the defendant was acting in the scope of his employment at the time of the incident out of which the suit arose, any such civil action or proceeding commenced in a State court shall be removed without bond at any time before trial by the Attorney General to the district court of the United States of the district and division embracing the place wherein it is pending and the proceeding deemed a tort action brought against the United States under the provisions of title 28 and all references thereto. Should a United States district court determine on a hearing on a motion to remand held before a trial on the merit that the case so removed is one in which a remedy by suit within the meaning of subsection (a) of this section is not available against the United States, the case shall be remanded to the State Court: *Provided*, That where such a remedy is precluded because of the availability of a remedy through proceedings for compensation or other benefits from the United States as provided by any other law, the case shall be dismissed, but in the event the running of any limitation of time for commencing, or filing an application or claim in, such proceedings for compensation or other benefits shall be deemed to have been suspended during the pendency of the civil action or proceeding under this section.

(d) The Attorney General may compromise or settle any claim asserted in such civil action or proceeding in the manner provided in section 2677 of title 28 and with the same effect.

(e) For purposes of this section, the provisions of section 2680(h) of title 28 shall not apply to assault or battery arising out of negligence in the performance of medical, surgical, dental, or related functions, including the conduct of clinical studies or investigations.

(f) The Secretary or his designee may, to the extent that he deems appropriate, hold harmless or provide liability insurance for any officer or employee of the Public Health Service for damage for personal injury, including death, negligently caused by such officer or employee while acting within the scope of his office or employment and as a result of the performance of medical, surgical, dental, or related functions, including the conduct of clinical studies or investigations, if such employee is assigned to a foreign country or detailed to a State or political subdivision thereof or to a non-profit institution, and if the circumstances are such as are likely to preclude the remedies of third persons against the United States described in section 2679(b) of title 28, for such damage or injury.

(g)(1)(A) For purposes of this section and subject to the approval by the Secretary of an application under subparagraph (D), an entity described in paragraph (4), and any officer, governing board member, or employee of such an entity, and any contractor of such an entity who is a physician or other licensed or certified health care practitioner (subject to paragraph (5)), shall be deemed to be an employee of the Public Health Service for a calendar year that begins during a fiscal year for which a transfer was made under subsection (k)(3) (subject to paragraph (3)). The remedy

against the United States for an entity described in paragraph (4) and any officer, governing board member, employee, or contractor (subject to paragraph (5)) of such an entity who is deemed to be an employee of the Public Health Service pursuant to this paragraph shall be exclusive of any other civil action or proceeding to the same extent as the remedy against the United States is exclusive pursuant to subsection (a).

(B) The deeming of any entity or officer, governing board member, employee, or contractor of the entity to be an employee of the Public Health Service for purposes of this section shall apply with respect to services provided—

(i) to all patients of the entity, and

(ii) subject to subparagraph (C), to individuals who are not patients of the entity.

(C) Subparagraph (B)(ii) applies to services provided to individuals who are not patients of an entity if the Secretary determines, after reviewing an application submitted under subparagraph (D), that the provision of the services to such individuals—

(i) benefits patients of the entity and general populations that could be served by the entity through community-wide intervention efforts within the communities served by such entity;

(ii) facilitates the provision of services to patients of the entity; or

(iii) are otherwise required under an employment contract (or similar arrangement) between the entity and an officer, governing board member, employee, or contractor of the entity.

(D) The Secretary may not under subparagraph (A) deem an entity or an officer, governing board member, employee, or contractor of the entity to be an employee of the Public Health Service for purposes of this section, and may not apply such deeming to services described in subparagraph (B)(ii), unless the entity has submitted an application for such deeming to the Secretary in such form and such manner as the Secretary shall prescribe. The application shall contain detailed information, along with supporting documentation, to verify that the entity, and the officer, governing board member, employee, or contractor of the entity, as the case may be, meets the requirements of subparagraphs (B) and (C) of this paragraph and that the entity meets the requirements of paragraphs (1) through (4) of subsection (h).

(E) The Secretary shall make a determination of whether an entity or an officer, governing board member, employee, or contractor of the entity is deemed to be an employee of the Public Health Service for purposes of this section within 30 days after the receipt of an application under subparagraph (D). The determination of the Secretary that an entity or an officer, governing board member, employee, or contractor of the entity is deemed to be an employee of the Public Health Service for purposes of this section shall apply for the period specified by the Secretary under subparagraph (A).

(F) Once the Secretary makes a determination that an entity or an officer, governing board member, employee, or contractor of an entity is deemed to be an employee of the Public Health Service for purposes of this section, the determination shall be final and

binding upon the Secretary and the Attorney General and other parties to any civil action or proceeding. Except as provided in subsection (i), the Secretary and the Attorney General may not determine that the provision of services which are the subject of such a determination are not covered under this section.

(G) In the case of an entity described in paragraph (4) that has not submitted an application under subparagraph (D):

(i) The Secretary may not consider the entity in making estimates under subsection (k)(1).

(ii) This section does not affect any authority of the entity to purchase medical malpractice liability insurance coverage with Federal funds provided to the entity under section 329, 330, or 340A.

(H) In the case of an entity described in paragraph (4) for which an application under subparagraph (D) is in effect, the entity may, through notifying the Secretary in writing, elect to terminate the applicability of this subsection to the entity. With respect to such election by the entity:

(i) The election is effective upon the expiration of the 30-day period beginning on the date on which the entity submits such notification.

(ii) Upon taking effect, the election terminates the applicability of this subsection to the entity and each officer, governing board member, employee, and contractor of the entity.

(iii) Upon the effective date for the election, clauses (i) and (ii) of subparagraph (G) apply to the entity to the same extent and in the same manner as such clauses apply to an entity that has not submitted an application under subparagraph (D).

(iv) If after making the election the entity submits an application under subparagraph (D), the election does not preclude the Secretary from approving the application (and[11] thereby restoring the applicability of this subsection to the entity and each officer, governing board member, employee, and contractor of the entity, subject to the provisions of this subsection and the subsequent provisions of this section.

(2) If, with respect to an entity or person deemed to be an employee for purposes of paragraph (1), a cause of action is instituted against the United States pursuant to this section, any claim of the entity or person for benefits under an insurance policy with respect to medical malpractice relating to such cause of action shall be subrogated to the United States.

(3) This subsection shall apply with respect to a cause of action arising from an act or omission which occurs on or after January 1, 1993.

(4) An entity described in this paragraph is a public or nonprofit private entity receiving Federal funds under section 330.

(5) For purposes of paragraph (1), an individual may be considered a contractor of an entity described in paragraph (4) only if—

(A) the individual normally performs on average at least 32½ hours of service per week for the entity for the period of the contract; or

[11] So in law. See section 5(a) of Public Law 104–73 (109 Stat. 779). There is no closing parenthesis.

(B) in the case of an individual who normally performs an average of less than 32½ hours of services per week for the entity for the period of the contract, the individual is a licensed or certified provider of services in the fields of family practice, general internal medicine, general pediatrics, or obstetrics and gynecology.

(h) The Secretary may not approve an application under subsection (g)(1)(D) unless the Secretary determines that the entity—

(1) has implemented appropriate policies and procedures to reduce the risk of malpractice and the risk of lawsuits arising out of any health or health-related functions performed by the entity;

(2) has reviewed and verified the professional credentials, references, claims history, fitness, professional review organization findings, and license status of its physicians and other licensed or certified health care practitioners, and, where necessary, has obtained the permission from these individuals to gain access to this information;

(3) has no history of claims having been filed against the United States as a result of the application of this section to the entity or its officers, employees, or contractors as provided for under this section, or, if such a history exists, has fully cooperated with the Attorney General in defending against any such claims and either has taken, or will take, any necessary corrective steps to assure against such claims in the future; and

(4) will fully cooperate with the Attorney General in providing information relating to an estimate described under subsection (k).

(i)(1) Notwithstanding subsection (g)(1), the Attorney General, in consultation with the Secretary, may on the record determine, after notice and opportunity for a full and fair hearing, that an individual physician or other licensed or certified health care practitioner who is an officer, employee, or contractor of an entity described in subsection (g)(4) shall not be deemed to be an employee of the Public Health Service for purposes of this section, if treating such individual as such an employee would expose the Government to an unreasonably high degree of risk of loss because such individual—

(A) does not comply with the policies and procedures that the entity has implemented pursuant to subsection (h)(1);

(B) has a history of claims filed against him or her as provided for under this section that is outside the norm for licensed or certified health care practitioners within the same specialty;

(C) refused to reasonably cooperate with the Attorney General in defending against any such claim;

(D) provided false information relevant to the individual's performance of his or her duties to the Secretary, the Attorney General, or an applicant for or recipient of funds under this Act; or

(E) was the subject of disciplinary action taken by a State medical licensing authority or a State or national professional society.

(2) A final determination by the Attorney General under this subsection that an individual physician or other licensed or certified health care professional shall not be deemed to be an employee of the Public Health Service shall be effective upon receipt by the entity employing such individual of notice of such determination, and shall apply only to acts or omissions occurring after the date such notice is received.

(j) In the case of a health care provider who is an officer, employee, or contractor of an entity described in subsection (g)(4), section 335(e) shall apply with respect to the provider to the same extent and in the same manner as such section applies to any member of the National Health Service Corps.

(k)(1)(A) For each fiscal year, the Attorney General, in consultation with the Secretary, shall estimate by the beginning of the year the amount of all claims which are expected to arise under this section (together with related fees and expenses of witnesses) for which payment is expected to be made in accordance with section 1346 and chapter 171 of title 28, United States Code, from the acts or omissions, during the calendar year that begins during that fiscal year, of entities described in subsection (g)(4) and of officers, employees, or contractors (subject to subsection (g)(5)) of such entities.

(B) The estimate under subparagraph (A) shall take into account—

(i) the value and frequency of all claims for damage for personal injury, including death, resulting from the performance of medical, surgical, dental, or related functions by entities described in subsection (g)(4) or by officers, employees, or contractors (subject to subsection (g)(5)) of such entities who are deemed to be employees of the Public Health Service under subsection (g)(1) that, during the preceding 5-year period, are filed under this section or, with respect to years occurring before this subsection takes effect, are filed against persons other than the United States,

(ii) the amounts paid during that 5-year period on all claims described in clause (i), regardless of when such claims were filed, adjusted to reflect payments which would not be permitted under section 1346 and chapter 171 of title 28, United States Code, and

(iii) amounts in the fund established under paragraph (2) but unspent from prior fiscal years.

(2) Subject to appropriations, for each fiscal year, the Secretary shall establish a fund of an amount equal to the amount estimated under paragraph (1) that is attributable to entities receiving funds under each of the grant programs described in paragraph (4) of subsection (g), but not to exceed a total of $10,000,000 for each such fiscal year. Appropriations for purposes of this paragraph shall be made separate from appropriations made for purposes of sections 329, 330 and 340A.

(3) In order for payments to be made for judgments against the United States (together with related fees and expenses of witnesses) pursuant to this section arising from the acts or omissions

of entities described in subsection (g)(4) and of officers,[12] employees, or contractors (subject to subsection (g)(5)) of such entities, the total amount contained within the fund established by the Secretary under paragraph (2) for a fiscal year shall be transferred not later than the December 31 that occurs during the fiscal year to the appropriate accounts in the Treasury.

(l)(1) If a civil action or proceeding is filed in a State court against any entity described in subsection (g)(4) or any officer, governing board member, employee, or any contractor of such an entity for damages described in subsection (a), the Attorney General, within 15 days after being notified of such filing, shall make an appearance in such court and advise such court as to whether the Secretary has determined under subsections (g) and (h), that such entity, officer, governing board member, employee, or contractor of the entity is deemed to be an employee of the Public Health Service for purposes of this section with respect to the actions or omissions that are the subject of such civil action or proceeding. Such advice shall be deemed to satisfy the provisions of subsection (c) that the Attorney General certify that an entity, officer, governing board member, employee, or contractor of the entity was acting within the scope of their employment or responsibility.

(2) If the Attorney General fails to appear in State court within the time period prescribed under paragraph (1), upon petition of any entity or officer, governing board member, employee, or contractor of the entity named, the civil action or proceeding shall be removed to the appropriate United States district court. The civil action or proceeding shall be stayed in such court until such court conducts a hearing, and makes a determination, as to the appropriate forum or procedure for the assertion of the claim for damages described in subsection (a) and issues an order consistent with such determination.

(m)(1) An entity or officer, governing board member, employee, or contractor of an entity described in subsection (g)(1) shall, for purposes of this section, be deemed to be an employee of the Public Health Service with respect to services provided to individuals who are enrollees of a managed care plan if the entity contracts with such managed care plan for the provision of services.

(2) Each managed care plan which enters into a contract with an entity described in subsection (g)(4) shall deem the entity and any officer, governing board member, employee, or contractor of the entity as meeting whatever malpractice coverage requirements such plan may require of contracting providers for a calendar year if such entity or officer, governing board member, employee, or contractor of the entity has been deemed to be an employee of the Public Health Service for purposes of this section for such calendar year. Any plan which is found by the Secretary on the record, after notice and an opportunity for a full and fair hearing, to have violated this subsection shall upon such finding cease, for a period to be determined by the Secretary, to receive and to be eligible to receive any Federal funds under titles XVIII or XIX of the Social Security Act.

[12] Section 3(2) of Public Law 104–73 (109 Stat. 778) provides that subsection (k)(3) is amended by inserting "governing board member," after "officer,". The amendment cannot be executed because the latter term does not appear. (Compare "officer," and "officers,".)

(3) For purposes of this subsection, the term "managed care plan" shall mean health maintenance organizations and similar entities that contract at-risk with payors for the provision of health services or plan enrollees and which contract with providers (such as entities described in subsection (g)(4)) for the delivery of such services to plan enrollees.

(n)(1) Not later than one year after the date of the enactment of the Federally Supported Health Centers Assistance Act of 1995, the Comptroller General of the United States shall submit to the Congress a report on the following:

(A) The medical malpractice liability claims experience of entities that have been deemed to be employees for purposes of this section.

(B) The risk exposure of such entities.

(C) The value of private sector risk-management services, and the value of risk-management services and procedures required as a condition of receiving a grant under section 329, 330, or 340A.

(D) A comparison of the costs and the benefits to taxpayers of maintaining medical malpractice liability coverage for such entities pursuant to this section, taking into account—

(i) a comparison of the costs of premiums paid by such entities for private medical malpractice liability insurance with the cost of coverage pursuant to this section; and

(ii) an analysis of whether the cost of premiums for private medical malpractice liability insurance coverage is consistent with the liability claims experience of such entities.

(2) The report under paragraph (1) shall include the following:

(A) A comparison of—

(i) an estimate of the aggregate amounts that such entities (together with the officers, governing board members, employees, and contractors of such entities who have been deemed to be employees for purposes of this section) would have directly or indirectly paid in premiums to obtain medical malpractice liability insurance coverage if this section were not in effect; with

(ii) the aggregate amounts by which the grants received by such entities under this Act were reduced pursuant to subsection (k)(2).

(B) A comparison of—

(i) an estimate of the amount of privately offered such insurance that such entities (together with the officers, governing board members, employees, and contractors of such entities who have been deemed to be employees for purposes of this section) purchased during the three-year period beginning on January 1, 1993; with

(ii) an estimate of the amount of such insurance that such entities (together with the officers, governing board members, employees, and contractors of such entities who have been deemed to be employees for purposes of this section) will purchase after the date of the enactment of the Federally Supported Health Centers Assistance Act of 1995.

(C) An estimate of the medical malpractice liability loss history of such entities for the 10-year period preceding October 1, 1996, including but not limited to the following:

(i) Claims that have been paid and that are estimated to be paid, and legal expenses to handle such claims that have been paid and that are estimated to be paid, by the Federal Government pursuant to deeming entities as employees for purposes of this section.

(ii) Claims that have been paid and that are estimated to be paid, and legal expenses to handle such claims that have been paid and that are estimated to be paid, by private medical malpractice liability insurance.

(D) An analysis of whether the cost of premiums for private medical malpractice liability insurance coverage is consistent with the liability claims experience of entities that have been deemed as employees for purposes of this section.

(3) In preparing the report under paragraph (1), the Comptroller General of the United States shall consult with public and private entities with expertise on the matters with which the report is concerned.

(o)(1) For purposes of this section, a free clinic health professional shall in providing a qualifying health service to an individual, or an officer, governing board member, employee, or contractor of a free clinic shall in providing services for the free clinic, be deemed to be an employee of the Public Health Service for a calendar year that begins during a fiscal year for which a transfer was made under paragraph (6)(D). The preceding sentence is subject to the provisions of this subsection.

(2) In providing a health service to an individual, a health care practitioner shall for purposes of this subsection be considered to be a free clinic health professional if the following conditions are met:

(A) The service is provided to the individual at a free clinic, or through offsite programs or events carried out by the free clinic.

(B) The free clinic is sponsoring the health care practitioner pursuant to paragraph (5)(C).

(C) The service is a qualifying health service (as defined in paragraph (4)).

(D) Neither the health care practitioner nor the free clinic receives any compensation for the service from the individual or from any third-party payor (including reimbursement under any insurance policy or health plan, or under any Federal or State health benefits program). With respect to compliance with such condition:

(i) The health care practitioner may receive repayment from the free clinic for reasonable expenses incurred by the health care practitioner in the provision of the service to the individual.

(ii) The free clinic may accept voluntary donations for the provision of the service by the health care practitioner to the individual.

(E) Before the service is provided, the health care practitioner or the free clinic provides written notice to the indi-

vidual of the extent to which the legal liability of the health care practitioner is limited pursuant to this subsection (or in the case of an emergency, the written notice is provided to the individual as soon after the emergency as is practicable). If the individual is a minor or is otherwise legally incompetent, the condition under this subparagraph is that the written notice be provided to a legal guardian or other person with legal responsibility for the care of the individual.

(F) At the time the service is provided, the health care practitioner is licensed or certified in accordance with applicable law regarding the provision of the service.

(3)(A) For purposes of this subsection, the term "free clinic" means a health care facility operated by a nonprofit private entity meeting the following requirements:

(i) The entity does not, in providing health services through the facility, accept reimbursement from any third-party payor (including reimbursement under any insurance policy or health plan, or under any Federal or State health benefits program).

(ii) The entity, in providing health services through the facility, either does not impose charges on the individuals to whom the services are provided, or imposes a charge according to the ability of the individual involved to pay the charge.

(iii) The entity is licensed or certified in accordance with applicable law regarding the provision of health services.

(B) With respect to compliance with the conditions under subparagraph (A), the entity involved may accept voluntary donations for the provision of services.

(4) For purposes of this subsection, the term "qualifying health service" means any medical assistance required or authorized to be provided in the program under title XIX of the Social Security Act, without regard to whether the medical assistance is included in the plan submitted under such program by the State in which the health care practitioner involved provides the medical assistance. References in the preceding sentence to such program shall as applicable be considered to be references to any successor to such program.

(5) Subsection (g) (other than paragraphs (3) through (5)) and subsections (h), (i), and (l) apply to a health care practitioner for purposes of this subsection to the same extent and in the same manner as such subsections apply to an officer, governing board member, employee, or contractor of an entity described in subsection (g)(4), subject to paragraph (6) and subject to the following:

(A) The first sentence of paragraph (1) applies in lieu of the first sentence of subsection (g)(1)(A).

(B) This subsection may not be construed as deeming any free clinic to be an employee of the Public Health Service for purposes of this section.

(C) With respect to a free clinic, a health care practitioner is not a free clinic health professional unless the free clinic sponsors the health care practitioner. For purposes of this subsection, the free clinic shall be considered to be sponsoring the health care practitioner if—

(i) with respect to the health care practitioner, the free clinic submits to the Secretary an application meeting the requirements of subsection (g)(1)(D); and

(ii) the Secretary, pursuant to subsection (g)(1)(E), determines that the health care practitioner is deemed to be an employee of the Public Health Service.

(D) In the case of a health care practitioner who is determined by the Secretary pursuant to subsection (g)(1)(E) to be a free clinic health professional, this subsection applies to the health care practitioner (with respect to the free clinic sponsoring the health care practitioner pursuant to subparagraph (C)) for any cause of action arising from an act or omission of the health care practitioner occurring on or after the date on which the Secretary makes such determination.

(E) Subsection (g)(1)(F) applies to a health care practitioner for purposes of this subsection only to the extent that, in providing health services to an individual, each of the conditions specified in paragraph (2) is met.

(6)(A) For purposes of making payments for judgments against the United States (together with related fees and expenses of witnesses) pursuant to this section arising from the acts or omissions of free clinic health professionals, there is authorized to be appropriated $10,000,000 for each fiscal year.

(B) The Secretary shall establish a fund for purposes of this subsection. Each fiscal year amounts appropriated under subparagraph (A) shall be deposited in such fund.

(C) Not later than May 1 of each fiscal year, the Attorney General, in consultation with the Secretary, shall submit to the Congress a report providing an estimate of the amount of claims (together with related fees and expenses of witnesses) that, by reason of the acts or omissions of free clinic health professionals, will be paid pursuant to this section during the calendar year that begins in the following fiscal year. Subsection (k)(1)(B) applies to the estimate under the preceding sentence regarding free clinic health professionals to the same extent and in the same manner as such subsection applies to the estimate under such subsection regarding officers, governing board members, employees, and contractors of entities described in subsection (g)(4).

(D) Not later than December 31 of each fiscal year, the Secretary shall transfer from the fund under subparagraph (B) to the appropriate accounts in the Treasury an amount equal to the estimate made under subparagraph (C) for the calendar year beginning in such fiscal year, subject to the extent of amounts in the fund.

(7)(A) This subsection takes effect on the date of the enactment of the first appropriations Act that makes an appropriation under paragraph (6)(A), except as provided in subparagraph (B)(i).

(B)(i) Effective on the date of the enactment of the Health Insurance Portability and Accountability Act of 1996—

(I) the Secretary may issue regulations for carrying out this subsection, and the Secretary may accept and consider applications submitted pursuant to paragraph (5)(C); and

(II) reports under paragraph (6)(C) may be submitted to the Congress.

(ii) For the first fiscal year for which an appropriation is made under subparagraph (A) of paragraph (6), if an estimate under subparagraph (C) of such paragraph has not been made for the calendar year beginning in such fiscal year, the transfer under subparagraph (D) of such paragraph shall be made notwithstanding the lack of the estimate, and the transfer shall be made in an amount equal to the amount of such appropriation.

(p) ADMINISTRATION OF SMALLPOX COUNTERMEASURES BY HEALTH PROFESSIONALS.—

(1) IN GENERAL.—For purposes of this section, and subject to other provisions of this subsection, a covered person shall be deemed to be an employee of the Public Health Service with respect to liability arising out of administration of a covered countermeasure against smallpox to an individual during the effective period of a declaration by the Secretary under paragraph (2)(A).

(2) DECLARATION BY SECRETARY CONCERNING COUNTERMEASURE AGAINST SMALLPOX.—

(A) AUTHORITY TO ISSUE DECLARATION.—

(i) IN GENERAL.—The Secretary may issue a declaration, pursuant to this paragraph, concluding that an actual or potential bioterrorist incident or other actual or potential public health emergency makes advisable the administration of a covered countermeasure to a category or categories of individuals.

(ii) COVERED COUNTERMEASURE.—The Secretary shall specify in such declaration the substance or substances that shall be considered covered countermeasures (as defined in paragraph (7)(A)) for purposes of administration to individuals during the effective period of the declaration.

(iii) EFFECTIVE PERIOD.—The Secretary shall specify in such declaration the beginning and ending dates of the effective period of the declaration, and may subsequently amend such declaration to shorten or extend such effective period, provided that the new closing date is after the date when the declaration is amended.

(iv) PUBLICATION.—The Secretary shall promptly publish each such declaration and amendment in the Federal Register.

(B) LIABILITY OF UNITED STATES ONLY FOR ADMINISTRATIONS WITHIN SCOPE OF DECLARATION.—Except as provided in paragraph (5)(B)(ii), the United States shall be liable under this subsection with respect to a claim arising out of the administration of a covered countermeasure to an individual only if—

(i) the countermeasure was administered by a qualified person, for a purpose stated in paragraph (7)(A)(i), and during the effective period of a declaration by the Secretary under subparagraph (A) with respect to such countermeasure; and

(ii)(I) the individual was within a category of individuals covered by the declaration; or

(II) the qualified person administering the countermeasure had reasonable grounds to believe that such individual was within such category.

(C) PRESUMPTION OF ADMINISTRATION WITHIN SCOPE OF DECLARATION IN CASE OF ACCIDENTAL VACCINIA INOCULATION.—

(i) IN GENERAL.—If vaccinia vaccine is a covered countermeasure specified in a declaration under subparagraph (A), and an individual to whom the vaccinia vaccine is not administered contracts vaccinia, then, under the circumstances specified in clause (ii), the individual—

(I) shall be rebuttably presumed to have contracted vaccinia from an individual to whom such vaccine was administered as provided by clauses (i) and (ii) of subparagraph (B); and

(II) shall (unless such presumption is rebutted) be deemed for purposes of this subsection to be an individual to whom a covered countermeasure was administered by a qualified person in accordance with the terms of such declaration and as described by subparagraph (B).

(ii) CIRCUMSTANCES IN WHICH PRESUMPTION APPLIES.—The presumption and deeming stated in clause (i) shall apply if—

(I) the individual contracts vaccinia during the effective period of a declaration under subparagraph (A) or by the date 30 days after the close of such period; or

(II) the individual has resided with, or has had contact with, an individual to whom such vaccine was administered as provided by clauses (i) and (ii) of subparagraph (B) and contracts vaccinia after such date.

(D) ACTS AND OMISSIONS DEEMED TO BE WITHIN SCOPE OF EMPLOYMENT.—

(i) IN GENERAL.—In the case of a claim arising out of alleged transmission of vaccinia from an individual described in clause (ii), acts or omissions by such individual shall be deemed to have been taken within the scope of such individual's office or employment for purposes of—

(I) subsection (a); and

(II) section 1346(b) and chapter 171 of title 28, United States Code.

(ii) INDIVIDUALS TO WHOM DEEMING APPLIES.—An individual is described by this clause if—

(I) vaccinia vaccine was administered to such individual as provided by subparagraph (B); and

(II) such individual was within a category of individuals covered by a declaration under subparagraph (A)(i).

(3) EXHAUSTION; EXCLUSIVITY; OFFSET.—

(A) EXHAUSTION.—

(i) IN GENERAL.—A person may not bring a claim under this subsection unless such person has exhausted such remedies as are available under part C of this title, except that if the Secretary fails to make a final determination on a request for benefits or compensation filed in accordance with the requirements of such part within 240 days after such request was filed, the individual may seek any remedy that may be available under this section.

(ii) TOLLING OF STATUTE OF LIMITATIONS.—The time limit for filing a claim under this subsection, or for filing an action based on such claim, shall be tolled during the pendency of a request for benefits or compensation under part C of this title.

(iii) CONSTRUCTION.—This subsection shall not be construed as superseding or otherwise affecting the application of a requirement, under chapter 171 of title 28, United States Code, to exhaust administrative remedies.

(B) EXCLUSIVITY.—The remedy provided by subsection (a) shall be exclusive of any other civil action or proceeding for any claim or suit this subsection encompasses, except for a proceeding under part C of this title.

(C) OFFSET.—The value of all compensation and benefits provided under part C of this title for an incident or series of incidents shall be offset against the amount of an award, compromise, or settlement of money damages in a claim or suit under this subsection based on the same incident or series of incidents.

(4) CERTIFICATION OF ACTION BY ATTORNEY GENERAL.—Subsection (c) applies to actions under this subsection, subject to the following provisions:

(A) NATURE OF CERTIFICATION.—The certification by the Attorney General that is the basis for deeming an action or proceeding to be against the United States, and for removing an action or proceeding from a State court, is a certification that the action or proceeding is against a covered person and is based upon a claim alleging personal injury or death arising out of the administration of a covered countermeasure.

(B) CERTIFICATION OF ATTORNEY GENERAL CONCLUSIVE.—The certification of the Attorney General of the facts specified in subparagraph (A) shall conclusively establish such facts for purposes of jurisdiction pursuant to this subsection.

(5) COVERED PERSON TO COOPERATE WITH UNITED STATES.—

(A) IN GENERAL.—A covered person shall cooperate with the United States in the processing and defense of a claim or action under this subsection based upon alleged acts or omissions of such person.

(B) CONSEQUENCES OF FAILURE TO COOPERATE.—Upon the motion of the United States or any other party and upon finding that such person has failed to so cooperate—

(i) the court shall substitute such person as the party defendant in place of the United States and, upon motion, shall remand any such suit to the court in which it was instituted if it appears that the court lacks subject matter jurisdiction;

(ii) the United States shall not be liable based on the acts or omissions of such person; and

(iii) the Attorney General shall not be obligated to defend such action.

(6) RECOURSE AGAINST COVERED PERSON IN CASE OF GROSS MISCONDUCT OR CONTRACT VIOLATION.—

(A) IN GENERAL.—Should payment be made by the United States to any claimant bringing a claim under this subsection, either by way of administrative determination, settlement, or court judgment, the United States shall have, notwithstanding any provision of State law, the right to recover for that portion of the damages so awarded or paid, as well as interest and any costs of litigation, resulting from the failure of any covered person to carry out any obligation or responsibility assumed by such person under a contract with the United States or from any grossly negligent, reckless, or illegal conduct or willful misconduct on the part of such person.

(B) VENUE.—The United States may maintain an action under this paragraph against such person in the district court of the United States in which such person resides or has its principal place of business.

(7) DEFINITIONS.—As used in this subsection, terms have the following meanings:

(A) COVERED COUNTERMEASURE.—The term "covered countermeasure" or "covered countermeasure against smallpox", means a substance that is—

(i)(I) used to prevent or treat smallpox (including the vaccinia or another vaccine); or

(II)[13] used to control or treat the adverse effects of vaccinia inoculation or of administration of another covered countermeasure; and

(ii) specified in a declaration under paragraph (2).

(B) COVERED PERSON.—The term "covered person", when used with respect to the administration of a covered countermeasure, means a person who is—

(i) a manufacturer or distributor of such countermeasure;

(ii) a health care entity under whose auspices[14]—

(I) such countermeasure was administered;

(II) a determination was made as to whether, or under what circumstances, an individual should receive a covered countermeasure;

[13] Indentation is so in law. See section 3(e) of Public Law 108–20 (117 Stat. 647).

[14] Clause (ii) is shown according to the probable intent of the Congress. In amending the clause to create a subclause (I), section 3(f)(2)(B) of Public Law 108–20 (117 Stat. 647) provided that the clause is amended by redesignating certain words "as clause (I) and indenting accordingly". The reference in the amendatory instructions to "clause (I)" probably should be to "subclause (I)", and the use in the instructions of the word "accordingly" requires the exercise of editorial judgment.

(III) the immediate site of administration on the body of a covered countermeasure was monitored, managed, or cared for; or

(IV) an evaluation was made of whether the administration of a countermeasure was effective;

(iii) a qualified person who administered such countermeasure;

(iv) a State, a political subdivision of a State, or an agency or official of a State or of such a political subdivision, if such State, subdivision, agency, or official has established requirements, provided policy guidance, supplied technical or scientific advice or assistance, or otherwise supervised or administered a program with respect to administration of such countermeasures;

(v) in the case of a claim arising out of alleged transmission of vaccinia from an individual—

(I) the individual who allegedly transmitted the vaccinia, if vaccinia vaccine was administered to such individual as provided by paragraph (2)(B) and such individual was within a category of individuals covered by a declaration under paragraph (2)(A)(i); or

(II) an entity that employs an individual described by clause (I) or where such individual has privileges or is otherwise authorized to provide health care;

(vi) an official, agent, or employee of a person described in clause (i), (ii), (iii), or (iv);

(vii) a contractor of, or a volunteer working for, a person described in clause (i), (ii), or (iv), if the contractor or volunteer performs a function for which a person described in clause (i), (ii), or (iv) is a covered person; or

(viii) an individual who has privileges or is otherwise authorized to provide health care under the auspices of an entity described in clause (ii) or (v)(II).

(C) QUALIFIED PERSON.—The term "qualified person", when used with respect to the administration of a covered countermeasure, means a licensed health professional or other individual who [15]—

(i) is authorized to administer such countermeasure under the law of the State in which the countermeasure was administered; or

(ii) is otherwise authorized by the Secretary to administer such countermeasure.

(D) ARISING OUT OF ADMINISTRATION OF A COVERED COUNTERMEASURE.—The term "arising out of administration of a covered countermeasure", when used with respect

[15] Subparagraph (C) is shown according to the probable intent of the Congress. In amending the subparagraph to create a clause (i), section 3(g) of Public Law 108–20 (117 Stat. 648) provided that the subparagraph is amended by redesignating certain words "as clause (i) and indenting accordingly". The use in the amendatory instructions of the word "accordingly" requires the exercise of editorial judgment.

to a claim or liability, includes a claim or liability arising out of—

(i) determining whether, or under what conditions, an individual should receive a covered countermeasure;

(ii) obtaining informed consent of an individual to the administration of a covered countermeasure;

(iii) monitoring, management, or care of an immediate site of administration on the body of a covered countermeasure, or evaluation of whether the administration of the countermeasure has been effective; or

(iv) transmission of vaccinia virus by an individual to whom vaccinia vaccine was administered as provided by paragraph (2)(B).

ADMINISTRATION OF GRANTS IN CERTAIN MULTIGRANT PROJECTS.

SEC. 226.[16]**[**235**]** For the purpose of facilitating the administration of, and expediting the carrying out of the purposes of, the programs established by titles VII, VIII, and IX, and sections 304, 314(a), 314(b), 314(c), 314(d), and 314(e) of this Act in situations in which grants are sought or made under two or more of such programs with respect to a single project, the Secretary is authorized to promulgate regulations—

(1) under which the administrative functions under such programs with respect to such project will be performed by a single administrative unit which is the administrative unit charged with the administration of any of such programs or is the administrative unit charged with the supervision of two or more of such programs;

(2) designed to reduce the number of applications, reports, and other materials required under such programs to be submitted with respect to such project, and otherwise to simplify, consolidate, and make uniform (to the extent feasible), the data and information required to be contained in such applications, reports, and other materials; and

(3) under which inconsistent or duplicative requirements imposed by such programs will be revised and made uniform with respect to such project;

except that nothing in this section shall be construed to authorize the Secretary to waive or suspend, with respect to any such project, any requirement with respect to any of such programs if such requirement is imposed by law or by any regulation required by law.

ORPHAN PRODUCTS BOARD.

SEC. 227.**[**236**]** (a) There is established in the Department of Health and Human Services a board for the development of drugs (including biologics) and devices (including diagnostic products) for rare diseases or conditions to be known as the Orphan Products Board. The Board shall be comprised of the Assistant Secretary for Health of the Department of Health and Human Services and rep-

[16] Former section 225 was repealed by section 408(b)(1) of Public Law 94–484 (90 Stat. 2281). Subpart III of part D of title III now applies to the matter with which former section 225 was concerned.

resentatives, selected by the Secretary, of the Food and Drug Administration, the National Institutes of Health, the Centers for Disease Control and Prevention, and any other Federal department or agency which the Secretary determines has activities relating to drugs and devices for rare diseases or conditions. The Assistant Secretary for Health shall chair the Board.

(b) The function of the Board shall be to promote the development of drugs and devices for rare diseases or conditions and the coordination among Federal, other public, and private agencies in carrying out their respective functions relating to the development of such articles, such diseases or conditions.

(c) In the case of drugs for rare diseases or conditions the Board shall—

(1) evaluate—

(A) the effect of subchapter B of the Federal Food, Drug, and Cosmetic Act on the development of such drugs, and

(B) the implementation of such subchapter;[17]

(2) evaluate the activities of the National Institutes of Health for the development of drugs for such diseases or conditions,

(3) assure appropriate coordination among the Food and Drug Administration, the National Institutes of Health and the Centers for Disease Control and Prevention in the carrying out of their respective functions relating to the development of drugs for such diseases or conditions to assure that the activities of each agency are complementary.

(4) assure appropriate coordination among all interested Federal agencies, manufacturers, and organizations representing patients, in their activities relating to such drugs,

(5) with the consent of the sponsor of a drug for a rare disease or condition exempt under section 505(i) of the Federal Food, Drug, and Cosmetic Act or regulations issued under such section, inform physicians and the public respecting the availability of such drug for such disease or condition and inform physicians and the public respecting the availability of drugs approved under section 505(c) of such Act or licensed under section 351 of this Act for rare diseases or conditions,

(6) seek business entities and others to undertake the sponsorship of drugs for rare diseases or conditions, seek investigators to facilitate the development of such drugs, and seek business entities to participate in the distribution of such drugs, and

(7) recognize the efforts of public and private entities and individuals in seeking the development of drugs for rare diseases or conditions and in developing such drugs.

(d) The Board shall consult with interested persons respecting the activities of the Board under this section and as part of such consultation shall provide the opportunity for the submission of oral views.

[17] So in law. The semicolon probably should be a comma.

(e) The Board shall submit to the Committee on Labor and Human Resources of the Senate and the Committee on Energy and Commerce of the House of Representatives an annual report—

(1) identifying the drugs which have been designated under section 526 of the Federal Food, Drug, and Cosmetic Act for a rare disease or condition,

(2) describing the activities of the Board, and

(3) containing the results of the evaluations carried out by the Board.

The Director of the National Institutes of Health shall submit to the Board for inclusion in the annual report a report on the rare disease and condition research activities of the Institutes of the National Institutes of Health; the Secretary of the Treasury shall submit to the Board for inclusion in the annual report a report on the use of the credit against tax provided by section 44H of the Internal Revenue Code of 1954; and the Secretary of Health and Human Services shall submit to the Board for inclusion in the annual report a report on the program of assistance under section 5 of the Orphan Drug Act for the development of drugs for rare diseases and conditions. Each annual report shall be submitted by June 1 of each year for the preceding calendar year.

SILVIO O. CONTE SENIOR BIOMEDICAL RESEARCH SERVICE.

SEC. 228.[237] (a)(1) There shall be in the Public Health Service a Silvio O. Conte Senior Biomedical Research Service, not to exceed 500 members.

(2) The authority established in paragraph (1) regarding the number of members in the Silvio O. Conte Senior Biomedical Research Service is in addition to any authority established regarding the number of members in the commissioned Regular Corps, in the Reserve Corps, and in the Senior Executive Service. Such paragraph may not be construed to require that the number of members in the commissioned Regular Corps, in the Reserve Corps, or in the Senior Executive Service be reduced to offset the number of members serving in the Silvio O. Conte Senior Biomedical Research Service (in this section referred to as the "Service").

(b) The Service shall be appointed by the Secretary without regard to the provisions of title 5, United States Code, regarding appointment, and shall consist of individuals outstanding in the field of biomedical research or clinical research evaluation. No individual may be appointed to the Service unless such individual (1) has earned a doctoral level degree in biomedicine or a related field, and (2) meets the qualification standards prescribed by the Office of Personnel Management for appointment to a position at GS–15 of the General Schedule. Notwithstanding any previous applicability to an individual who is a member of the Service, the provisions of subchapter I of chapter 35 (relating to retention preference), chapter 43 (relating to performance appraisal and performance actions), chapter 51 (relating to classification), subchapter III of chapter 53 (relating to General Schedule pay rates), and chapter 75 (relating to adverse actions) of title 5, United States Code, shall not apply to any member of the Service.

(c) The Secretary shall develop a performance appraisal system designed to—

(1) provide for the systematic appraisal of the performance of members, and

(2) encourage excellence in performance by members.

(d)(1) The Secretary shall determine, subject to the provisions of this subsection, the pay of members of the Service.

(2) The pay of a member of the Service shall not be less than the minimum rate payable for GS–15 of the General Schedule and shall not exceed the rate payable for level I of the Executive Schedule unless approved by the President under section 5377(d)(2) of title 5, United States Code.

(e) The Secretary may, upon the request of a member who—

(1) performed service in the employ of an institution of higher education immediately prior to his appointment as a member of the Service, and

(2) retains the right to continue to make contributions to the retirement system of such institution,

contribute an amount not to exceed 10 percent per annum of the member's basic pay to such institution's retirement system on behalf of such member. A member who requests that such contribution be made shall not be covered by, or earn service credit under, any retirement system established for employees of the United States under title 5, United States Code, but such service shall be creditable for determining years of service under section 6303(a) of such title.

(f) Subject to the following sentence, the Secretary may, notwithstanding the provisions of title 5, United States Code, regarding appointment, appoint an individual who is separated from the Service involuntarily and without cause to a position in the competitive civil service at GS–15 of the General Schedule, and such appointment shall be a career appointment. In the case of such an individual who immediately prior to his appointment to the Service was not a career appointee in the civil service or the Senior Executive Service, such appointment shall be in the excepted civil service and may not exceed a period of 2 years.

(g) The Secretary shall promulgate such rules and regulations, not inconsistent with this section, as may be necessary for the efficient administration of the Service.

SEC. 229.[18] [237a] HEALTH AND HUMAN SERVICES OFFICE ON WOMEN'S HEALTH.

(a) ESTABLISHMENT OF OFFICE.—There is established within the Office of the Secretary, an Office on Women's Health (referred to in this section as the "Office"). The Office shall be headed by a Deputy Assistant Secretary for Women's Health who may report to the Secretary.

(b) DUTIES.—The Secretary, acting through the Office, with respect to the health concerns of women, shall—

[18] Section 3509 of the Patient Protection and Affordable Care Act (Public Law 111–148, enacted March 23, 2010) established offices of womens health in the Office of the Secretary of HHS (this section), the Centers for Disease Control and Prevention (section 310A of this Act), the Agency for Healthcare Research and Quality (section 925 of this Act), the Health Resources and Services Administration (section 713 of the Social Security Act), and the Food and Drug Administration (section 1011 of the Federal Food, Drug, and Cosmetic Act).

(1) establish short-range and long-range goals and objectives within the Department of Health and Human Services and, as relevant and appropriate, coordinate with other appropriate offices on activities within the Department that relate to disease prevention, health promotion, service delivery, research, and public and health care professional education, for issues of particular concern to women throughout their lifespan;

(2) provide expert advice and consultation to the Secretary concerning scientific, legal, ethical, and policy issues relating to women's health;

(3) monitor the Department of Health and Human Services' offices, agencies, and regional activities regarding women's health and identify needs regarding the coordination of activities, including intramural and extramural multidisciplinary activities;

(4) establish a Department of Health and Human Services Coordinating Committee on Women's Health, which shall be chaired by the Deputy Assistant Secretary for Women's Health and composed of senior level representatives from each of the agencies and offices of the Department of Health and Human Services;

(5) establish a National Women's Health Information Center to—

(A) facilitate the exchange of information regarding matters relating to health information, health promotion, preventive health services, research advances, and education in the appropriate use of health care;

(B) facilitate access to such information;

(C) assist in the analysis of issues and problems relating to the matters described in this paragraph; and

(D) provide technical assistance with respect to the exchange of information (including facilitating the development of materials for such technical assistance);

(6) coordinate efforts to promote women's health programs and policies with the private sector; and

(7) through publications and any other means appropriate, provide for the exchange of information between the Office and recipients of grants, contracts, and agreements under subsection (c), and between the Office and health professionals and the general public.

(c) GRANTS AND CONTRACTS REGARDING DUTIES.—

(1) AUTHORITY.—In carrying out subsection (b), the Secretary may make grants to, and enter into cooperative agreements, contracts, and interagency agreements with, public and private entities, agencies, and organizations.

(2) EVALUATION AND DISSEMINATION.—The Secretary shall directly or through contracts with public and private entities, agencies, and organizations, provide for evaluations of projects carried out with financial assistance provided under paragraph (1) and for the dissemination of information developed as a result of such projects.

(d) REPORTS.—Not later than 1 year after the date of enactment of this section, and every second year thereafter, the Sec-

retary shall prepare and submit to the appropriate committees of Congress a report describing the activities carried out under this section during the period for which the report is being prepared.

(e) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2010 through 2014.

PART B—MISCELLANEOUS PROVISIONS

GIFTS.

SEC. 231.[238] (a) The Secretary is authorized to accept on behalf of the United States gifts made unconditionally by will or otherwise for the benefit of the Service or for the carrying out of any of its functions. Conditional gifts may be so accepted if recommended by the Surgeon General, and the principal of and income from any such conditional gift shall be held, invested, reinvested, and used in accordance with its conditions, but no gift shall be accepted which is conditioned upon any expenditure not to be met therefrom or from the income thereof unless such expenditure has been approved by Act of Congress.

(b) Any unconditional gift of money accepted, pursuant to the authority granted in subsection (a) of this section, the net proceeds from the liquidation (pursuant to subsection (c) or subsection (d) of this section) of any other property so accepted, and the proceeds of insurance on any such gift property not used for its restoration, shall be deposited in the Treasury of the United States and are hereby appropriated and shall be held in trust by the Secretary of the Treasury for the benefit of the Service, and he may invest and reinvest such funds in interest-bearing obligations of the United States or in obligations guaranteed as to both principal and interest by the United States. Such gifts and the income from such investments shall be available for expenditure in the operation of the Service and the performance of its functions, subject to the same examination and audit as is provided for appropriations made for the Service by Congress.

(c) The evidences of any unconditional gift of intangible personal property, other than money, accepted pursuant to the authority granted in subsection (a) of this section shall be deposited with the Secretary of the Treasury and he, in his discretion, may hold them, or liquidate them except that they shall be liquidated upon the request of the Secretary, whenever necessary to meet payments required in the operation of the Service or the performance of its functions. The proceeds and income from any such property held by the Secretary of the Treasury shall be available for expenditure as is provided in subsection (b) of this section.

(d) The Secretary shall hold any real property or any tangible personal property accepted unconditionally pursuant to the authority granted in subsection (a) of this section and he shall permit such property to be used for the operation of the Service and the performance of its functions or he may lease or hire such property, and may insure such property, and deposit the income thereof with the Secretary of the Treasury to be available for expenditure as provided in subsection (b) of this section: *Provided,* That the in-

come from any such real property or tangible personal property shall be available for expenditure in the discretion of the Secretary for the maintenance, preservation, or repair and insurance of such property and that any proceeds from insurance may be used to restore the property insured. Any such property when not required for the operation of the Service or the performance of its functions may be liquidated by the Secretary, and the proceeds thereof deposited with the Secretary of the Treasury, whenever in his judgment the purposes of the gifts will be served thereby.

USE OF IMMIGRATION STATION HOSPITALS.

SEC. 232.[238a] The Immigration and Naturalization Service may, by agreement of the heads of the departments concerned, permit the Public Health Service to use hospitals at immigration stations for the care of Public Health Service patients. The Surgeon General shall reimburse the Immigration and Naturalization Service for the actual cost of furnishing fuel, light, water, telephone, and similar supplies and services, which reimbursement shall be covered into the proper Immigration and Naturalization Service appropriation, or such costs may be paid from working funds established as provided by law, but no charge shall be made for the expense of physical upkeep of the hospitals. The Immigration and Naturalization Service shall reimburse the Surgeon General for the care and treatment of persons detained in hospitals of the Public Health Service at the request of the Immigration and Naturalization Service unless such persons are entitled to care and treatment under section 322(a). [19]

MONEY COLLECTED FOR CARE OF PATIENTS.

SEC. 233.[238b] Money collected as provided by law for expenses incurred in the care and treatment of foreign seamen, and money received for the care and treatment of pay patients, including any amounts received from any executive department on account of care and treatment of pay patients, shall be covered into the appropriation from which the expenses of such care and treatment were paid.

TRANSPORTATION OF REMAINS OF OFFICERS.

SEC. 234.[238c] Appropriations available for traveling expenses of the Service shall be available for meeting the cost of preparation for burial and of transportation to the place of burial of remains of commissioned officers, and of personnel specified in regulations, who die in line of duty. Appropriations available for carrying out the provisions of this Act shall also be available for the payment of such expenses relating to the recovery, care, and disposition of the remains of personnel or their dependents as may be authorized under other provisions of law.

[19] Subsection (a) of section 322 was repealed by section 986 of Public Law 97–35, and the Public Law redesignated former subsection (c) as subsection (a). Section 232 (above) was enacted before this repeal and redesignation. Current section 322(a) authorizes the treatment and care of certain persons. (Section 232 was originally enacted as section 502, and was subsequently redesignated by Public Laws 98–24, 99–660, 100–690, and 103–43.)

GRANTS TO FEDERAL INSTITUTIONS.

SEC. 235.[238d] Appropriations to the Public Health Service available under this Act for research, training, or demonstration project grants or for grants to expand existing treatment and research programs and facilities for alcoholism, narcotic addiction, drug abuse, and drug dependence and appropriations under title VI of the Mental Health Systems Act shall also be available, on the same terms and conditions as apply to non-Federal institutions, for grants for the same purpose to Federal institutions, except that grants to such Federal institutions may be funded at 100 per centum of the costs.

TRANSFER OF FUNDS.

SEC. 236.[238e] For the purpose of any reorganization under section 202, the Secretary, with the approval of the Director of the Bureau of the Budget,[20] is authorized to make such transfers of funds between appropriations as may be necessary for the continuance of transferred functions.

AVAILABILITY OF APPROPRIATIONS.

SEC. 237.[238f] Appropriations for carrying out the purposes of this Act shall be available for expenditure for personal services and rent at the seat of Government; books of reference, periodicals, and exhibits; printing and binding; transporting in Government-owned automotive equipment, to and from school, children of personnel who have quarters for themselves and their families at stations determined by the Surgeon General to be isolated stations; expenses incurred in pursuing, identifying, and returning prisoners who escape from any hospital, institution, or station of the Service or from the custody of any officer or employee of the Service, including rewards for the capture of such prisoners; furnishing, repairing, and cleaning such wearing apparel as may be prescribed by the Surgeon General for use by employees in the performance of their official duties; reimbursing officers and employees, subject to regulations of the Secretary, for the cost of repairing or replacing their personal belongings damaged or destroyed by patients while such officers or employees are engaged in the performance of their official duties; and maintenance of buildings of the National Institutes of Health.

UNAUTHORIZED WEARING OF UNIFORMS.

SEC. 238.[238g] Except as may be authorized by regulations of the President, the insignia and uniform of commissioned officers of the Service, or any distinctive part of such insignia or uniform, or any insignia or uniform any part of which is similar to a distinctive part thereof, shall not be worn, after the promulgation of such regulations, by any person other than a commissioned officer of the Service.

[20] Now the Office of Management and Budget.

BIANNUAL REPORT.

SEC. 239.[238h] The Surgeon General shall transmit to the Secretary, for submission to the Congress, on January 1, 1995, and on January 1, every 2 years thereafter, a full report of the administration of the functions of the Service under this Act, including a detailed statement of receipts and disbursements.

MEMORIALS AND OTHER ACKNOWLEDGMENTS.

SEC. 240.[238i] The Secretary may provide for suitably acknowledging, within the Department (whether by memorials, designations, or other suitable acknowledgments), (1) efforts of persons who have contributed substantially to the health of the Nation and (2) gifts for use in activities of the Department related to health.

EVALUATION OF PROGRAMS.

SEC. 241.[238j] (a) IN GENERAL.—Such portion as the Secretary shall determine, but not less than 0.2 percent nor more than 1 percent, of any amounts appropriated for programs authorized under this Act shall be made available for the evaluation (directly, or by grants of contracts) of the implementation and effectiveness of such programs.

(b) REPORT ON EVALUATIONS.—Not later than February 1 of each year, the Secretary shall prepare and submit to the Committee on Labor and Human Resources of the Senate and the Committee on Energy and Commerce of the House of Representatives a report summarizing the findings of the evaluations conducted under subsection (a).

CONTRACT AUTHORITY.

SEC. 242.[238k] The authority of the Secretary to enter into contracts under this Act shall be effective for any fiscal year only to such extent or in such amounts as are provided in advance by appropriation Acts.

RECOVERY.

SEC. 243.[238l] (a) If any facility with respect to which funds have been paid under the Community Mental Health Centers Act (as such Act was in effect prior to October 1, 1981) is, at any time within twenty years after the completion of remodeling, construction, or expansion or after the date of its acquisition—

(1) sold or transferred to any entity (A) which would not have been qualified to file an application under section 222 of such Act (as such section was in effect prior to October 1, 1981) or (B) which is disapproved as a transferee by the State mental health agency or by another entity designated by the chief executive officer of the State, or

(2) ceases to be used by a community mental health center in the provision of comprehensive mental health services,

the United States shall be entitled to recover from the transferor, transferee, or owner of the facility, the base amount prescribed by subsection (c)(1) plus the interest (if any) prescribed by subsection (c)(2).

(b) The transferor and transferee of a facility that is sold or transferred as described in subsection (a)(1), or the owner of a facility the use of which changes as described in subsection (a)(2), shall provide the Secretary written notice of such sale, transfer, or change within 10 days after the date on which such sale, transfer, or cessation of use occurs or within 30 days after the date of enactment of this subsection, whichever is later.

(c)(1) The base amount that the United States is entitled to recover under subsection (a) is the amount bearing the same ratio to the then value (as determined by the agreement of the parties or in an action brought in the district court of the United States for the district in which the facility is situated) of so much of the facility as constituted an approved project or projects as the amount of the Federal participation bore to the cost of the remodeling, construction, expansion, or acquisition of the project or projects.

(2)(A) The interest that the United States is entitled to recover under subsection (a) is the interest for the period (if any) described in subparagraph (B) at a rate (determined by the Secretary) based on the average of the bond equivalent rates of ninety-one-day Treasury bills auctioned during that period.

(B) The period referred to in subparagraph (A) is the period beginning—

(i) if notice is provided as prescribed by subsection (b), 191 days after the date on which such sale, transfer, or cessation of use occurs, or

(ii) if notice is not provided as prescribed by subsection (b), 11 days after such sale, transfer, or cessation of use occurs,

and ending on the date the amount the United States is entitled to recover is collected.

(d) The Secretary may waive the recovery rights of the United States under subsection (a) with respect to a facility (under such conditions as the Secretary may establish by regulation) if the Secretary determines that there is good cause for waiving such rights.

(e) The right of recovery of the United States under subsection (a) shall not, prior to judgment, constitute a lien on any facility.

USE OF FISCAL AGENTS.

SEC. 244.[238m] (a) The Secretary may enter into contracts with fiscal agents—

(1)(A) to determine the amounts payable to persons who, on behalf of the Indian Health Service, furnish health services to eligible Indians,

(B) to determine the amounts payable to persons who, on behalf of the Public Health Service, furnish health services to individuals pursuant to section 319 or 322,

(2) to receive, disburse, and account for funds in making payments described in paragraph (1),

(3) to make such audits of records as may be necessary to assure that these payments are proper, and

(4) to perform such additional functions as may be necessary to carry out the functions described in paragraphs (1) through (3).

(b)(1) Contracts under subsection (a) may be entered into without regard to section 3709 of the Revised Statutes (41 U.S.C. 5) or any other provision of law requiring competition.

(2) No such contract shall be entered into with an entity unless the Secretary finds that the entity will perform its obligations under the contract efficiently and effectively and will meet such requirements as to financial responsibility, legal authority, and other matters as he finds pertinent.

(c) A contract under subsection (a) may provide for advances of funds to enable entities to make payments under the contract.

(d) Subsections (d) and (e) of section 1842 of the Social Security Act shall apply to contracts with entities under subsection (a) in the same manner as they apply to contracts with carriers under that section.

(e) In this section, the term "fiscal agent" means a carrier described in section 1842(f)(1) of the Social Security Act and includes, with respect to contracts under subsection (a)(1)(A), an Indian tribe or tribal organization acting under contract with the Secretary under the Indian Self-Determination Act (Public Law 93–638).

ABORTION-RELATED DISCRIMINATION IN GOVERNMENTAL ACTIVITIES REGARDING TRAINING AND LICENSING OF PHYSICIANS.

SEC. 245.[238n] (a) IN GENERAL.—The Federal Government, and any State or local government that receives Federal financial assistance, may not subject any health care entity to discrimination on the basis that—

(1) the entity refuses to undergo training in the performance of induced abortions, to require or provide such training, to perform such abortions, or to provide referrals for such training or such abortions;

(2) the entity refuses to make arrangements for any of the activities specified in paragraph (1); or

(3) the entity attends (or attended) a post-graduate physician training program, or any other program of training in the health professions, that does not (or did not) perform induced abortions or require, provide or refer for training in the performance of induced abortions, or make arrangements for the provision of such training.

(b) ACCREDITATION OF POSTGRADUATE PHYSICIAN TRAINING PROGRAMS.—

(1) IN GENERAL.—In determining whether to grant a legal status to a health care entity (including a license or certificate), or to provide such entity with financial assistance, services or other benefits, the Federal Government, or any State or local government that receives Federal financial assistance, shall deem accredited any postgraduate physician training program that would be accredited but for the accrediting agency's reliance upon an accreditation standards[21] that requires an entity to perform an induced abortion or require, provide, or refer for training in the performance of induced abortions, or make arrangements for such training, regardless of whether such standard provides exceptions or exemptions. The govern-

[21] So in law. Probably should read "standard".

ment involved shall formulate such regulations or other mechanisms, or enter into such agreements with accrediting agencies, as are necessary to comply with this subsection.

(2) RULES OF CONSTRUCTION.—

(A) IN GENERAL.—With respect to subclauses (I) and (II) of section 705(a)(2)(B)(i) (relating to a program of insured loans for training in the health professions), the requirements in such subclauses regarding accredited internship or residency programs are subject to paragraph (1) of this subsection.

(B) EXCEPTIONS.—This section shall not—

(i) prevent any health care entity from voluntarily electing to be trained, to train, or to arrange for training in the performance of, to perform, or to make referrals for induced abortions; or

(ii) prevent an accrediting agency or a Federal, State or local government from establishing standards of medical competency applicable only to those individuals who have voluntarily elected to perform abortions.

(c) DEFINITIONS.—For purposes of this section:

(1) The term "financial assistance", with respect to a government program, includes governmental payments provided as reimbursement for carrying out health-related activities.

(2) The term "health care entity" includes an individual physician, a postgraduate physician training program, and a participant in a program of training in the health professions.

(3) The term "postgraduate physician training program" includes a residency training program.

SEC. 246.[238o] RESTRICTION ON USE OF FUNDS FOR ASSISTED SUICIDE, EUTHANASIA, AND MERCY KILLING.

Appropriations for carrying out the purposes of this Act shall not be used in a manner inconsistent with the Assisted Suicide Funding Restriction Act of 1997.[22]

RECOMMENDATIONS AND GUIDELINES REGARDING AUTOMATED EXTERNAL DEFIBRILLATORS FOR FEDERAL BUILDINGS.

SEC. 247.[238p] (a) GUIDELINES ON PLACEMENT.—The Secretary shall establish guidelines with respect to placing automated external defibrillator devices in Federal buildings. Such guidelines shall take into account the extent to which such devices may be used by lay persons, the typical number of employees and visitors in the buildings, the extent of the need for security measures regarding the buildings, buildings or portions of buildings in which there are special circumstances such as high electrical voltage or extreme heat or cold, and such other factors as the Secretary determines to be appropriate.

(b) RELATED RECOMMENDATIONS.—The Secretary shall publish in the Federal Register the recommendations of the Secretary on the appropriate implementation of the placement of automated ex-

[22] Public Law 105–12 (111 Stat. 23).

ternal defibrillator devices under subsection (a), including procedures for the following:

(1) Implementing appropriate training courses in the use of such devices, including the role of cardiopulmonary resuscitation.

(2) Proper maintenance and testing of the devices.

(3) Ensuring coordination with appropriate licensed professionals in the oversight of training of the devices.

(4) Ensuring coordination with local emergency medical systems regarding the placement and incidents of use of the devices.

(c) CONSULTATIONS; CONSIDERATION OF CERTAIN RECOMMENDATIONS.—In carrying out this section, the Secretary shall—

(1) consult with appropriate public and private entities;

(2) consider the recommendations of national and local public-health organizations for improving the survival rates of individuals who experience cardiac arrest in nonhospital settings by minimizing the time elapsing between the onset of cardiac arrest and the initial medical response, including defibrillation as necessary; and

(3) consult with and counsel other Federal agencies where such devices are to be used.

(d) DATE CERTAIN FOR ESTABLISHING GUIDELINES AND RECOMMENDATIONS.—The Secretary shall comply with this section not later than 180 days after the date of the enactment of the Cardiac Arrest Survival Act of 2000.

(e) DEFINITIONS.—For purposes of this section:

(1) The term "automated external defibrillator device" has the meaning given such term in section 248.

(2) The term "Federal building" includes a building or portion of a building leased or rented by a Federal agency, and includes buildings on military installations of the United States.

LIABILITY REGARDING EMERGENCY USE OF AUTOMATED EXTERNAL DEFIBRILLATORS.

SEC. 248.[238q] (a) GOOD SAMARITAN PROTECTIONS REGARDING AEDS.—Except as provided in subsection (b), any person who uses or attempts to use an automated external defibrillator device on a victim of a perceived medical emergency is immune from civil liability for any harm resulting from the use or attempted use of such device; and in addition, any person who acquired the device is immune from such liability, if the harm was not due to the failure of such acquirer of the device—

(1) to notify local emergency response personnel or other appropriate entities of the most recent placement of the device within a reasonable period of time after the device was placed;

(2) to properly maintain and test the device; or

(3) to provide appropriate training in the use of the device to an employee or agent of the acquirer when the employee or agent was the person who used the device on the victim, except that such requirement of training does not apply if—

(A) the employee or agent was not an employee or agent who would have been reasonably expected to use the device; or

(B) the period of time elapsing between the engagement of the person as an employee or agent and the occurrence of the harm (or between the acquisition of the device and the occurrence of the harm, in any case in which the device was acquired after such engagement of the person) was not a reasonably sufficient period in which to provide the training.

(b) INAPPLICABILITY OF IMMUNITY.—Immunity under subsection (a) does not apply to a person if—

(1) the harm involved was caused by willful or criminal misconduct, gross negligence, reckless misconduct, or a conscious, flagrant indifference to the rights or safety of the victim who was harmed;

(2) the person is a licensed or certified health professional who used the automated external defibrillator device while acting within the scope of the license or certification of the professional and within the scope of the employment or agency of the professional;

(3) the person is a hospital, clinic, or other entity whose purpose is providing health care directly to patients, and the harm was caused by an employee or agent of the entity who used the device while acting within the scope of the employment or agency of the employee or agent; or

(4) the person is an acquirer of the device who leased the device to a health care entity (or who otherwise provided the device to such entity for compensation without selling the device to the entity), and the harm was caused by an employee or agent of the entity who used the device while acting within the scope of the employment or agency of the employee or agent.

(c) RULES OF CONSTRUCTION.—

(1) IN GENERAL.—The following applies with respect to this section:

(A) This section does not establish any cause of action, or require that an automated external defibrillator device be placed at any building or other location.

(B) With respect to a class of persons for which this section provides immunity from civil liability, this section supersedes the law of a State only to the extent that the State has no statute or regulations that provide persons in such class with immunity for civil liability arising from the use by such persons of automated external defibrillator devices in emergency situations (within the meaning of the State law or regulation involved).

(C) This section does not waive any protection from liability for Federal officers or employees under—

(i) section 224; or

(ii) sections 1346(b), 2672, and 2679 of title 28, United States Code, or under alternative benefits provided by the United States where the availability of

such benefits precludes a remedy under section 1346(b) of title 28.

(2) CIVIL ACTIONS UNDER FEDERAL LAW.—

(A) IN GENERAL.—The applicability of subsections (a) and (b) includes applicability to any action for civil liability described in subsection (a) that arises under Federal law.

(B) FEDERAL AREAS ADOPTING STATE LAW.—If a geographic area is under Federal jurisdiction and is located within a State but out of the jurisdiction of the State, and if, pursuant to Federal law, the law of the State applies in such area regarding matters for which there is no applicable Federal law, then an action for civil liability described in subsection (a) that in such area arises under the law of the State is subject to subsections (a) through (c) in lieu of any related State law that would apply in such area in the absence of this subparagraph.

(d) FEDERAL JURISDICTION.—In any civil action arising under State law, the courts of the State involved have jurisdiction to apply the provisions of this section exclusive of the jurisdiction of the courts of the United States.

(e) DEFINITIONS.—

(1) PERCEIVED MEDICAL EMERGENCY.—For purposes of this section, the term "perceived medical emergency" means circumstances in which the behavior of an individual leads a reasonable person to believe that the individual is experiencing a life-threatening medical condition that requires an immediate medical response regarding the heart or other cardiopulmonary functioning of the individual.

(2) OTHER DEFINITIONS.—For purposes of this section:

(A) The term "automated external defibrillator device" means a defibrillator device that—

(i) is commercially distributed in accordance with the Federal Food, Drug, and Cosmetic Act;

(ii) is capable of recognizing the presence or absence of ventricular fibrillation, and is capable of determining without intervention by the user of the device whether defibrillation should be performed;

(iii) upon determining that defibrillation should be performed, is able to deliver an electrical shock to an individual; and

(iv) in the case of a defibrillator device that may be operated in either an automated or a manual mode, is set to operate in the automated mode.

(B)(i) The term "harm" includes physical, nonphysical, economic, and noneconomic losses.

(ii) The term "economic loss" means any pecuniary loss resulting from harm (including the loss of earnings or other benefits related to employment, medical expense loss, replacement services loss, loss due to death, burial costs, and loss of business or employment opportunities) to the extent recovery for such loss is allowed under applicable State law.

(iii) The term "noneconomic losses" means losses for physical and emotional pain, suffering, inconvenience,

physical impairment, mental anguish, disfigurement, loss of enjoyment of life, loss of society and companionship, loss of consortium (other than loss of domestic service), hedonic damages, injury to reputation and all other nonpecuniary losses of any kind or nature.

PART C—SMALLPOX EMERGENCY PERSONNEL PROTECTION

SEC. 261.[239] GENERAL PROVISIONS.

(a) DEFINITIONS.—For purposes of this part:

(1) COVERED COUNTERMEASURE.—The term "covered countermeasure" means a covered countermeasure as specified in a Declaration made pursuant to section 224(p).

(2) COVERED INDIVIDUAL.—The term "covered individual" means an individual—

(A) who is a health care worker, law enforcement officer, firefighter, security personnel, emergency medical personnel, other public safety personnel, or support personnel for such occupational specialities;

(B) who is or will be functioning in a role identified in a State, local, or Department of Health and Human Services smallpox emergency response plan (as defined in paragraph (7)) approved by the Secretary;

(C) who has volunteered and been selected to be a member of a smallpox emergency response plan described in subparagraph (B) prior to the time at which the Secretary publicly announces that an active case of smallpox has been identified either within or outside of the United States; and

(D) to whom a smallpox vaccine is administered pursuant to such approved plan during the effective period of the Declaration (including the portion of such period before the enactment of this part).

(3) COVERED INJURY.—The term "covered injury" means an injury, disability, illness, condition, or death (other than a minor injury such as minor scarring or minor local reaction) determined, pursuant to the procedures established under section 262, to have been sustained by an individual as the direct result of—

(A) administration to the individual of a covered countermeasure during the effective period of the Declaration; or

(B) accidental vaccinia inoculation of the individual in circumstances in which—

(i) the vaccinia is contracted during the effective period of the Declaration or within 30 days after the end of such period;

(ii) smallpox vaccine has not been administered to the individual; and

(iii) the individual has been in contact with an individual who is (or who was accidentally inoculated by) a covered individual.

(4) DECLARATION.—The term "Declaration" means the Declaration Regarding Administration of Smallpox Counter-

measures issued by the Secretary on January 24, 2003, and published in the Federal Register on January 28, 2003.

(5) EFFECTIVE PERIOD OF THE DECLARATION.—The term "effective period of the Declaration" means the effective period specified in the Declaration, unless extended by the Secretary.

(6) ELIGIBLE INDIVIDUAL.—The term "eligible individual" means an individual who is (as determined in accordance with section 262)—

(A) a covered individual who sustains a covered injury in the manner described in paragraph (3)(A); or

(B) an individual who sustains a covered injury in the manner described in paragraph (3)(B).

(7) SMALLPOX EMERGENCY RESPONSE PLAN.—The term "smallpox emergency response plan" or "plan" means a response plan detailing actions to be taken in preparation for a possible smallpox-related emergency during the period prior to the identification of an active case of smallpox either within or outside the United States.

(b) VOLUNTARY PROGRAM.—The Secretary shall ensure that a State, local, or Department of Health and Human Services plan to vaccinate individuals that is approved by the Secretary establishes procedures to ensure, consistent with the Declaration and any applicable guidelines of the Centers for Disease Control and Prevention, that—

(1) potential participants are educated with respect to contraindications, the voluntary nature of the program, and the availability of potential benefits and compensation under this part;

(2) there is voluntary screening provided to potential participants that can identify health conditions relevant to contraindications; and

(3) there is appropriate post-inoculation medical surveillance that includes an evaluation of adverse health effects that may reasonably appear to be due to such vaccine and prompt referral of, or the provision of appropriate information to, any individual requiring health care as a result of such adverse health event.

SEC. 262.[239a] DETERMINATION OF ELIGIBILITY AND BENEFITS.

(a) IN GENERAL.—The Secretary shall establish procedures for determining, as applicable with respect to an individual—

(1) whether the individual is an eligible individual;

(2) whether an eligible individual has sustained a covered injury or injuries for which medical benefits or compensation may be available under sections 264 and 265, and the amount of such benefits or compensation; and

(3) whether the covered injury or injuries of an eligible individual caused the individual's death for purposes of benefits under section 266.

(b) COVERED INDIVIDUALS.—The Secretary may accept a certification, by a Federal, State, or local government entity or private health care entity participating in the administration of covered countermeasures under the Declaration, that an individual is a covered individual.

(c) CRITERIA FOR REIMBURSEMENT.—

(1) INJURIES SPECIFIED IN INJURY TABLE.—In any case where an injury or other adverse effect specified in the injury table established under section 263 as a known effect of a vaccine manifests in an individual within the time period specified in such table, such injury or other effect shall be presumed to have resulted from administration of such vaccine.

(2) OTHER DETERMINATIONS.—In making determinations other than those described in paragraph (1) as to the causation or severity of an injury, the Secretary shall employ a preponderance of the evidence standard and take into consideration all relevant medical and scientific evidence presented for consideration, and may obtain and consider the views of qualified medical experts.

(d) DEADLINE FOR FILING REQUEST.—The Secretary shall not consider any request for a benefit under this part with respect to an individual, unless—

(1) in the case of a request based on the administration of the vaccine to the individual, the individual files with the Secretary an initial request for benefits or compensation under this part not later than one year after the date of administration of the vaccine; or

(2) in the case of a request based on accidental vaccinia inoculation, the individual files with the Secretary an initial request for benefits or compensation under this part not later than two years after the date of the first symptom or manifestation of onset of the adverse effect.

(e) STRUCTURED SETTLEMENTS AT SECRETARY'S OPTION.—In any case in which there is a reasonable likelihood that compensation or payment under section 264, 265, or 266(b) will be required for a period in excess of one year from the date an individual is determined eligible for such compensation or payment, the Secretary shall have the discretion to make a lump-sum payment, purchase an annuity or medical insurance policy, or execute an appropriate structured settlement agreement, provided that such payment, annuity, policy, or agreement is actuarially determined to have a value equal to the present value of the projected total amount of benefits or compensation that the individual is eligible to receive under such section or sections.

(f) REVIEW OF DETERMINATION.—

(1) SECRETARY'S REVIEW AUTHORITY.—The Secretary may review a determination under this section at any time on the Secretary's own motion or on application, and may affirm, vacate, or modify such determination in any manner the Secretary deems appropriate. The Secretary shall develop a process by which an individual may file a request for reconsideration of any determination made by the Secretary under this section.

(2) JUDICIAL AND ADMINISTRATIVE REVIEW.—No court of the United States, or of any State, District, territory or possession thereof, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary under this section. No officer or employee of the United

States shall review any action by the Secretary under this section (unless the President specifically directs otherwise).

SEC. 263.[239b] SMALLPOX VACCINE INJURY TABLE.

(a)[23] SMALLPOX VACCINE INJURY TABLE.—

(1) ESTABLISHMENT REQUIRED.—The Secretary shall establish by interim final regulation a table identifying adverse effects (including injuries, disabilities, illnesses, conditions, and deaths) that shall be presumed to result from the administration of (or exposure to) a smallpox vaccine, and the time period in which the first symptom or manifestation of onset of each such adverse effect must manifest in order for such presumption to apply.

(2) AMENDMENTS.—The Secretary may by regulation amend the table established under paragraph (1). An amendment to the table takes effect on the date of the promulgation of the final rule that makes the amendment, and applies to all requests for benefits or compensation under this part that are filed on or after such date or are pending as of such date. In addition, the amendment applies retroactively to an individual who was not with respect to the injury involved an eligible individual under the table as in effect before the amendment but who with respect to such injury is an eligible individual under the table as amended. With respect to a request for benefits or compensation under this part by an individual who becomes an eligible individual as described in the preceding sentence, the Secretary may not provide such benefits or compensation unless the request (or amendment to a request, as applicable) is filed before the expiration of one year after the effective date of the amendment to the table in the case of an individual to whom the vaccine was administered and before the expiration of two years after such effective date in the case of a request based on accidental vaccinia inoculation.

SEC. 264.[239c] MEDICAL BENEFITS.

(a) IN GENERAL.—Subject to the succeeding provisions of this section, the Secretary shall make payment or reimbursement for medical items and services as reasonable and necessary to treat a covered injury of an eligible individual, including the services, appliances, and supplies prescribed or recommended by a qualified physician, which the Secretary considers likely to cure, give relief, reduce the degree or the period of disability, or aid in lessening the amount of monthly compensation.

(b) BENEFITS SECONDARY TO OTHER COVERAGE.—Payment or reimbursement for services or benefits under subsection (a) shall be secondary to any obligation of the United States or any third party (including any State or local governmental entity, private insurance carrier, or employer) under any other provision of law or contractual agreement, to pay for or provide such services or benefits.

[23] Subsection (a) designation so in law. Section 263 does not contain a subsection (b). See the amendment made by section 2 of Public Law 108–20 (117 Stat. 638, 641), which added a new part C to title II.

SEC. 265.[239d] COMPENSATION FOR LOST EMPLOYMENT INCOME.

(a) IN GENERAL.—Subject to the succeeding provisions of this section, the Secretary shall provide compensation to an eligible individual for loss of employment income (based on such income at the time of injury) incurred as a result of a covered injury, at the rate specified in subsection (b).

(b) AMOUNT OF COMPENSATION.—

(1) IN GENERAL.—Compensation under subsection (a) shall be at the rate of 66⅔ percent of the relevant pay period (weekly, monthly, or otherwise), except as provided in paragraph (2).

(2) AUGMENTED COMPENSATION FOR DEPENDENTS.—If an eligible individual has one or more dependents, the basic compensation for loss of employment income as described in paragraph (1) shall be augmented at the rate of 8⅓ percent.

(3) CONSIDERATION OF OTHER PROGRAMS.—

(A) IN GENERAL.—The Secretary may consider the provisions of sections 8114, 8115, and 8146a of title 5, United States Code, and any implementing regulations, in determining the amount of payment under subsection (a) and the circumstances under which such payments are reasonable and necessary.

(B) MINORS.—With respect to an eligible individual who is a minor, the Secretary may consider the provisions of section 8113 of title 5, United States Code, and any implementing regulations, in determining the amount of payment under subsection (a) and the circumstances under which such payments are reasonable and necessary.

(4) TREATMENT OF SELF-EMPLOYMENT INCOME.—For purposes of this section, the term "employment income" includes income from self-employment.

(c) LIMITATIONS.—

(1) BENEFITS SECONDARY TO OTHER COVERAGE.—

(A) IN GENERAL.—Any compensation under subsection (a) shall be secondary to the obligation of the United States or any third party (including any State or local governmental entity, private insurance carrier, or employer), under any other law or contractual agreement, to pay compensation for loss of employment income or to provide disability or retirement benefits.

(B) RELATION TO OTHER OBLIGATIONS.—Compensation under subsection (a) shall not be made to an eligible individual to the extent that the total of amounts paid to the individual under such subsection and under the other obligations referred to in subparagraph (A) is an amount that exceeds the rate specified in subsection (b)(1). If under any such other obligation a lump-sum payment is made, such payment shall, for purposes of this paragraph, be deemed to be received over multiple years rather than received in a single year. The Secretary may, in the discretion of the Secretary, determine how to apportion such payment over multiple years.

(2) NO BENEFITS IN CASE OF DEATH.—No payment shall be made under subsection (a) in compensation for loss of employment income subsequent to the receipt, by the survivor or sur-

vivors of an eligible individual, of benefits under section 266 for death.

(3) LIMIT ON TOTAL BENEFITS.—

(A) IN GENERAL.—Except as provided in subparagraph (B)—

(i) total compensation paid to an individual under subsection (a) shall not exceed $50,000 for any year; and

(ii) the lifetime total of such compensation for the individual may not exceed an amount equal to the amount authorized to be paid under section 266.

(B) PERMANENT AND TOTAL DISABILITY.—The limitation under subparagraph (A)(ii) does not apply in the case of an eligible individual who is determined to have a covered injury or injuries meeting the definition of disability in section 216(i) of the Social Security Act (42 U.S.C. 416(i)).

(4) WAITING PERIOD.—

(A) IN GENERAL.—Except as provided in subparagraph (B), an eligible individual shall not be provided compensation under this section for the first 5 work days of loss of employment income.

(B) EXCEPTION.—Subparagraph (A) does not apply if the period of loss of employment income of an eligible individual is 10 or more work days.

(5) TERMINATION OF BENEFITS.—No payment shall be made under subsection (a) in compensation for loss of employment income once the eligible individual involves reaches the age of 65.

(d) BENEFIT IN ADDITION TO MEDICAL BENEFITS.—A benefit under subsection (a) shall be in addition to any amounts received by an eligible individual under section 264.

SEC. 266.[239e] PAYMENT FOR DEATH.

(a) DEATH BENEFIT.—

(1) IN GENERAL.—The Secretary shall pay, in the case of an eligible individual whose death is determined to have resulted from a covered injury or injuries, a death benefit in the amount determined under paragraph (2) to the survivor or survivors in the same manner as death benefits are paid pursuant to the Public Safety Officers' Benefits Program under subpart 1 of part L of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3796 et seq.) with respect to an eligible deceased (except that in the case of an eligible individual who is a minor with no living parent, the legal guardian shall be considered the survivor in the place of the parent).

(2) BENEFIT AMOUNT.—

(A) IN GENERAL.—The amount of the death benefit under paragraph (1) in a fiscal year shall equal the amount of the comparable benefit calculated under the Public Safety Officers' Benefits Program under subpart 1 of part L of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3796 et seq.) in such fiscal

year, without regard to any reduction attributable to a limitation on appropriations, but subject to subparagraph (B).

(B) REDUCTION FOR PAYMENTS FOR LOST EMPLOYMENT INCOME.—The amount of the benefit as determined under subparagraph (A) shall be reduced by the total amount of any benefits paid under section 265 with respect to lost employment income.

(3) LIMITATIONS.—

(A) IN GENERAL.—No benefit is payable under paragraph (1) with respect to the death of an eligible individual if—

(i) a disability benefit is paid with respect to such individual under the Public Safety Officers' Benefits Program under subpart 1 of part L of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3796 et seq.); or

(ii) a death benefit is paid or payable with respect to such individual under the Public Safety Officers' Benefits Program under subpart 1 of part L of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3796 et seq.).

(B) EXCEPTION IN THE CASE OF A LIMITATION ON APPROPRIATIONS FOR DISABILITY BENEFITS UNDER PSOB.—In the event that disability benefits available to an eligible individual under the Public Safety Officers' Benefits Program under subpart 1 of part L of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3796 et seq.) are reduced because of a limitation on appropriations, and such reduction would affect the amount that would be payable under subparagraph (A) without regard to this subparagraph, benefits shall be available under paragraph (1) to the extent necessary to ensure that the survivor or survivors of such individual receives a total amount equal to the amount described in paragraph (2).

(b) ELECTION IN CASE OF DEPENDENTS.—

(1) IN GENERAL.—In the case of an eligible individual whose death is determined to have resulted from a covered injury or injuries, if the individual had one or more dependents under the age of 18, the legal guardian of the dependents may, in lieu of the death benefit under subsection (a), elect to receive on behalf of the aggregate of such dependents payments in accordance with this subsection. An election under the preceding sentence is effective in lieu of a request under subsection (a) by an individual who is not the legal guardian of such dependents.

(2) AMOUNT OF PAYMENTS.—Payments under paragraph (1) with respect to an eligible individual described in such paragraph shall be made as if such individual were an eligible individual to whom compensation would be paid under subsection (a) of section 265, with the rate augmented in accordance with subsection (b)(2) of such section and with such individual considered to be an eligible individual described in subsection (c)(3)(B) of such section.

(3) LIMITATIONS.—

(A) AGE OF DEPENDENTS.—No payments may be made under paragraph (1) once the youngest of the dependents involved reaches the age of 18.

(B) BENEFITS SECONDARY TO OTHER COVERAGE.—

(i) IN GENERAL.—Any payment under paragraph (1) shall be secondary to the obligation of the United States or any third party (including any State or local governmental entity, private insurance carrier, or employer), under any other law or contractual agreement, to pay compensation for loss of employment income or to provide disability benefits, retirement benefits, life insurance benefits on behalf of dependents under the age of 18, or death benefits.

(ii) RELATION TO OTHER OBLIGATIONS.—Payments under paragraph (1) shall not be made to with respect to an eligible individual to the extent that the total of amounts paid with respect to the individual under such paragraph and under the other obligations referred to in clause (i) is an amount that exceeds the rate of payment that applies under paragraph (2). If under any such other obligation a lump-sum payment is made, such payment shall, for purposes of this subparagraph, be deemed to be received over multiple years rather than received in a single year. The Secretary may, in the discretion of the Secretary, determine how to apportion such payment over multiple years.

(c) BENEFIT IN ADDITION TO MEDICAL BENEFITS.—A benefit under subsection (a) or (b) shall be in addition to any amounts received by an eligible individual under section 264.

SEC. 267.[239f] ADMINISTRATION.

(a) ADMINISTRATION BY AGREEMENT WITH OTHER AGENCY OR AGENCIES.—The Secretary may administer any or all of the provisions of this part through Memorandum of Agreement with the head of any appropriate Federal agency.

(b) REGULATIONS.—The head of the agency administering this part or provisions thereof (including any agency head administering such Act or provisions through a Memorandum of Agreement under subsection (a)) may promulgate such implementing regulations as may be found necessary and appropriate. Initial implementing regulations may be interim final regulations.

SEC. 268.[239g] AUTHORIZATION OF APPROPRIATIONS.

For the purpose of carrying out this part, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2003 through 2007, to remain available until expended, including administrative costs and costs of provision and payment of benefits. The Secretary's payment of any benefit under section 264, 265, or 266 shall be subject to the availability of appropriations under this section.

SEC. 269.[239h] RELATIONSHIP TO OTHER LAWS.

Except as explicitly provided herein, nothing in this part shall be construed to override or limit any rights an individual may have

to seek compensation, benefits, or redress under any other provision of Federal or State law.

PART D—UNITED STATES PUBLIC HEALTH SCIENCES TRACK

SEC. 271.[239l] ESTABLISHMENT.

(a) UNITED STATES PUBLIC HEALTH SERVICES TRACK.—

(1) IN GENERAL.—There is hereby authorized to be established a United States Public Health Sciences Track (referred to in this part as the "Track"), at sites to be selected by the Secretary, with authority to grant appropriate advanced degrees in a manner that uniquely emphasizes team-based service, public health, epidemiology, and emergency preparedness and response. It shall be so organized as to graduate not less than—

(A) 150 medical students annually, 10 of whom shall be awarded studentships to the Uniformed Services University of Health Sciences;

(B) 100 dental students annually;

(C) 250 nursing students annually;

(D) 100 public health students annually;

(E) 100 behavioral and mental health professional students annually;

(F) 100 physician assistant or nurse practitioner students annually; and

(G) 50 pharmacy students annually.

(2) LOCATIONS.—The Track shall be located at existing and accredited, affiliated health professions education training programs at academic health centers located in regions of the United States determined appropriate by the Surgeon General, in consultation with the National Health Care Workforce Commission established in section 5101 of the Patient Protection and Affordable Care Act.

(b) NUMBER OF GRADUATES.—Except as provided in subsection (a), the number of persons to be graduated from the Track shall be prescribed by the Secretary. In so prescribing the number of persons to be graduated from the Track, the Secretary shall institute actions necessary to ensure the maximum number of first-year enrollments in the Track consistent with the academic capacity of the affiliated sites and the needs of the United States for medical, dental, and nursing personnel.

(c) DEVELOPMENT.—The development of the Track may be by such phases as the Secretary may prescribe subject to the requirements of subsection (a).

(d) INTEGRATED LONGITUDINAL PLAN.—The Surgeon General shall develop an integrated longitudinal plan for health professions continuing education throughout the continuum of health-related education, training, and practice. Training under such plan shall emphasize patient-centered, interdisciplinary, and care coordination skills. Experience with deployment of emergency response teams shall be included during the clinical experiences.

(e) FACULTY DEVELOPMENT.—The Surgeon General shall develop faculty development programs and curricula in decentralized venues of health care, to balance urban, tertiary, and inpatient venues.

SEC. 272.[239l–1] ADMINISTRATION.

(a) IN GENERAL.—The business of the Track shall be conducted by the Surgeon General with funds appropriated for and provided by the Department of Health and Human Services. The National Health Care Workforce Commission shall assist the Surgeon General in an advisory capacity.

(b) FACULTY.—

(1) IN GENERAL.—The Surgeon General, after considering the recommendations of the National Health Care Workforce Commission, shall obtain the services of such professors, instructors, and administrative and other employees as may be necessary to operate the Track, but utilize when possible, existing affiliated health professions training institutions. Members of the faculty and staff shall be employed under salary schedules and granted retirement and other related benefits prescribed by the Secretary so as to place the employees of the Track faculty on a comparable basis with the employees of fully accredited schools of the health professions within the United States.

(2) TITLES.—The Surgeon General may confer academic titles, as appropriate, upon the members of the faculty.

(3) NONAPPLICATION OF PROVISIONS.—The limitations in section 5373 of title 5, United States Code, shall not apply to the authority of the Surgeon General under paragraph (1) to prescribe salary schedules and other related benefits.

(c) AGREEMENTS.—The Surgeon General may negotiate agreements with agencies of the Federal Government to utilize on a reimbursable basis appropriate existing Federal medical resources located in the United States (or locations selected in accordance with section 271(a)(2)). Under such agreements the facilities concerned will retain their identities and basic missions. The Surgeon General may negotiate affiliation agreements with accredited universities and health professions training institutions in the United States. Such agreements may include provisions for payments for educational services provided students participating in Department of Health and Human Services educational programs.

(d) PROGRAMS.—The Surgeon General may establish the following educational programs for Track students:

(1) Postdoctoral, postgraduate, and technological programs.

(2) A cooperative program for medical, dental, physician assistant, pharmacy, behavioral and mental health, public health, and nursing students.

(3) Other programs that the Surgeon General determines necessary in order to operate the Track in a cost-effective manner.

(e) CONTINUING MEDICAL EDUCATION.—The Surgeon General shall establish programs in continuing medical education for members of the health professions to the end that high standards of health care may be maintained within the United States.

(f) AUTHORITY OF THE SURGEON GENERAL.—

(1) IN GENERAL.—The Surgeon General is authorized—

(A) to enter into contracts with, accept grants from, and make grants to any nonprofit entity for the purpose of carrying out cooperative enterprises in medical, dental, physician assistant, pharmacy, behavioral and mental health, public health, and nursing research, consultation, and education;

(B) to enter into contracts with entities under which the Surgeon General may furnish the services of such professional, technical, or clerical personnel as may be necessary to fulfill cooperative enterprises undertaken by the Track;

(C) to accept, hold, administer, invest, and spend any gift, devise, or bequest of personal property made to the Track, including any gift, devise, or bequest for the support of an academic chair, teaching, research, or demonstration project;

(D) to enter into agreements with entities that may be utilized by the Track for the purpose of enhancing the activities of the Track in education, research, and technological applications of knowledge; and

(E) to accept the voluntary services of guest scholars and other persons.

(2) LIMITATION.—The Surgeon General may not enter into any contract with an entity if the contract would obligate the Track to make outlays in advance of the enactment of budget authority for such outlays.

(3) SCIENTISTS.—Scientists or other medical, dental, or nursing personnel utilized by the Track under an agreement described in paragraph (1) may be appointed to any position within the Track and may be permitted to perform such duties within the Track as the Surgeon General may approve.

(4) VOLUNTEER SERVICES.—A person who provides voluntary services under the authority of subparagraph (E) of paragraph (1) shall be considered to be an employee of the Federal Government for the purposes of chapter 81 of title 5, relating to compensation for work-related injuries, and to be an employee of the Federal Government for the purposes of chapter 171 of title 28, relating to tort claims. Such a person who is not otherwise employed by the Federal Government shall not be considered to be a Federal employee for any other purpose by reason of the provision of such services.

SEC. 273.[239l–2] STUDENTS; SELECTION; OBLIGATION.

(a) STUDENT SELECTION.—

(1) IN GENERAL.—Medical, dental, physician assistant, pharmacy, behavioral and mental health, public health, and nursing students at the Track shall be selected under procedures prescribed by the Surgeon General. In so prescribing, the Surgeon General shall consider the recommendations of the National Health Care Workforce Commission.

(2) PRIORITY.—In developing admissions procedures under paragraph (1), the Surgeon General shall ensure that such pro-

cedures give priority to applicant medical, dental, physician assistant, pharmacy, behavioral and mental health, public health, and nursing students from rural communities and underrepresented minorities.

(b) CONTRACT AND SERVICE OBLIGATION.—

(1) CONTRACT.—Upon being admitted to the Track, a medical, dental, physician assistant, pharmacy, behavioral and mental health, public health, or nursing student shall enter into a written contract with the Surgeon General that shall contain—

(A) an agreement under which—

(i) subject to subparagraph (B), the Surgeon General agrees to provide the student with tuition (or tuition remission) and a student stipend (described in paragraph (2)) in each school year for a period of years (not to exceed 4 school years) determined by the student, during which period the student is enrolled in the Track at an affiliated or other participating health professions institution pursuant to an agreement between the Track and such institution; and

(ii) subject to subparagraph (B), the student agrees—

(I) to accept the provision of such tuition and student stipend to the student;

(II) to maintain enrollment at the Track until the student completes the course of study involved;

(III) while enrolled in such course of study, to maintain an acceptable level of academic standing (as determined by the Surgeon General);

(IV) if pursuing a degree from a school of medicine or osteopathic medicine, dental, public health, or nursing school or a physician assistant, pharmacy, or behavioral and mental health professional program, to complete a residency or internship in a specialty that the Surgeon General determines is appropriate; and

(V) to serve for a period of time (referred to in this part as the "period of obligated service") within the Commissioned Corps of the Public Health Service equal to 2 years for each school year during which such individual was enrolled at the College, reduced as provided for in paragraph (3);

(B) a provision that any financial obligation of the United States arising out of a contract entered into under this part and any obligation of the student which is conditioned thereon, is contingent upon funds being appropriated to carry out this part;

(C) a statement of the damages to which the United States is entitled for the student's breach of the contract; and

(D) such other statements of the rights and liabilities of the Secretary and of the individual, not inconsistent with the provisions of this part.

(2) TUITION AND STUDENT STIPEND.—

(A) TUITION REMISSION RATES.—The Surgeon General, based on the recommendations of the National Health Care Workforce Commission, shall establish Federal tuition remission rates to be used by the Track to provide reimbursement to affiliated and other participating health professions institutions for the cost of educational services provided by such institutions to Track students. The agreement entered into by such participating institutions under paragraph (1)(A)(i) shall contain an agreement to accept as payment in full the established remission rate under this subparagraph.

(B) STIPEND.—The Surgeon General, based on the recommendations of the National Health Care Workforce Commission, shall establish and update Federal stipend rates for payment to students under this part.

(3) REDUCTIONS IN THE PERIOD OF OBLIGATED SERVICE.—The period of obligated service under paragraph (1)(A)(ii)(V) shall be reduced—

(A) in the case of a student who elects to participate in a high-needs speciality residency (as determined by the National Health Care Workforce Commission), by 3 months for each year of such participation (not to exceed a total of 12 months); and

(B) in the case of a student who, upon completion of their residency, elects to practice in a Federal medical facility (as defined in section 781(e)) that is located in a health professional shortage area (as defined in section 332), by 3 months for year of full-time practice in such a facility (not to exceed a total of 12 months).

(c) SECOND 2 YEARS OF SERVICE.—During the third and fourth years in which a medical, dental, physician assistant, pharmacy, behavioral and mental health, public health, or nursing student is enrolled in the Track, training should be designed to prioritize clinical rotations in Federal medical facilities in health professional shortage areas, and emphasize a balance of hospital and community-based experiences, and training within interdisciplinary teams.

(d) DENTIST, PHYSICIAN ASSISTANT, PHARMACIST, BEHAVIORAL AND MENTAL HEALTH PROFESSIONAL, PUBLIC HEALTH PROFESSIONAL, AND NURSE TRAINING.—The Surgeon General shall establish provisions applicable with respect to dental, physician assistant, pharmacy, behavioral and mental health, public health, and nursing students that are comparable to those for medical students under this section, including service obligations, tuition support, and stipend support. The Surgeon General shall give priority to health professions training institutions that train medical, dental, physician assistant, pharmacy, behavioral and mental health, public health, and nursing students for some significant period of time together, but at a minimum have a discrete and shared core curriculum.

(e) ELITE FEDERAL DISASTER TEAMS.—The Surgeon General, in consultation with the Secretary, the Director of the Centers for Disease Control and Prevention, and other appropriate military and

Federal government agencies, shall develop criteria for the appointment of highly qualified Track faculty, medical, dental, physician assistant, pharmacy, behavioral and mental health, public health, and nursing students, and graduates to elite Federal disaster preparedness teams to train and to respond to public health emergencies, natural disasters, bioterrorism events, and other emergencies.

(f) STUDENT DROPPED FROM TRACK IN AFFILIATE SCHOOL.—A medical, dental, physician assistant, pharmacy, behavioral and mental health, public health, or nursing student who, under regulations prescribed by the Surgeon General, is dropped from the Track in an affiliated school for deficiency in conduct or studies, or for other reasons, shall be liable to the United States for all tuition and stipend support provided to the student.

SEC. 274.[239l–3] FUNDING.

Beginning with fiscal year 2010, the Secretary shall transfer from the Public Health and Social Services Emergency Fund such sums as may be necessary to carry out this part.

PUBLIC HEALTH SERVICE ACT

As Amended Through P.L. 113–48, Enacted November 13, 2013

TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

PART A—RESEARCH AND INVESTIGATION

IN GENERAL.

SEC. 301.[241] (a) The Secretary shall conduct in the Service, and encourage, cooperate with, and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man, including water purification, sewage treatment, and pollution of lakes and streams. In carrying out the foregoing the Secretary is authorized to—

(1) collect and make available through publications and other appropriate means, information as to, and the practical application of, such research and other activities;

(2) make available research facilities of the Service to appropriate public authorities, and to health officials and scientists engaged in special study;

(3) make grants-in-aid to universities, hospitals, laboratories, and other public or private institutions, and to individuals for such research projects as are recommended by the advisory council to the entity of the Department supporting such projects and make, upon recommendation of the advisory council to the appropriate entity of the Department, grants-in-aid to public or nonprofit universities, hospitals, laboratories, and other institutions for the general support of their research;

(4) secure from time to time and for such periods as he deems advisable, the assistance and advice of experts, scholars, and consultants from the United States or abroad;

(5) for purposes of study, admit and treat at institutions, hospitals, and stations of the Service, persons not otherwise eligible for such treatment;

(6) make available, to health officials, scientists, and appropriate public and other nonprofit institutions and organizations, technical advice and assistance on the application of statistical methods to experiments, studies, and surveys in health and medical fields;

(7) enter into contracts, including contracts for research in accordance with and subject to the provisions of law applicable to contracts entered into by the military departments under title 10, United States Code, sections 2353 and 2354, except

that determination, approval, and certification required thereby shall be by the Secretary of Health, Education, and Welfare; and

(8) adopt, upon recommendations of the advisory councils to the appropriate entities of the Department or, with respect to mental health, the National Advisory Mental Health Council, such additional means as the Secretary considers necessary or appropriate to carry out the purposes of this section.

The Secretary may make available to individuals and entities, for biomedical and behavioral research, substances and living organisms. Such substances and organisms shall be made available under such terms and conditions (including payment for them) as the Secretary determines appropriate.

(b)(1) The Secretary shall conduct and may support through grants and contracts studies and testing of substances for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects. In carrying out this paragraph, the Secretary shall consult with entities of the Federal Government, outside of the Department of Health, Education, and Welfare, engaged in comparable activities. The Secretary, upon request of such an entity and under appropriate arrangements for the payment of expenses, may conduct for such entity studies and testing of substances for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects.

(2)(A) The Secretary shall establish a comprehensive program of research into the biological effects of low-level ionizing radiation under which program the Secretary shall conduct such research and may support such research by others through grants and contracts.

(B) The Secretary shall conduct a comprehensive review of Federal programs of research on the biological effects of ionizing radiation.

(3) The Secretary shall conduct and may support through grants and contracts research and studies on human nutrition, with particular emphasis on the role of nutrition in the prevention and treatment of disease and on the maintenance and promotion of health, and programs for the dissemination of information respecting human nutrition to health professionals and the public. In carrying out activities under this paragraph, the Secretary shall provide for the coordination of such of these activities as are performed by the different divisions within the Department of Health, Education, and Welfare and shall consult with entities of the Federal Government, outside of the Department of Health, Education, and Welfare, engaged in comparable activities. The Secretary, upon request of such an entity and under appropriate arrangements for the payment of expenses, may conduct and support such activities for such entity.

(4) The Secretary shall publish a biennial report which contains—

(A) a list of all substances (i) which either are known to be carcinogens or may reasonably be anticipated to be carcinogens and (ii) to which a significant number of persons residing in the United States are exposed;

(B) information concerning the nature of such exposure and the estimated number of persons exposed to such substances;

(C) a statement identifying (i) each substance contained in the list under subparagraph (A) for which no effluent, ambient, or exposure standard has been established by a Federal agency, and (ii) for each effluent, ambient, or exposure standard established by a Federal agency with respect to a substance contained in the list under subparagraph (A), the extent to which, on the basis of available medical, scientific, or other data, such standard, and the implementation of such standard by the agency, decreases the risk to public health from exposure to the substance; and

(D) a description of (i) each request received during the year involved—

(I) from a Federal agency outside the Department of Health, Education, and Welfare for the Secretary, or

(II) from an entity within the Department of Health, Education, and Welfare to any other entity within the Department,

to conduct research into, or testing for, the carcinogenicity of substances or to provide information described in clause (ii) of subparagraph (C), and (ii) how the Secretary and each such other entity, respectively, have responded to each such request.

(5) The authority of the Secretary to enter into any contract for the conduct of any study, testing, program, research, or review, or assessment under this subsection shall be effective for any fiscal year only to such extent or in such amounts as are provided in advance in Appropriation Acts.

(c) The Secretary may conduct biomedical research, directly or through grants or contracts, for the identification, control, treatment, and prevention of diseases (including tropical diseases) which do not occur to a significant extent in the United States.

(d) The Secretary may authorize persons engaged in biomedical, behavioral, clinical, or other research (including research on mental health, including research on the use and effect of alcohol and other psychoactive drugs) to protect the privacy of individuals who are the subject of such research by withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals. Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals.

(e) The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall expand, intensify, and coordinate the activities of the Centers for Disease Control and Prevention with respect to preterm labor and delivery and infant mortality.

NARCOTICS.

SEC. 302.[242] (a) In carrying out the purposes of section 301 with respect to drugs the use or misuse of which might result in drug abuse or dependency, the studies and investigations author-

ized therein shall include the use and misuse of narcotic drugs and other drugs. Such studies and investigations shall further include the quantities of crude opium, coca leaves, and their salts, derivatives, and preparations, and other drugs subject to control under the Controlled Substances Act and Controlled Substances Import and Export Act, together with reserves thereof, necessary to supply the normal and emergency medicinal and scientific requirements of the United States. The results of studies and investigations of the quantities of narcotic drugs or other drugs subject to control under such Acts, together with reserves of such drugs, that are necessary to supply the normal and emergency medicinal and scientific requirements of the United States, shall be reported not later than the first day of April of each year to the Attorney General, to be used at his discretion in determining manufacturing quotas or importation requirements under such Acts.

(b) The Surgeon General shall cooperate with States for the purpose of aiding them to solve their narcotic drug problems and shall give authorized representatives of the States the benefit of his experience in the care, treatment, and rehabilitation of narcotic addicts to the end that each State may be encouraged to provide adequate facilities and methods for the care and treatment of its narcotic addicts.

GENERAL AUTHORITY RESPECTING RESEARCH, EVALUATIONS, AND DEMONSTRATIONS IN HEALTH STATISTICS, HEALTH SERVICES, AND HEALTH CARE TECHNOLOGY ASSESSMENT.

SEC. 304.[1] [242b] (a) The Secretary may, through the Agency for Health Care Policy and Research or the National Center for Health Statistics or using National Research Service Awards or other appropriate authorities, undertake and support training programs to provide for an expanded and continuing supply of individuals qualified to perform the research, evaluation, and demonstration projects set forth in section 306 and in title IX.

(b) To implement subsection (a) and section 306, the Secretary may, in addition to any other authority which under other provisions of this Act or any other law may be used by him to implement such subsection, do the following:

(1) Utilize personnel and equipment, facilities, and other physical resources of the Department of Health and Human Services, permit appropriate (as determined by the Secretary) entities and individuals to utilize the physical resources of such Department, provide technical assistance and advice, make grants to public and nonprofit private entities and individuals, and, when appropriate, enter into contracts with public and private entities and individuals.

(2) Admit and treat at hospitals and other facilities of the Service persons not otherwise eligible for admission and treatment at such facilities.

(3) Secure, from time to time and for such periods as the Secretary deems advisable but in accordance with section 3109 of title 5, United States Code, the assistance and advice of con-

[1] Former section 303 was repealed by section 3201(b)(1) of Public Law 106–310 (114 Stat. 1190).

sultants from the United States or abroad. The Secretary may for the purpose of carrying out the functions set forth in sections 305,[2] 306, and 309, obtain (in accordance with section 3109 of title 5 of the United States Code, but without regard to the limitation in such section on the number of days or the period of service) for each of the centers the services of not more than fifteen experts who have appropriate scientific or professional qualifications.

(4) Acquire, construct, improve, repair, operate, and maintain laboratory, research, and other necessary facilities and equipment, and such other real or personal property (including patents) as the Secretary deems necessary; and acquire, without regard to the Act of March 3, 1877 (40 U.S.C. 34), by lease or otherwise, through the Administrator of General Services, buildings or parts of buildings in the District of Columbia or communities located adjacent to the District of Columbia.

(c)(1) The Secretary shall coordinate all health services research, evaluations, and demonstrations, all health statistical and epidemiological activities, and all research, evaluations, and demonstrations respecting the assessment of health care technology undertaken and supported through units of the Department of Health and Human Services. To the maximum extent feasible such coordination shall be carried out through the Agency for Health Care Policy and Research and the National Center for Health Statistics.

(2) The Secretary shall coordinate the health services research, evaluations, and demonstrations, the health statistical and (where appropriate) epidemiological activities, and the research, evaluations, and demonstrations respecting the assessment of health care technology authorized by this Act through the Agency for Health Care Policy and Research and the National Center for Health Statistics.

NATIONAL CENTER FOR HEALTH STATISTICS.

SEC. 306.[3]**[**242k**]** (a) There is established in the Department of Health and Human Services the National Center for Health Statistics (hereinafter in this section referred to as the "Center") which shall be under the direction of a Director who shall be appointed by the Secretary. The Secretary, acting through the Center, shall conduct and support statistical and epidemiological activities for the purpose of improving the effectiveness, efficiency, and quality of health services in the United States.

(b) In carrying out subsection (a), the Secretary, acting through the Center—

(1) shall collect statistics on—

(A) the extent and nature of illness and disability of the population of the United States (or of any groupings of the people included in the population), including life expectancy, the incidence of various acute and chronic illnesses, and infant and maternal morbidity and mortality,

[2] See footnote for section 306.

[3] Former section 305 was repealed by section 6103(d)(1)(A) of Public Law 101–239 (103 Stat. 2205). Title IX now applies to the matter with which former section 305 was concerned.

(B) the impact of illness and disability of the population on the economy of the United States and on other aspects of the well-being of its population (or of such groupings),

(C) environmental, social, and other health hazards,

(D) determinants of health,

(E) health resources, including physicians, dentists, nurses, and other health professionals by specialty and type of practice and the supply of services by hospitals, extended care facilities, home health agencies, and other health institutions,

(F) utilization of health care, including utilization of (i) ambulatory health services by specialties and types of practice of the health professionals providing such services, and (ii) services of hospitals, extended care facilities, home health agencies, and other institutions,

(G) health care costs and financing, including the trends in health care prices and cost, the sources of payments for health care services, and Federal, State, and local governmental expenditures for health care services, and

(H) family formation, growth, and dissolution;

(2) shall undertake and support (by grant or contract) research, demonstrations, and evaluations respecting new or improved methods for obtaining current data on the matters referred to in paragraph (1);

(3) may undertake and support (by grant or contract) epidemiological research, demonstrations, and evaluations on the matters referred to in paragraph (1); and

(4) may collect, furnish, tabulate, and analyze statistics, and prepare studies, on matters referred to in paragraph (1) upon request of public and nonprofit private entities under arrangements under which the entities will pay the cost of the service provided.

Amounts appropriated to the Secretary from payments made under arrangements made under paragraph (4) shall be available to the Secretary for obligation until expended.

(c) The Center shall furnish such special statistical and epidemiological compilations and surveys as the Committee on Labor and Human Resources and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives may request. Such statistical and epidemiological compilations and surveys shall not be made subject to the payment of the actual or estimated cost of the preparation of such compilations and surveys.

(d) To insure comparability and reliability of health statistics, the Secretary shall, through the Center, provide adequate technical assistance to assist State and local jurisdictions in the development of model laws dealing with issues of confidentiality and comparability of data.

(e) For the purpose of producing comparable and uniform health information and statistics, there is established the Cooperative Health Statistics System. The Secretary, acting through the Center, shall—

(1) coordinate the activities of Federal agencies involved in the design and implementation of the System;

(2) undertake and support (by grant or contract) research, development, demonstrations, and evaluations respecting the System;

(3) make grants to and enter into contracts with State and local health agencies to assist them in meeting the costs of data collection and other activities carried out under the System; and

(4) review the statistical activities of the Department of Health and Human Services to assure that they are consistent with the System.

States participating in the System shall designate a State agency to administer or be responsible for the administration of the statistical activities within the State under the System. The Secretary, acting through the Center, shall prescribe guidelines to assure that statistical activities within States participating in the system[4] produce uniform and timely data and assure appropriate access to such data.

(f) To assist in carrying out this section, the Secretary, acting through the Center, shall cooperate and consult with the Departments of Commerce and Labor and any other interested Federal departments or agencies and with State and local health departments and agencies. For such purpose he shall utilize insofar as possible the services or facilities of any agency of the Federal Government and, without regard to section 3709 of the Revised Statutes (41 U.S.C. 5), of any appropriate State or other public agency, and may, without regard to such section, utilize the services or facilities of any private agency, organization, group, or individual, in accordance with written agreements between the head of such agency, organization, or group and the Secretary or between such individual and the Secretary. Payment, if any, for such services or facilities shall be made in such amounts as may be provided in such agreement.

(g) To secure uniformity in the registration and collection of mortality, morbidity, and other health data, the Secretary shall prepare and distribute suitable and necessary forms for the collection and compilation of such data.

(h)(1) There shall be an annual collection of data from the records of births, deaths, marriages, and divorces in registration areas. The data shall be obtained only from and restricted to such records of the States and municipalities which the Secretary, in his discretion, determines possess records affording satisfactory data in necessary detail and form. The Secretary shall encourage States and registration areas to obtain detailed data on ethnic and racial populations, including subpopulations of Hispanics, Asian Americans, and Pacific Islanders with significant representation in the State or registration area. Each State or registration area shall be paid by the Secretary the Federal share of its reasonable costs (as determined by the Secretary) for collecting and transcribing (at the request of the Secretary and by whatever method authorized by him) its records for such data.

[4] So in law. Probably should be capitalized.

(2) There shall be an annual collection of data from a statistically valid sample concerning the general health, illness, and disability status of the civilian noninstitutionalized population. Specific topics to be addressed under this paragraph, on an annual or periodic basis, shall include the incidence of illness and accidental injuries, prevalence of chronic diseases and impairments, disability, physician visits, hospitalizations, and the relationship between demographic and socioeconomic characteristics and health characteristics.

(i) The Center may provide to public and nonprofit private entities technical assistance in the effective use in such activities of statistics collected or compiled by the Center.

(j) In carrying out the requirements of section 304(c) and paragraph (1) of subsection (e) of this section, the Secretary shall coordinate health statistical and epidemiological activities of the Department of Health and Human Services by—

(1) establishing standardized means for the collection of health information and statistics under laws administered by the Secretary;

(2) developing, in consultation with the National Committee on Vital and Health Statistics, and maintaining the minimum sets of data needed on a continuing basis to fulfill the collection requirements of subsection (b)(1);

(3) after consultation with the National Committee on Vital and Health Statistics, establishing standards to assure the quality of health statistical and epidemiological data collection, processing, and analysis;

(4) in the case of proposed health data collections of the Department which are required to be reviewed by the Director of the Office of Management and Budget under section 3509 of title 44, United States Code, reviewing such proposed collections to determine whether they conform with the minimum sets of data and the standards promulgated pursuant to paragraphs (2) and (3), and if any such proposed collection is found not to be in conformance, by taking such action as may be necessary to assure that it will conform to such sets of data and standards, and

(5) periodically reviewing ongoing health data collections of the Department, subject to review under such section 3509, to determine if the collections are being conducted in accordance with the minimum sets of data and the standards promulgated pursuant to paragraphs (2) and (3) and, if any such collection is found not to be in conformance, by taking such action as may be necessary to assure that the collection will conform to such sets of data and standards not later than the nineteenth day after the date of the completion of the review of the collection.

(k)(1) There is established in the Office of the Secretary a committee to be known as the National Committee on Vital and Health Statistics (hereinafter in this subsection, referred to as the "Committee") which shall consist of 18 members.

(2) The members of the Committee shall be appointed from among persons who have distinguished themselves in the fields of health statistics, electronic interchange of health care information,

privacy and security of electronic information, population-based public health, purchasing or financing health care services, integrated computerized health information systems, health services research, consumer interests in health information, health data standards, epidemiology, and the provision of health services. Members of the Committee shall be appointed for terms of 4 years.

(3) Of the members of the Committee—

(A) 1 shall be appointed, not later than 60 days after the date of the enactment of the Health Insurance Portability and Accountability Act of 1996, by the Speaker of the House of Representatives after consultation with the Minority Leader of the House of Representatives;

(B) 1 shall be appointed, not later than 60 days after the date of the enactment of the Health Insurance Portability and Accountability Act of 1996, by the President pro tempore of the Senate after consultation with the Minority Leader of the Senate; and

(C) 16 shall be appointed by the Secretary.

(4) Members of the Committee shall be compensated in accordance with section 208(c).

(5) The Committee—

(A) shall assist and advise the Secretary—

(i) to delineate statistical problems bearing on health and health services which are of national or international interest;

(ii) to stimulate studies of such problems by other organizations and agencies whenever possible or to make investigations of such problems through subcommittees;

(iii) to determine, approve, and revise the terms, definitions, classifications, and guidelines for assessing health status and health services, their distribution and costs, for use (I) within the Department of Health and Human Services, (II) by all programs administered or funded by the Secretary, including the Federal-State-local cooperative health statistics system referred to in subsection (e), and (III) to the extent possible as determined by the head of the agency involved, by the Department of Veterans Affairs, the Department of Defense, and other Federal agencies concerned with health and health services;

(iv) with respect to the design of and approval of health statistical and health information systems concerned with the collection, processing, and tabulation of health statistics within the Department of Health and Human Services, with respect to the Cooperative Health Statistics System established under subsection (e), and with respect to the standardized means for the collection of health information and statistics to be established by the Secretary under subsection (j)(1);

(v) to review and comment on findings and proposals developed by other organizations and agencies and to make recommendations for their adoption or implementation by local, State, national, or international agencies;

(vi) to cooperate with national committees of other countries and with the World Health Organization and

other national agencies in the studies of problems of mutual interest;

(vii) to issue an annual report on the state of the Nation's health, its health services, their costs and distributions, and to make proposals for improvement of the Nation's health statistics and health information systems; and

(viii) in complying with the requirements imposed on the Secretary under part C of title XI of the Social Security Act;

(B) shall study the issues related to the adoption of uniform data standards for patient medical record information and the electronic exchange of such information;

(C) shall report to the Secretary not later than 4 years after the date of the enactment of the Health Insurance Portability and Accountability Act of 1996 recommendations and legislative proposals for such standards and electronic exchange; and

(D) shall be responsible generally for advising the Secretary and the Congress on the status of the implementation of part C of title XI of the Social Security Act.

(6) In carrying out health statistical activities under this part, the Secretary shall consult with, and seek the advice of, the Committee and other appropriate professional advisory groups.

(7) Not later than 1 year after the date of the enactment of the Health Insurance Portability and Accountability Act of 1996, and annually thereafter, the Committee shall submit to the Congress, and make public, a report regarding the implementation of part C of title XI of the Social Security Act. Such report shall address the following subjects, to the extent that the Committee determines appropriate:

(A) The extent to which persons required to comply with part C of title XI of the Social Security Act are cooperating in implementing the standards adopted under such part.

(B) The extent to which such entities are meeting the security standards adopted under such part and the types of penalties assessed for noncompliance with such standards.

(C) Whether the Federal and State Governments are receiving information of sufficient quality to meet their responsibilities under such part.

(D) Any problems that exist with respect to implementation of such part.

(E) The extent to which timetables under such part are being met.

(l) In carrying out this section, the Secretary, acting through the Center, shall collect and analyze adequate health data that is specific to particular ethnic and racial populations, including data collected under national health surveys. Activities carried out under this subsection shall be in addition to any activities carried out under subsection (m).

(m)(1) The Secretary, acting through the Center, may make grants to public and nonprofit private entities for—

(A) the conduct of special surveys or studies on the health of ethnic and racial populations or subpopulations;

(B) analysis of data on ethnic and racial populations and subpopulations; and

(C) research on improving methods for developing statistics on ethnic and racial populations and subpopulations.

(2) The Secretary, acting through the Center, may provide technical assistance, standards, and methodologies to grantees supported by this subsection in order to maximize the data quality and comparability with other studies.

(3) Provisions of section 308(d) do not apply to surveys or studies conducted by grantees under this subsection unless the Secretary, in accordance with regulations the Secretary may issue, determines that such provisions are necessary for the conduct of the survey or study and receives adequate assurance that the grantee will enforce such provisions.

(4)(A) Subject to subparagraph (B), the Secretary, acting through the Center, shall collect data on Hispanics and major Hispanic subpopulation groups and American Indians, and for developing special area population studies on major Asian American and Pacific Islander populations.

(B) The provisions of subparagraph (A) shall be effective with respect to a fiscal year only to the extent that funds are appropriated pursuant to paragraph (3) of subsection (n), and only if the amounts appropriated for such fiscal year pursuant to each of paragraphs (1) and (2) of subsection (n) equal or exceed the amounts so appropriated for fiscal year 1997.

(n)(1) For health statistical and epidemiological activities undertaken or supported under subsections (a) through (l), there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1991 through 2003.

(2) For activities authorized in paragraphs (1) through (3) of subsection (m), there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1999 through 2003. Of such amounts, the Secretary shall use not more than 10 percent for administration and for activities described in subsection (m)(2).

(3) For activities authorized in subsection (m)(4), there are authorized to be appropriated $1,000,000 for fiscal year 1998, and such sums as may be necessary for each of the fiscal years 1999 through 2002.

INTERNATIONAL COOPERATION.

SEC. 307.[242*l*] (a) The Secretary may participate with other countries in cooperative endeavors in—

(1) biomedical research, health care technology, and the health services research and statistical analysis authorized under section 306 and title IX; and

(2) biomedical research, health care services, health care research, or other related activities in furtherance of the activities, objectives or goals authorized under the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008.

(b) In connection with the cooperative endeavors authorized by subsection (a), the Secretary may—

(1) make such use of resources offered by participating foreign countries as he may find necessary and appropriate;

(2) establish and maintain fellowships in the United States and in participating foreign countries;

(3) make grants to public institutions or agencies and to nonprofit private institutions or agencies in the United States and in participating foreign countries for the purpose of establishing and maintaining the fellowships authorized by paragraph (2);

(4) make grants or loans of equipment and materials, for use by public or nonprofit private institutions or agencies, or by individuals, in participating foreign countries;

(5) participate and otherwise cooperate in any international meetings, conferences, or other activities concerned with biomedical research, health services research, health statistics, or health care technology;

(6) facilitate the interchange between the United States and participating foreign countries, and among participating foreign countries, of research scientists and experts who are engaged in experiments or programs of biomedical research, health services research, health statistical activities, or health care technology activities, and in carrying out such purpose may pay per diem compensation, subsistence, and travel for such scientists and experts when away from their places of residence at rates not to exceed those provided in section 5703(b) of title 5, United States Code, for persons in the Government service employed intermittently;

(7) procure, in accordance with section 3109 of title 5, United States Code, the temporary or intermittent services of experts or consultants;

(8) enter into contracts with individuals for the provision of services (as defined in section 104 of part 37 of title 48, Code of Federal Regulations (48 CFR 37.104)) in participating foreign countries, which individuals may not be deemed employees of the United States for the purpose of any law administered by the Office of Personnel Management;

(9) provide such funds by advance or reimbursement to the Secretary of State, as may be necessary, to pay the costs of acquisition, lease, construction, alteration, equipping, furnishing or management of facilities outside of the United States; and

(10) in consultation with the Secretary of State, through grant or cooperative agreement, make funds available to public or nonprofit private institutions or agencies in foreign countries in which the Secretary is participating in activities described under subsection (a) to acquire, lease, construct, alter, or renovate facilities in those countries.

(c) The Secretary may provide to personnel appointed or assigned by the Secretary to serve abroad, allowances and benefits similar to those provided under chapter 9 of title I of the Foreign Service Act of 1980 (22 U.S.C. 4081 et seq.). Leaves of absence for personnel under this subsection shall be on the same basis as that provided under subchapter I of chapter 63 of title 5, United States Code or section 903 of the Foreign Service Act of 1980 (22 U.S.C. 4083), to individuals serving in the Foreign Service.

(d) In carrying out immunization programs and other programs in developing countries for the prevention, treatment, and control of infectious diseases, including HIV/AIDS, tuberculosis, and malaria, the Director of the Centers for Disease Control and Prevention, in coordination with the Coordinator of United States Government Activities to Combat HIV/AIDS Globally, the National Institutes of Health, national and local government, and other organizations, such as the World Health Organization and the United Nations Children's Fund, shall develop and implement effective strategies to improve injection safety, including eliminating unnecessary injections, promoting sterile injection practices and technologies, strengthening the procedures for proper needle and syringe disposal, and improving the education and information provided to the public and to health professionals.

GENERAL PROVISIONS RESPECTING EFFECTIVENESS, EFFICIENCY, AND QUALITY OF HEALTH SERVICES.

SEC. 308.[242m] (a)(1) Not later than March 15 of each year, the Secretary shall submit to the President and Congress the following reports:

(A) A report on health care costs and financing. Such report shall include a description and analysis of the statistics collected under section 306(b)(1)(G).

(B) A report on health resources. Such report shall include a description and analysis, by geographical area, of the statistics collected under section 306(b)(1)(E).

(C) A report on the utilization of health resources. Such report shall include a description and analysis, by age, sex, income, and geographic area, of the statistics collected under section 306(b)(1)(F).

(D) A report on the health of the Nation's people. Such report shall include a description and analysis, by age, sex, income, and geographic area, of the statistics collected under section 306(b)(1)(A).

(2) The reports required in paragraph (1) shall be prepared through the National Center for Health Statistics.

(3) The Office of Management and Budget may review any report required by paragraph (1) of this subsection before its submission to Congress, but the Office may not revise any such report or delay its submission beyond the date prescribed for its submission, and may submit to Congress its comments respecting any such report.

(b)(1) No grant or contract may be made under section 304, 306, or 307 unless an application therefor has been submitted to the Secretary in such form and manner, and containing such information, as the Secretary may by regulation prescribe and unless a peer review group referred to in paragraph (2) has recommended the application for approval.

(2)(A) Each application submitted for a grant or contract under section 306 in an amount exceeding $50,000 of direct costs and for a health services research, evaluation, or demonstration project, or for a grant under section 306(m), shall be submitted to a peer review group for an evaluation of the technical and scientific merits

of the proposals made in each such application. The Director of the National Center for Health Statistics shall establish such peer review groups as may be necessary to provide for such an evaluation of each such application.

(B) A peer review group to which an application is submitted pursuant to subparagraph (A) shall report its finding and recommendations respecting the application to the Secretary, acting through the Director of the National Center for Health Statistics, in such form and manner as the Secretary shall by regulation prescribe. The Secretary may not approve an application described in such subparagraph unless a peer review group has recommended the application for approval.

(C) The Secretary, acting through the Director of the National Center for Health Statistics, shall make appointments to the peer review groups required in subparagraph (A) from among persons who are not officers or employees of the United States and who possess appropriate technical and scientific qualifications, except that peer review groups regarding grants under section 306(m) may include appropriately qualified such officers and employees.

(c) The Secretary shall take such action as may be necessary to assure that statistics developed under sections 304 and 306 are of high quality, timely, comprehensive as well as specific, standardized, and adequately analyzed and indexed, and shall publish, make available, and disseminate such statistics on as wide a basis as is practicable.

(d) No information, if an establishment or person supplying the information or described in it is identifiable, obtained in the course of activities undertaken or supported under section 304, 306, or 307 may be used for any purpose other than the purpose for which it was supplied unless such establishment or person has consented (as determined under regulations of the Secretary) to its use for such other purpose and in the case of information obtained in the course of health statistical or epidemiological activities under section 304 or 306, such information may not be published or released in other form if the particular establishment or person supplying the information or described in it is identifiable unless such establishment or person has consented (as determined under regulations of the Secretary) to its publication or release in other form.

(e)(1) Payments of any grant or under any contract under section 304, 306, or 307 may be made in advance or by way of reimbursement, and in such installments and on such conditions, as the Secretary deems necessary to carry out the purposes of such section.

(2) The amounts otherwise payable to any person under a grant or contract made under section 304, 306, or 307 shall be reduced by—

(A) amounts equal to the fair market value of any equipment or supplies furnished to such person by the Secretary for the purpose of carrying out the project with respect to which such grant or contract is made, and

(B) amounts equal to the pay, allowances, traveling expenses, and related personnel expenses attributable to the performance of services by an officer or employee of the Government in connection with such project, if such officer or em-

ployee was assigned or detailed by the Secretary to perform such services,

but only if such person requested the Secretary to furnish such equipment or supplies, or such services, as the case may be.

(f) Contracts may be entered into under section 304 or 306 without regard to section 3324 of title 31, United States Code, and section 3709 of the Revised Statutes (41 U.S.C. 5).

HEALTH CONFERENCES AND HEALTH EDUCATION INFORMATION.

SEC. 310.[5] [242o] (a) A conference of the health authorities in and among the several States shall be called annually by the Secretary. Whenever in his opinion the interests of the public health would be promoted by a conference, the Secretary may invite as many of such health authorities and officials of other State or local public or private agencies, institutions, or organizations to confer as he deems necessary or proper. Upon the application of health authorities of five or more States it shall be the duty of the Secretary to call a conference of all State health authorities joining in the request. Each State represented at any conference shall be entitled to a single vote. Whenever at any such conference matters relating to mental health are to be discussed, the mental health authorities of the respective States shall be invited to attend.

(b) From time to time the Secretary shall issue information related to public health, in the form of publications or otherwise, for the use of the public, and shall publish weekly reports of health conditions in the United States and other countries and other pertinent health information for the use of persons and institutions concerned with health services.

SEC. 310A.[242s] CENTERS FOR DISEASE CONTROL AND PREVENTION OFFICE OF WOMEN'S HEALTH.

(a) ESTABLISHMENT.—There is established within the Office of the Director of the Centers for Disease Control and Prevention, an office to be known as the Office of Women's Health (referred to in this section as the "Office"). The Office shall be headed by a director who shall be appointed by the Director of such Centers.

(b) PURPOSE.—The Director of the Office shall—

(1) report to the Director of the Centers for Disease Control and Prevention on the current level of the Centers' activity regarding women's health conditions across, where appropriate, age, biological, and sociocultural contexts, in all aspects of the Centers' work, including prevention programs, public and professional education, services, and treatment;

(2) establish short-range and long-range goals and objectives within the Centers for women's health and, as relevant and appropriate, coordinate with other appropriate offices on activities within the Centers that relate to prevention, research, education and training, service delivery, and policy development, for issues of particular concern to women;

(3) identify projects in women's health that should be conducted or supported by the Centers;

[5] Former section 309 was repealed by section 6103(d)(1)(B) of Public Law 101–239 (103 Stat. 2205).

(4) consult with health professionals, nongovernmental organizations, consumer organizations, women's health professionals, and other individuals and groups, as appropriate, on the policy of the Centers with regard to women; and

(5) serve as a member of the Department of Health and Human Services Coordinating Committee on Women's Health (established under section 229(b)(4)).

(c) DEFINITION.—As used in this section, the term "women's health conditions", with respect to women of all age, ethnic, and racial groups, means diseases, disorders, and conditions—

(1) unique to, significantly more serious for, or significantly more prevalent in women; and

(2) for which the factors of medical risk or type of medical intervention are different for women, or for which there is reasonable evidence that indicates that such factors or types may be different for women.

(d) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2010 through 2014.

PART B—FEDERAL-STATE COOPERATION

IN GENERAL.

SEC. 311.[243] (a) The Secretary is authorized to accept from State and local authorities any assistance in the enforcement of quarantine regulations made pursuant to this Act which such authorities may be able and willing to provide. The Secretary shall also assist States and their political subdivisions in the prevention and suppression of communicable diseases and with respect to other public health matters, shall cooperate with and aid State and local authorities in the enforcement of their quarantine and other health regulations, and shall advise the several States on matters relating to the preservation and improvement of the public health.

(b) The Secretary shall encourage cooperative activities between the States with respect to comprehensive and continuing planning as to their current and future health needs, the establishment and maintenance of adequate public health services, and otherwise carrying out the public health activities. The Secretary is also authorized to train personnel for State and local health work. The Secretary may charge only private entities reasonable fees for the training of their personnel under the preceding sentence.

(c)(1) The Secretary is authorized to develop (and may take such action as may be necessary to implement) a plan under which personnel, equipment, medical supplies, and other resources of the Service and other agencies under the jurisdiction of the Secretary may be effectively used to control epidemics of any disease or condition and to meet other health emergencies or problems. The Secretary may enter into agreements providing for the cooperative planning between the Service and public and private community health programs and agencies to cope with health problems (including epidemics and health emergencies).

(2) The Secretary may, at the request of the appropriate State or local authority, extend temporary (not in excess of six months)

assistance to States or localities in meeting health emergencies of such a nature as to warrant Federal assistance. The Secretary may require such reimbursement of the United States for assistance provided under this paragraph as he may determine to be reasonable under the circumstances. Any reimbursement so paid shall be credited to the applicable appropriation for the Service for the year in which such reimbursement is received.

SEC. 312.[244] PUBLIC ACCESS DEFIBRILLATION PROGRAMS.

(a) IN GENERAL.—The Secretary shall award grants to States, political subdivisions of States, Indian tribes, and tribal organizations to develop and implement public access defibrillation programs—

(1) by training and equipping local emergency medical services personnel, including firefighters, police officers, paramedics, emergency medical technicians, and other first responders, to administer immediate care, including cardiopulmonary resuscitation and automated external defibrillation, to cardiac arrest victims;

(2) by purchasing automated external defibrillators, placing the defibrillators in public places where cardiac arrests are likely to occur, and training personnel in such places to administer cardiopulmonary resuscitation and automated external defibrillation to cardiac arrest victims;

(3) by setting procedures for proper maintenance and testing of such devices, according to the guidelines of the manufacturers of the devices;

(4) by providing training to members of the public in cardiopulmonary resuscitation and automated external defibrillation;

(5) by integrating the emergency medical services system with the public access defibrillation programs so that emergency medical services personnel, including dispatchers, are informed about the location of automated external defibrillators in their community; and

(6) by encouraging private companies, including small businesses, to purchase automated external defibrillators and provide training for their employees to administer cardiopulmonary resuscitation and external automated defibrillation to cardiac arrest victims in their community.

(b) PREFERENCE.—In awarding grants under subsection (a), the Secretary shall give a preference to a State, political subdivision of a State, Indian tribe, or tribal organization that—

(1) has a particularly low local survival rate for cardiac arrests, or a particularly low local response rate for cardiac arrest victims; or

(2) demonstrates in its application the greatest commitment to establishing and maintaining a public access defibrillation program.

(c) USE OF FUNDS.—A State, political subdivision of a State, Indian tribe, or tribal organization that receives a grant under subsection (a) may use funds received through such grant to—

(1) purchase automated external defibrillators that have been approved, or cleared for marketing, by the Food and Drug Administration;

(2) provide automated external defibrillation and basic life support training in automated external defibrillator usage through nationally recognized courses;

(3) provide information to community members about the public access defibrillation program to be funded with the grant;

(4) provide information to the local emergency medical services system regarding the placement of automated external defibrillators in public places;

(5) produce materials to encourage private companies, including small businesses, to purchase automated external defibrillators;

(6) establish an information clearinghouse, that shall be administered by an organization that has substantial expertise in pediatric education, pediatric medicine, and electrophysiology and sudden death, that provides information to increase public access to defibrillation in schools; and

(7) further develop strategies to improve access to automated external defibrillators in public places.

(d) APPLICATION.—

(1) IN GENERAL.—To be eligible to receive a grant under subsection (a), a State, political subdivision of a State, Indian tribe, or tribal organization shall prepare and submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may reasonably require.

(2) CONTENTS.—An application submitted under paragraph (1) shall—

(A) describe the comprehensive public access defibrillation program to be funded with the grant and demonstrate how such program would make automated external defibrillation accessible and available to cardiac arrest victims in the community;

(B) contain procedures for implementing appropriate nationally recognized training courses in performing cardiopulmonary resuscitation and the use of automated external defibrillators;

(C) contain procedures for ensuring direct involvement of a licensed medical professional and coordination with the local emergency medical services system in the oversight of training and notification of incidents of the use of the automated external defibrillators;

(D) contain procedures for proper maintenance and testing of the automated external defibrillators, according to the labeling of the manufacturer;

(E) contain procedures for ensuring notification of local emergency medical services system personnel, including dispatchers, of the location and type of devices used in the public access defibrillation program; and

(F) provide for the collection of data regarding the effectiveness of the public access defibrillation program to be

funded with the grant in affecting the out-of-hospital cardiac arrest survival rate.

(e) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $25,000,000 for for[6] each of fiscal years 2003 through 2014. Not more than 10 percent of amounts received under a grant awarded under this section may be used for administrative expenses.

SEC. 313.[245] PUBLIC ACCESS DEFIBRILLATION DEMONSTRATION PROJECTS.

(a) IN GENERAL.—The Secretary shall award grants to political subdivisions of States, Indian tribes, and tribal organizations to develop and implement innovative, comprehensive, community-based public access defibrillation demonstration projects that—

(1) provide cardiopulmonary resuscitation and automated external defibrillation to cardiac arrest victims in unique settings;

(2) provide training to community members in cardiopulmonary resuscitation and automated external defibrillation; and

(3) maximize community access to automated external defibrillators.

(b) USE OF FUNDS.—A recipient of a grant under subsection (a) shall use the funds provided through the grant to—

(1) purchase automated external defibrillators that have been approved, or cleared for marketing, by the Food and Drug Administration;

(2) provide basic life training in automated external defibrillator usage through nationally recognized courses;

(3) provide information to community members about the public access defibrillation demonstration project to be funded with the grant;

(4) provide information to the local emergency medical services system regarding the placement of automated external defibrillators in the unique settings; and

(5) further develop strategies to improve access to automated external defibrillators in public places.

(c) APPLICATION.—

(1) IN GENERAL.—To be eligible to receive a grant under subsection (a), a political subdivision of a State, Indian tribe, or tribal organization shall prepare and submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may reasonably require.

(2) CONTENTS.—An application submitted under paragraph (1) may—

(A) describe the innovative, comprehensive, community-based public access defibrillation demonstration project to be funded with the grant;

(B) explain how such public access defibrillation demonstration project represents innovation in providing public access to automated external defibrillation; and

[6] The words "for for" so in law.

(C) provide for the collection of data regarding the effectiveness of the demonstration project to be funded with the grant in—

(i) providing emergency cardiopulmonary resuscitation and automated external defibrillation to cardiac arrest victims in the setting served by the demonstration project; and

(ii) affecting the cardiac arrest survival rate in the setting served by the demonstration project.

(d) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $5,000,000 for each of fiscal years 2002 through 2006. Not more than 10 percent of amounts received under a grant awarded under this section may be used for administrative expenses.

GRANTS FOR COMPREHENSIVE HEALTH PLANNING AND PUBLIC HEALTH SERVICES.

Grants to States for Comprehensive State Health Planning

SEC. 314.[246] (a)(1) AUTHORIZATION.—In order to assist the States in comprehensive and continuing planning for their current and future health needs, the Secretary is authorized during the period beginning July 1, 1966, and ending June 30, 1973, to make grants to States which have submitted, and had approved by the Secretary, State plans for comprehensive State health planning. For the purposes of carrying out this subsection, there are hereby authorized to be appropriated $2,500,000 for the fiscal year ending June 30, 1967, $7,000,000 for the fiscal year ending June 30, 1968, $10,000,000 for the fiscal year ending June 30, 1969, $15,000,000 for the fiscal year ending June 30, 1970, $15,000,000 for the fiscal year ending June 30, 1971, $17,000,000 for the fiscal year ending June 30, 1972, $20,000,000 for the fiscal year ending June 30, 1973, and $10,000,000 for the fiscal year ending June 30, 1974.

(2) STATE PLANS FOR COMPREHENSIVE STATE HEALTH PLANNING.—In order to be approved for purposes of this subsection, a State plan for comprehensive State health planning must—

(A) designate, or provide for the establishment of, a single State agency, which may be an interdepartmental agency, as the sole agency for administering or supervising the administration of the State's health planning functions under the plan;

(B) provide for the establishment of a State health planning council, which shall include representatives of Federal, State, and local agencies (including as an ex officio member, if there is located in such State one or more hospitals or other health care facilities of the Department of Veterans Affairs, the individual whom the Secretary of Veterans Affairs shall have designated to serve on such council as the representative of the hospitals or other health care facilities of such Department which are located in such State) and nongovernmental organizations and groups concerned with health (including representation of the regional medical program or programs included in whole or in part within the State) and of consumers of health services, to advise such State agency in carrying out its functions under the plan, and a majority of the membership of such

council shall consist of representatives of consumers of health services;

(C) set forth policies and procedures for the expenditure of funds under the plan, which, in the judgment of the Secretary, are designed to provide for comprehensive State planning for health services (both public and private and including home health care), including the facilities and persons required for the provision of such services, to meet the health needs of the people of the State and including environmental considerations as they relate to public health;

(D) provide for encouraging cooperative efforts among governmental or nongovernmental agencies, organizations and groups concerned with health services, facilities, or manpower, and for cooperative efforts between such agencies, organizations, and groups and similar agencies, organizations, and groups in the fields of education, welfare, and rehabilitation;

(E) contain or be supported by assurances satisfactory to the Secretary that the funds paid under this subsection will be used to supplement and, to the extent practicable, to increase the level of funds that would otherwise be made available by the State for the purpose of comprehensive health planning and not to supplant such non-Federal funds;

(F)[7] provide such methods of administration (including methods relating to the establishment and maintenance of personnel standards on a merit basis, except that the Secretary shall exercise no authority with respect to the selection, tenure of office, and compensation of any individual employed in accordance with such methods) as are found by the Secretary to be necessary for the proper and efficient operation of the plan;

(G) provide that the State agency will make such reports, in such form and containing such information, as the Secretary may from time to time reasonably require, and will keep such records and afford such access thereto as the Secretary finds necessary to assure the correctness and verification of such reports;

(H) provide that the State agency will from time to time, but not less often than annually, review its State plan approved under this subsection and submit to the Secretary appropriate modifications thereof;

(I) effective July 1, 1968, (i) provide for assisting each health care facility in the State to develop a program for capital expenditures for replacement, modernization, and expansion which is consistent with an overall State plan developed in accordance with criteria established by the Secretary after consultation with the State which will meet the needs of the State for health care facilities, equipment, and services without duplication and otherwise in the most efficient and economical manner, and (ii) provide that the State agency furnishing such

[7] Section 208(a)(3) of Public Law 91–648 (42 U.S.C. 4728) transferred to the United States Civil Service Commission all functions, powers, and duties of the Secretary under any law applicable to a grant program which requires the establishment and maintenance of personnel standards on a merit basis with respect to the program. Reorganization Plan No. 2 of 1978 (42 U.S.C. 1101 note) transferred to the Office of Personnel Management all functions of the United States Civil Service Commission.

assistance will periodically review the program (developed pursuant to clause (i)) of each health care facility in the State and recommended appropriate modification thereof;

(J) provide for such fiscal control and fund accounting procedures as may be necessary to assure proper disbursement of and accounting for funds paid to the State under this subsection; and

(K) contain such additional information and assurances as the Secretary may find necessary to carry out the purposes of this subsection.

(3)(A) STATE ALLOTMENTS.—From the sums appropriated for such purpose for each fiscal year, the several States shall be entitled to allotments determined, in accordance with regulations, on the basis of the population and the per capita income of the respective States; except that no such allotment to any State for any fiscal year shall be less than 1 per centum of the sum appropriated for such fiscal year pursuant to paragraph (1). Any such allotment to a State for a fiscal year shall remain available for obligation by the State, in accordance with the provisions of this subsection and the State's plan approved thereunder, until the close of the succeeding fiscal year.

(B) The amount of any allotment to a State under subparagraph (A) for any fiscal year which the Secretary determines will not be required by the State, during the period for which it is available, for the purposes for which allotted shall be available for reallotment by the Secretary from time to time, on such date or dates as he may fix, to other States with respect to which such a determination has not been made, in proportion to the original allotments to such States under subparagraph (A) for such fiscal year, but with such proportionate amount for any of such other States being reduced to the extent it exceeds the sum the Secretary estimates such State needs and will be able to use during such period; and the total of such reductions shall be similarly reallotted among the States whose proportionate amounts were not so reduced. Any amount so reallotted to a State from funds appropriated pursuant to this subsection for a fiscal year shall be deemed part of its allotment under subparagraph (A) for such fiscal year.

(4) PAYMENTS TO STATES.—From each State's allotment for a fiscal year under this subsection, the State shall from time to time be paid the Federal share of the expenditures incurred during that year or the succeeding year pursuant to its State plan approved under this subsection. Such payments shall be made on the basis of estimates by the Secretary of the sums the State will need in order to perform the planning under its approved State plan under this subsection, but with such adjustments as may be necessary to take account of previously made underpayments or overpayments. The "Federal share" for any State for purposes of this subsection shall be all, or such part as the Secretary may determine, of the cost of such planning, except that in the case of the allotments for the fiscal year ending June 30, 1970, it shall not exceed 75 per centum, of such cost.

Project Grants for Areawide Health Planning

(b)(1)(A) The Secretary is authorized, during the period beginning July 1, 1966, and ending June 30, 1974, to make, with the approval of the State agency administering or supervising the administration of the State plan approved under subsection (a), project grants to any other public or nonprofit private agency or organization (but with appropriate representation of the interests of local government where the recipient of the grant is not a local government or combination thereof or an agency of such government or combination) to cover not to exceed 75 per centum of the costs of projects for developing (and from time to time revising) comprehensive regional, metropolitan area, or other local area plans for coordination of existing and planned health services, including the facilities and persons required for provision of such services; and including the provision of such services through home health care; except that in the case of project grants made in any State prior to July 1, 1968, approval of such State agency shall be required only if such State has such a State plan in effect at the time of such grants. No grant may be made under this subsection after June 30, 1970, to any agency or organization to develop or revise health plans for an area unless the Secretary determines that such agency or organization provides means for appropriate representation of the interests of the hospitals, other health care facilities, and practicing physicians serving such area, and the general public. For the purposes of carrying out this subsection, there are hereby authorized to be appropriated $5,000,000 for the fiscal year ending June 30, 1967, $7,500,000 for the fiscal year ending June 30, 1968, $10,000,000 for the fiscal year ending June 30, 1969, $15,000,000 for the fiscal year ending June 30, 1970, $20,000,000 for the fiscal year ending June 30, 1971, $30,000,000 for the fiscal year ending June 30, 1972, $40,000,000 for the fiscal year ending June 30, 1973, and $25,100,000 for the fiscal year ending June 30, 1974.

(B) Project grants may be made by the Secretary under subparagraph (A) to the State agency administering or supervising the administration of the State plan approved under subsection (a) with respect to a particular region or area, but only if (i) no application for such a grant with respect to such region or area has been filed by any other agency or organization qualified to receive such a grant, and (ii) such State agency certifies, and the Secretary finds, that ample opportunity has been afforded to qualified agencies and organizations to file application for such a grant with respect to such region or area and that it is improbable that, in the foresee-able future, any agency or organization which is qualified for such a grant will file application therefor.

(2)(A) In order to be approved under this subsection, an application for a grant under this subsection must contain or be supported by reasonable assurances that there has been or will be established, in or for the area with respect to which such grant is sought, an areawide health planning council. The membership of such council shall include representatives of public, voluntary, and non-profit private agencies, institutions, and organizations concerned with health (including representatives of the interests of

local government of the regional medical program for such area, and of consumers of health services). A majority of the members of such council shall consist of representatives of consumers of health services.

(B) In addition, an application for a grant under this subsection must contain or be supported by reasonable assurances that the areawide health planning agency has made provision for assisting health care facilities in its area to develop a program for capital expenditures for replacement, modernization, and expansion, which is consistent with an overall State plan which will meet the needs of the State and the area for health care facilities, equipment, and services without duplication and otherwise in the most efficient and economical manner.

Project Grants for Training, Studies, and Demonstrations

(c) The Secretary is also authorized, during the period beginning July 1, 1966, and ending June 30, 1974, to make grants to any public or nonprofit private agency, institution, or other organization to cover all or any part of the cost of projects for training, studies, or demonstrations looking toward the development of improved or more effective comprehensive health planning throughout the Nation. For the purposes of carrying out this subsection, there are hereby authorized to be appropriated $1,500,000 for the fiscal year ending June 30, 1967, $2,500,000 for the fiscal year ending June 30, 1968, $5,000,000 for the fiscal year ending June 30, 1969, $7,500,000 for the fiscal year ending June 30, 1970, $8,000,000 for the fiscal year ending June 30, 1971, $10,000,000 for the fiscal year ending June 30, 1972, $12,000,000 for the fiscal year ending June 30, 1973, and $4,700,000 for the fiscal year ending June 30, 1974.

FAMILY SUPPORT GROUPS FOR ALZHEIMER'S DISEASE PATIENTS.

SEC. 316.[8] **[**247a**]** (a) Subject to available appropriations, the Secretary, acting through the National Institute of Mental Health, the National Institutes of Health, and the Administration on Aging, shall promote the establishment of family support groups to provide, without charge, educational, emotional, and practical support to assist individuals with Alzheimer's disease or a related memory disorder and members of the families of such individuals. In promoting the establishment of such groups, the Secretary shall give priority to—

(1) university medical centers and other appropriate health care facilities which receive Federal funds from the Secretary and which conduct research on Alzheimer's disease or provide services to individuals with such disease; and

(2) community-based programs which receive funds from the Secretary, acting through the Administration on Aging.

(b) The Secretary shall promote the establishment of a national network to coordinate the family support groups described in subsection (a).

[8] With respect to section 315, subsection (d) of such section provided as follows: "This section shall cease to exist on March 31, 1989.". See section 1 of Public Law 100–471 (102 Stat. 2284).

PROJECT GRANTS FOR PREVENTIVE HEALTH SERVICES.

SEC. 317.[247b] (a) The Secretary may make grants to States, and in consultation with State health authorities, to political subdivisions of States and to other public entities to assist them in meeting the costs of establishing and maintaining preventive health service programs.

(b) No grant may be made under subsection (a) unless an application therefor has been submitted to, and approved by, the Secretary. Such an application shall be in such form and be submitted in such manner as the Secretary shall by regulation prescribe and shall provide—

(1) a complete description of the type and extent of the program for which the applicant is seeking a grant under subsection (a);

(2) with respect to each such program (A) the amount of Federal, State, and other funds obligated by the applicant in its latest annual accounting period for the provision of such program, (B) a description of the services provided by the applicant in such program in such period, (C) the amount of Federal funds needed by the applicant to continue providing such services in such program, and (D) if the applicant proposes changes in the provision of the services in such program, the priorities of such proposed changes, reasons for such changes, and the amount of Federal funds needed by the applicant to make such changes;

(3) assurances satisfactory to the Secretary that the program which will be provided with funds under a grant under subsection (a) will be provided in a manner consistent with the State health plan in effect under section 1524(c) and in those cases where the applicant is a State, that such program will be provided, where appropriate, in a manner consistent with any plans in effect under an application approved under section 315;

(4) assurances satisfactory to the Secretary that the applicant will provide for such fiscal control and fund accounting procedures as the Secretary by regulation prescribes to assure the proper disbursement of and accounting for funds received under grants under subsection (a);

(5) assurances satisfactory to the Secretary that the applicant will provide for periodic evaluation of its program or programs;

(6) assurances satisfactory to the Secretary that the applicant will make such reports (in such form and containing such information as the Secretary may by regulation prescribe) as the Secretary may reasonably require and keep such records and afford such access thereto as the Secretary may find necessary to assure the correctness of, and to verify, such reports;

(7) assurances satisfactory to the Secretary that the applicant will comply with any other conditions imposed by this section with respect to grants; and

(8) such other information as the Secretary may by regulation prescribe.

(c)(1) The Secretary shall not approve an application submitted under subsection (b) for a grant for a program for which a grant was previously made under subsection (a) unless the Secretary determines—

(A) the program for which the application was submitted is operating effectively to achieve its stated purpose,

(B) the applicant complied with the assurances provided the Secretary when applying for such previous grant, and

(C) the applicant will comply with the assurances provided with the application.

(2) The Secretary shall review annually the activities undertaken by each recipient of a grant under subsection (a) to determine if the program assisted by such grant is operating effectively to achieve its stated purposes and if the recipient is in compliance with the assurances provided the Secretary when applying for such grant.

(d) The amount of a grant under subsection (a) shall be determined by the Secretary. Payments under such grants may be made in advance on the basis of estimates or by the way of reimbursement, with necessary adjustments on account of underpayments or overpayments, and in such installments and on such terms and conditions as the Secretary finds necessary to carry out the purposes of such grants.

(e) The Secretary, at the request of a recipient of a grant under subsection (a), may reduce the amount of such grant by—

(1) the fair market value of any supplies (including vaccines and other preventive agents) or equipment furnished the grant recipient, and

(2) the amount of the pay, allowances, and travel expenses of any officer or employee of the Government when detailed to the grant recipient and the amount of any other costs incurred in connection with the detail of such officer or employee.

When the furnishing of such supplies or equipment or the detail of such an officer or employee is for the convenience of and at the request of such grant recipient and for the purpose of carrying out a program with respect to which the grant under subsection (a) is made. The amount by which any such grant is so reduced shall be available for payment by the Secretary of the costs incurred in furnishing the supplies or equipment, or in detailing the personnel, on which the reduction of such grant is based, and such amount shall be deemed as part of the grant and shall be deemed to have been paid to the grant recipient.

(f)(1) Each recipient of a grant under subsection (a) shall keep such records as the Secretary shall by regulation prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of such grant, the total cost of the undertaking in connection with which such grant was made, and the amount of that portion of the cost of the undertaking supplied by other sources, and such other records as will facilitate an effective audit.

(2) The Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, docu-

ments, papers, and records of the recipient of grants under subsection (a) that are pertinent to such grants.

(g)(1) Nothing in this section shall limit or otherwise restrict the use of funds which are granted to a State or to an agency or a political subdivision of a State under provisions of Federal law (other than this section) and which are available for the conduct of preventive health service programs from being used on connection with programs assisted through grants under subsection (a).

(2) Nothing in this section shall be construed to require any State or any agency or political subdivision of a State to have a preventive health service program which would require any person, who objects to any treatment provided under such a program, to be treated or to have any child or ward treated under such program.

(h) The Secretary shall include, as part of the report required by section 1705, a report on the extent of the problems presented by the diseases and conditions referred to in subsection (j) on the amount of funds obligated under grants under subsection (a) in the preceding fiscal year for each of the programs listed in subsection (j); and on the effectiveness of the activities assisted under grants under subsection (a) in controlling such diseases and conditions.

(i) The Secretary may provide technical assistance to States, State health authorities, and other public entities in connection with the operation of their preventive health service programs.

(j)(1) Except for grants for immunization programs the authorization of appropriations for which are established in paragraph (2), for grants under subsections (a) and (k)(1) for preventive health service programs to immunize without charge children, adolescents, and adults against vaccine-preventable diseases, there are authorized to be appropriated such sums as may be necessary. Not more than 10 percent ot the total amount appropriated under the preceding sentence for any fiscal year shall be available for grants under subsection (k)(1) for such fiscal year.

(2) For grants under subsection (a) for preventive health service programs for the provision without charge of immunizations with vaccines approved for use, and recommended for routine use, there are authorized to be appropriated such sums as may be necessary.

(k)(1) The Secretary may make grants to States, political subdivisions of States, and other public and nonprofit private entities for—

(A) research into the prevention and control of diseases that may be prevented through vaccination;

(B) demonstration projects for the prevention and control of such diseases;

(C) public information and education programs for the prevention and control of such diseases; and

(D) education, training, and clinical skills improvement activities in the prevention and control of such diseases for health professionals (including allied health personnel).

(2) The Secretary may make grants to States, political subdivisions of States, and other public and nonprofit private entities for—

(A) research into the prevention and control of diseases and conditions;

(B) demonstration projects for the prevention and control of such diseases and conditions;

(C) public information and education programs for the prevention and control of such diseases and conditions; and

(D) education, training, and clinical skills improvement activities in the prevention and control of such diseases and conditions for health professionals (including allied health personnel).

(3) No grant may be made under this subsection unless an application therefor is submitted to the Secretary in such form, at such time, and containing such information as the Secretary may by regulation prescribe.

(4) Subsections (d), (e), and (f) shall apply to grants under this subsection in the same manner as such subsections apply to grants under subsection (a).

(l) AUTHORITY TO PURCHASE RECOMMENDED VACCINES FOR ADULTS.—

(1) IN GENERAL.—The Secretary may negotiate and enter into contracts with manufacturers of vaccines for the purchase and delivery of vaccines for adults as provided for under subsection (e).

(2) STATE PURCHASE.—A State may obtain additional quantities of such adult vaccines (subject to amounts specified to the Secretary by the State in advance of negotiations) through the purchase of vaccines from manufacturers at the applicable price negotiated by the Secretary under this subsection.

(m) DEMONSTRATION PROGRAM TO IMPROVE IMMUNIZATION COVERAGE.—

(1) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish a demonstration program to award grants to States to improve the provision of recommended immunizations for children, adolescents, and adults through the use of evidence-based, population-based interventions for high-risk populations.

(2) STATE PLAN.—To be eligible for a grant under paragraph (1), a State shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require, including a State plan that describes the interventions to be implemented under the grant and how such interventions match with local needs and capabilities, as determined through consultation with local authorities.

(3) USE OF FUNDS.—Funds received under a grant under this subsection shall be used to implement interventions that are recommended by the Task Force on Community Preventive Services (as established by the Secretary, acting through the Director of the Centers for Disease Control and Prevention) or other evidence-based interventions, including—

(A) providing immunization reminders or recalls for target populations of clients, patients, and consumers;

(B) educating targeted populations and health care providers concerning immunizations in combination with one or more other interventions;

(C) reducing out-of-pocket costs for families for vaccines and their administration;

(D) carrying out immunization-promoting strategies for participants or clients of public programs, including assessments of immunization status, referrals to health care providers, education, provision of on-site immunizations, or incentives for immunization;

(E) providing for home visits that promote immunization through education, assessments of need, referrals, provision of immunizations, or other services;

(F) providing reminders or recalls for immunization providers;

(G) conducting assessments of, and providing feedback to, immunization providers;

(H) any combination of one or more interventions described in this paragraph; or

(I) immunization information systems to allow all States to have electronic databases for immunization records.

(4) CONSIDERATION.—In awarding grants under this subsection, the Secretary shall consider any reviews or recommendations of the Task Force on Community Preventive Services.

(5) EVALUATION.—Not later than 3 years after the date on which a State receives a grant under this subsection, the State shall submit to the Secretary an evaluation of progress made toward improving immunization coverage rates among high-risk populations within the State.

(6) REPORT TO CONGRESS.—Not later than 4 years after the date of enactment of the Affordable Health Choices Act, the Secretary shall submit to Congress a report concerning the effectiveness of the demonstration program established under this subsection together with recommendations on whether to continue and expand such program.

(7) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this subsection, such sums as may be necessary for each of fiscal years 2010 through 2014.

SCREENINGS, REFERRALS, AND EDUCATION REGARDING LEAD POISONING.

SEC. 317A.[247b–1] (a) AUTHORITY FOR GRANTS.—

(1) IN GENERAL.—Subject to paragraph (2), the Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make grants to States and political subdivisions of States for the initiation and expansion of community programs designed—

(A) to provide, for infants and children—

(i) screening for elevated blood lead levels;

(ii) referral for treatment of such levels; and

(iii) referral for environmental intervention associated with such levels; and

(B) to provide education about childhood lead poisoning.

(2) AUTHORITY REGARDING CERTAIN ENTITIES.—With respect to a geographic area with a need for activities authorized in paragraph (1), in any case in which neither the State nor the political subdivision in which such area is located has applied for a grant under paragraph (1), the Secretary may make a grant under such paragraph to any grantee under section 329, 330, or 340A for carrying out such activities in the area.

(3) PROVISION OF ALL SERVICES AND ACTIVITIES THROUGH EACH GRANTEE.—In making grants under paragraph (1), the Secretary shall ensure that each of the activities described in such paragraph is provided through each grantee under such paragraph. The Secretary may authorize such a grantee to provide the services and activities directly, or through arrangements with other providers.

(b) STATUS AS MEDICAID PROVIDER.—

(1) IN GENERAL.—Subject to paragraph (2), the Secretary may not make a grant under subsection (a) unless, in the case of any service described in such subsection that is made available pursuant to the State plan approved under title XIX of the Social Security Act for the State involved—

(A) the applicant for the grant will provide the service directly, and the applicant has entered into a participation agreement under the State plan and is qualified to receive payments under such plan; or

(B) the applicant will enter into an agreement with a provider under which the provider will provide the service, and the provider has entered into such a participation agreement and is qualified to receive such payments.

(2) WAIVER REGARDING CERTAIN SECONDARY AGREEMENTS.—

(A) In the case of a provider making an agreement pursuant to paragraph (1)(B) regarding the provision of services, the requirement established in such paragraph regarding a participation agreement shall be waived by the Secretary if the provider does not, in providing health care services, impose a charge or accept reimbursement available from any third-party payor, including reimbursement under any insurance policy or under any Federal or State health benefits plan.

(B) A determination by the Secretary of whether a provider referred to in subparagraph (A) meets the criteria for a waiver under such subparagraph shall be made without regard to whether the provider accepts voluntary donations regarding the provision of services to the public.

(c) PRIORITY IN MAKING GRANTS.—In making grants under subsection (a), the Secretary shall give priority to applications for programs that will serve areas with a high incidence of elevated blood lead levels in infants and children.

(d) GRANT APPLICATION.—No grant may be made under subsection (a), unless an application therefor has been submitted to, and approved by, the Secretary. Such an application shall be in such form and shall be submitted in such manner as the Secretary shall prescribe and shall include each of the following:

(1) A complete description of the program which is to be provided by or through the applicant.

(2) Assurances satisfactory to the Secretary that the program to be provided under the grant applied for will include educational programs designed to—

(A) communicate to parents, educators, and local health officials the significance and prevalence of lead poisoning in infants and children (including the sources of lead exposure, the importance of screening young children for lead, and the preventive steps that parents can take in reducing the risk of lead poisoning) which the program is designed to detect and prevent; and

(B) communicate to health professionals and paraprofessionals updated knowledge concerning lead poisoning and research (including the health consequences, if any, of low-level lead burden; the prevalence of lead poisoning among all socioeconomic groupings; the benefits of expanded lead screening; and the therapeutic and other interventions available to prevent and combat lead poisoning in affected children and families).

(3) Assurances satisfactory to the Secretary that the applicant will report on a quarterly basis the number of infants and children screened for elevated blood lead levels, the number of infants and children who were found to have elevated blood lead levels, the number and type of medical referrals made for such infants and children, the outcome of such referrals, and other information to measure program effectiveness.

(4) Assurances satisfactory to the Secretary that the applicant will make such reports respecting the program involved as the Secretary may require.

(5) Assurances satisfactory to the Secretary that the applicant will coordinate the activities carried out pursuant to subsection (a) with related activities and services carried out in the State by grantees under title V or XIX of the Social Security Act.

(6) Assurances satisfactory to the Secretary that Federal funds made available under such a grant for any period will be so used as to supplement and, to the extent practical, increase the level of State, local, and other non-Federal funds that would, in the absence of such Federal funds, be made available for the program for which the grant is to be made and will in no event supplant such State, local, and other non-Federal funds.

(7) Assurances satisfactory to the Secretary that the applicant will ensure complete and consistent reporting of all blood lead test results from laboratories and health care providers to State and local health departments in accordance with guidelines of the Centers for Disease Control and Prevention for standardized reporting as described in subsection (m).

(8) Such other information as the Secretary may prescribe.

(e) RELATIONSHIP TO SERVICES AND ACTIVITIES UNDER OTHER PROGRAMS.—

(1) IN GENERAL.—A recipient of a grant under subsection (a) may not make payments from the grant for any service or

activity to the extent that payment has been made, or can reasonably be expected to be made, with respect to such service or activity—

(A) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program; or

(B) by an entity that provides health services on a prepaid basis.

(2) APPLICABILITY TO CERTAIN SECONDARY AGREEMENTS FOR PROVISION OF SERVICES.—Paragraph (1) shall not apply in the case of a provider through which a grantee under subsection (a) provides services under such subsection if the Secretary has provided a waiver under subsection (b)(2) regarding the provider.

(f) METHOD AND AMOUNT OF PAYMENT.—The Secretary shall determine the amount of a grant made under subsection (a). Payments under such grants may be made in advance on the basis of estimates or by way of reimbursement, with necessary adjustments on account of underpayments or overpayments, and in such installments and on such terms and conditions as the Secretary finds necessary to carry out the purposes of such grants. Not more than 10 percent of any grant may be obligated for administrative costs.

(g) SUPPLIES, EQUIPMENT, AND EMPLOYEE DETAIL.—The Secretary, at the request of a recipient of a grant under subsection (a), may reduce the amount of such grant by—

(1) the fair market value of any supplies or equipment furnished the grant recipient; and

(2) the amount of the pay, allowances, and travel expenses of any officer or employee of the Government when detailed to the grant recipient and the amount of any other costs incurred in connection with the detail of such officer or employee;

when the furnishing of such supplies or equipment or the detail of such an officer or employee is for the convenience of and at the request of such grant recipient and for the purpose of carrying out a program with respect to which the grant under subsection (a) is made. The amount by which any such grant is so reduced shall be available for payment by the Secretary of the costs incurred in furnishing the supplies or equipment, or in detailing the personnel, on which the reduction of such grant is based, and such amount shall be deemed as part of the grant and shall be deemed to have been paid to the grant recipient.

(h) RECORDS.—Each recipient of a grant under subsection (a) shall keep such records as the Secretary shall prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of such grant, the total cost of the undertaking in connection with which such grant was made, and the amount of that portion of the cost of the undertaking supplied by other sources, and such other records as will facilitate an effective audit.

(i) AUDIT AND EXAMINATION OF RECORDS.—The Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and

records of the recipient of a grant under subsection (a), that are pertinent to such grant.

(j) ANNUAL REPORT.—

(1) IN GENERAL.—Not later than May 1 of each year, the Secretary shall submit to the Congress a report on the effectiveness during the preceding fiscal year of programs carried out with grants under subsection (a) and of any programs that are carried out by the Secretary pursuant to subsection (l)(2).

(2) CERTAIN REQUIREMENTS.—Each report under paragraph (1) shall include, in addition to any other information that the Secretary may require, the following information:

(A) The number of infants and children screened.

(B) Demographic information on the population of infants and children screened, including the age and racial or ethnic status of such population.

(C) The number of screening sites.

(D) A description of the severity of the extent of the blood lead levels of the infants and children screened, expressed in categories of severity.

(E) The sources of payment for the screenings.

(F) The number of grantees that have established systems to ensure mandatory reporting of all blood lead tests from laboratories and health care providers to State and local health departments.

(G) A comparison of the data provided pursuant to subparagraphs (A) through (F) with the equivalent data, if any, provided in the report under paragraph (1) preceding the report involved.

(k) INDIAN TRIBES.—For purposes of this section, the term "political subdivision" includes Indian tribes.

(l) FUNDING.—

(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $40,000,000 for fiscal year 1993, and such sums as may be necessary for each of the fiscal years 1994 through 2005.

(2) ALLOCATION FOR OTHER PROGRAMS.—Of the amounts appropriated under paragraph (1) for any fiscal year, the Secretary may reserve not more than 20 percent for carrying out programs regarding the activities described in subsection (a) in addition to the program of grants established in such subsection.

(m) GUIDELINES FOR STANDARDIZED REPORTING.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall develop national guidelines for the uniform reporting of all blood lead test results to State and local health departments.

EDUCATION, TECHNOLOGY ASSESSMENT, AND EPIDEMIOLOGY REGARDING LEAD POISONING.

SEC. 317B.[247b–3] (a) PREVENTION.—

(1) PUBLIC EDUCATION.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall carry out a program to educate health professionals and

paraprofessionals and the general public on the prevention of lead poisoning in infants and children. In carrying out the program, the Secretary shall make available information concerning the health effects of low-level lead toxicity, the causes of lead poisoning, and the primary and secondary preventive measures that may be taken to prevent such poisoning.

(2) INTERAGENCY TASK FORCE.—

(A) Not later than 6 months after the date of the enactment of the Preventive Health Amendments of 1992[9], the Secretary shall establish a council to be known as the Interagency Task Force on the Prevention of Lead Poisoning (in this paragraph referred to as the "Task Force"). The Task Force shall coordinate the efforts of Federal agencies to prevent lead poisoning.

(B) The Task Force shall be composed of—

(i) the Secretary, who shall serve as the chair of the Task Force;

(ii) the Secretary of Housing and Urban Development;

(iii) the Administrator of the Environmental Protection Agency; and

(iv) senior staff of each of the officials specified in clauses (i) through (iii), as selected by the officials respectively.

(C) The Task Force shall—

(i) review, evaluate, and coordinate current strategies and plans formulated by the officials serving as members of the Task Force, including—

(I) the plan of the Secretary of Health and Human Services entitled "Strategic Plan for the Elimination of Lead Poisoning", dated February 21, 1991;

(II) the plan of the Secretary of Housing and Urban Development entitled "Comprehensive and Workable Plan for the Abatement of Lead-Based Paint in Privately Owned Housing", dated December 7, 1990; and

(III) the strategy of the Administrator of the Environmental Protection Agency entitled "Strategy for Reducing Lead Exposures", dated February 21, 1991;

(ii) develop a unified implementation plan for programs that receive Federal financial assistance for activities related to the prevention of lead poisoning;

(iii) establish a mechanism for sharing and disseminating information among the agencies represented on the Task Force;

(iv) identify the most promising areas of research and education concerning lead poisoning;

(v) identify the practical and technological constraints to expanding lead poisoning prevention;

[9] Enacted October 27, 1992.

(vi) annually carry out a comprehensive review of Federal programs providing assistance to prevent lead poisoning, and not later than May 1 of each year, submit to the Committee on Labor and Human Resources of the Senate and the Committee on the Environment and Public Works of the Senate, and to the Committee on Energy and Commerce of the House of Representatives, a report that summarizes the findings made as a result of such review and that contains the recommendations of the Task Force on the programs and policies with respect to which the Task Force is established, including related budgetary recommendations; and

(vii) annually review and coordinate departmental and agency budgetary requests with respect to all lead poisoning prevention activities of the Federal Government.

(b) TECHNOLOGY ASSESSMENT AND EPIDEMIOLOGY.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall, directly or through grants or contracts—

(1) provide for the development of improved, more cost-effective testing measures for detecting lead toxicity in children;

(2) provide for the development of improved methods of assessing the prevalence of lead poisoning, including such methods as may be necessary to conduct individual assessments for each State;

(3) provide for the collection of data on the incidence and prevalence of lead poisoning of infants and children, on the demographic characteristics of infants and children with such poisoning (including racial and ethnic status), and on the source of payment for treatment for such poisoning (including the extent to which insurance has paid for such treatment); and

(4) provide for any applied research necessary to improve the effectiveness of programs for the prevention of lead poisoning in infants and children.

NATIONAL CENTER ON BIRTH DEFECTS AND DEVELOPMENTAL DISABILITIES.

SEC. 317C.[247b–4] (a) IN GENERAL.—

(1) NATIONAL CENTER.—There is established within the Centers for Disease Control and Prevention a center to be known as the National Center on Birth Defects and Developmental Disabilities (referred to in this section as the "Center"), which shall be headed by a director appointed by the Director of the Centers for Disease Control and Prevention.

(2) GENERAL DUTIES.—The Secretary shall carry out programs—

(A) to collect, analyze, and make available data on birth defects, developmental disabilities, and disabilities and health (in a manner that facilitates compliance with subsection (c)(2)), including data on the causes of such de-

fects and disabilities and on the incidence and prevalence of such defects and disabilities;

(B) to operate regional centers for the conduct of applied epidemiological research on the prevention of such defects and disabilities;

(C) to provide information and education to the public on the prevention of such defects and disabilities;

(D) to conduct research on and to promote the prevention of such defects and disabilities, and secondary health conditions among individuals with disabilities; and

(E) to support a National Spina Bifida Program to prevent and reduce suffering from the Nation's most common permanently disabling birth defect.

(3) FOLIC ACID.—The Secretary shall carry out section 317J through the Center.

(4) CERTAIN PROGRAMS.—

(A) TRANSFERS.—All programs and functions described in subparagraph (B) are transferred to the Center, effective upon the expiration of the 180-day period beginning on the date of the enactment of the Children's Health Act of 2000 [10].

(B) RELEVANT PROGRAMS.—The programs and functions described in this subparagraph are all programs and functions that—

(i) relate to birth defects; folic acid; cerebral palsy; intellectual disabilities; child development; newborn screening; autism; fragile X syndrome; fetal alcohol syndrome; pediatric genetic disorders; disability prevention; or other relevant diseases, disorders, or conditions as determined the Secretary; and

(ii) were carried out through the National Center for Environmental Health as of the day before the date of the enactment of the Act referred to in subparagraph (A).

(C) RELATED TRANSFERS.—Personnel employed in connection with the programs and functions specified in subparagraph (B), and amounts available for carrying out the programs and functions, are transferred to the Center, effective upon the expiration of the 180-day period beginning on the date of the enactment of the Act referred to in subparagraph (A). Such transfer of amounts does not affect the period of availability of the amounts, or the availability of the amounts with respect to the purposes for which the amounts may be expended.

(b) GRANTS AND CONTRACTS.—

(1) IN GENERAL.—In carrying out subsection (a), the Secretary may make grants to and enter into contracts with public and nonprofit private entities.

(2) SUPPLIES AND SERVICES IN LIEU OF AWARD FUNDS.—

(A) Upon the request of a recipient of an award of a grant or contract under paragraph (1), the Secretary may, subject to subparagraph (B), provide supplies, equipment,

[10] Public Law 106–310, enacted October 17, 2000.

and services for the purpose of aiding the recipient in carrying out the purposes for which the award is made and, for such purposes, may detail to the recipient any officer or employee of the Department of Health and Human Services.

(B) With respect to a request described in subparagraph (A), the Secretary shall reduce the amount of payments under the award involved by an amount equal to the costs of detailing personnel and the fair market value of any supplies, equipment, or services provided by the Secretary. The Secretary shall, for the payment of expenses incurred in complying with such request, expend the amounts withheld.

(3) APPLICATION FOR AWARD.—The Secretary may make an award of a grant or contract under paragraph (1) only if an application for the award is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out the purposes for which the award is to be made.

(c) BIENNIAL REPORT.—Not later than February 1 of fiscal year 1999 and of every second such year thereafter, the Secretary shall submit to the Committee on Commerce of the House of Representatives, and the Committee on Labor and Human Resources of the Senate, a report that, with respect to the preceding 2 fiscal years—

(1) contains information regarding the incidence and prevalence of birth defects, developmental disabilities, and the health status of individuals with disabilities and the extent to which these conditions have contributed to the incidence and prevalence of infant mortality and affected quality of life;

(2) contains information under paragraph (1) that is specific to various racial and ethnic groups (including Hispanics, non-Hispanic whites, Blacks, Native Americans, and Asian Americans);

(3) contains an assessment of the extent to which various approaches of preventing birth defects, developmental disabilities, and secondary health conditions among individuals with disabilities have been effective;

(4) describes the activities carried out under this section;

(5) contains information on the incidence and prevalence of individuals living with birth defects and disabilities or developmental disabilities, information on the health status of individuals with disabilities, information on any health disparities experienced by such individuals, and recommendations for improving the health and wellness and quality of life of such individuals;

(6) contains a summary of recommendations from all birth defects research conferences sponsored by the Centers for Disease Control and Prevention, including conferences related to spina bifida; and

(7) contains any recommendations of the Secretary regarding this section.

(d) APPLICABILITY OF PRIVACY LAWS.—The provisions of this section shall be subject to the requirements of section 552a of title

5, United States Code. All Federal laws relating to the privacy of information shall apply to the data and information that is collected under this section.

(e) ADVISORY COMMITTEE.—Notwithstanding any other provision of law, the members of the advisory committee appointed by the Director of the National Center for Environmental Health that have expertise in birth defects, developmental disabilities, and disabilities and health shall be transferred to and shall advise the National Center on Birth Defects and Developmental Disabilities effective on the date of enactment of the Birth Defects and Developmental Disabilities Prevention Act of 2003.

(f) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of fiscal years 2003 through 2007.

PREVENTIVE HEALTH MEASURES WITH RESPECT TO PROSTATE CANCER.

SEC. 317D.[247b–5] (a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make grants to States and local health departments for the purpose of enabling such States and departments to carry out programs that may include the following:

(1) To identify factors that influence the attitudes or levels of awareness of men and health care practitioners regarding screening for prostate cancer.

(2) To evaluate, in consultation with the Agency for Health Care Policy and Research and the National Institutes of Health, the effectiveness of screening strategies for prostate cancer.

(3) To identify, in consultation with the Agency for Health Care Policy and Research, issues related to the quality of life for men after prostrate cancer screening and followup.

(4) To develop and disseminate public information and education programs for prostate cancer, including appropriate messages about the risks and benefits of prostate cancer screening for the general public, health care providers, policy makers and other appropriate individuals.

(5) To improve surveillance for prostate cancer.

(6) To address the needs of underserved and minority populations regarding prostate cancer.

(7) Upon a determination by the Secretary, who shall take into consideration recommendations by the United States Preventive Services Task Force and shall seek input, where appropriate, from professional societies and other private and public entities, that there is sufficient consensus on the effectiveness of prostate cancer screening—

(A) to screen men for prostate cancer as a preventive health measure;

(B) to provide appropriate referrals for the medical treatment of men who have been screened under subparagraph (A) and to ensure, to the extent practicable, the provision of appropriate followup services and support services such as case management;

(C) to establish mechanisms through which State and local health departments can monitor the quality of screening procedures for prostate cancer, including the interpretation of such procedures; and

(D) to improve, in consultation with the Health Resources and Services Administration, the education, training, and skills of health practitioners (including appropriate allied health professionals) in the detection and control of prostate cancer.

(8) To evaluate activities conducted under paragraphs (1) through (7) through appropriate surveillance or program monitoring activities.

(b) REQUIREMENT OF MATCHING FUNDS.—

(1) IN GENERAL.—The Secretary may not make a grant under subsection (a) unless the applicant involved agrees, with respect to the costs to be incurred by the applicant in carrying out the purpose described in such section, to make available non-Federal contributions (in cash or in kind under paragraph (2)) toward such costs in an amount equal to not less than $1 for each $3 of Federal funds provided in the grant. Such contributions may be made directly or through donations from public or private entities.

(2) DETERMINATION OF AMOUNT OF NON-FEDERAL CONTRIBUTION.—

(A) Non-Federal contributions required in paragraph (1) may be in cash or in kind, fairly evaluated, including equipment or services (and excluding indirect or overhead costs). Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

(B) In making a determination of the amount of non-Federal contributions for purposes of paragraph (1), the Secretary may include only non-Federal contributions in excess of the average amount of non-Federal contributions made by the applicant involved toward the purpose described in subsection (a) for the 2-year period preceding the fiscal year for which the applicant involved is applying to receive a grant under such subsection.

(C) In making a determination of the amount of non-Federal contributions for purposes of paragraph (1), the Secretary shall, subject to subparagraphs (A) and (B) of this paragraph, include any non-Federal amounts expended pursuant to title XIX of the Social Security Act by the applicant involved toward the purpose described in paragraphs (1) and (2) of subsection (a).

(c) EDUCATION ON SIGNIFICANCE OF EARLY DETECTION.—The Secretary may not make a grant under subsection (a) unless the applicant involved agrees that, in carrying out subsection (a)(3), the applicant will carry out education programs to communicate to men, and to local health officials, the significance of the early detection of prostate cancer.

(d) REQUIREMENT OF PROVISION OF ALL SERVICES BY DATE CERTAIN.—The Secretary may not make a grant under subsection (a) unless the applicant involved agrees—

(1) to ensure that, initially and throughout the period during which amounts are received pursuant to the grant, not less than 60 percent of the grant is expended to provide each of the services or activities described in paragraphs (1) and (2) of such subsection;

(2) to ensure that, by the end of any second fiscal year of payments pursuant to the grant, each of the services or activities described in such subsection is provided; and

(3) to ensure that not more than 40 percent of the grant is expended to provide the services or activities described in paragraphs (3) through (6) of such section [11].

(e) ADDITIONAL REQUIRED AGREEMENTS.—

(1) PRIORITY FOR LOW-INCOME MEN.—The Secretary may not make a grant under subsection (a) unless the applicant involved agrees that low-income men, and men at risk of prostate cancer, will be given priority in the provision of services and activities pursuant to paragraphs (1) and (2) of such subsection.

(2) LIMITATION ON IMPOSITION OF FEES FOR SERVICES.—The Secretary may not make a grant under subsection (a) unless the applicant involved agrees that, if a charge is imposed for the provision of services or activities under the grant, such charge—

(A) will be made according to a schedule of charges that is made available to the public;

(B) will be adjusted to reflect the income of the man involved; and

(C) will not be imposed on any man with an income of less than 100 percent of the official poverty line, as established by the Director of the Office of Management and Budget and revised by the Secretary in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1981.

(3) RELATIONSHIP TO ITEMS AND SERVICES UNDER OTHER PROGRAMS.—The Secretary may not make a grant under subsection (a) unless the applicant involved agrees that the grant will not be expended to make payment for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to such item or service—

(A) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program; or

(B) by an entity that provides health services on a prepaid basis.

(4) COORDINATION WITH OTHER PROSTATE CANCER PROGRAMS.—The Secretary may not make a grant under subsection (a) unless the applicant involved agrees that the services and activities funded through the grant will be coordinated with other Federal, State, and local prostate cancer programs.

[11] So in law. Probably should be "subsection".

(5) LIMITATION ON ADMINISTRATIVE EXPENSES.—The Secretary may not make a grant under subsection (a) unless the applicant involved agrees that not more than 10 percent of the grant will be expended for administrative expenses with respect to the grant.

(6) RESTRICTIONS ON USE OF GRANT.—The Secretary may not make a grant under subsection (a) unless the applicant involved agrees that the grant will not be expended to provide inpatient hospital services for any individual.

(7) RECORDS AND AUDITS.—The Secretary may not make a grant under subsection (a) unless the applicant involved agrees that—

(A) the applicant will establish such fiscal control and fund accounting procedures as may be necessary to ensure the proper disbursal of, and accounting for, amounts received by the applicant under such section; and

(B) upon request, the applicant will provide records maintained pursuant to paragraph (1) to the Secretary or the Comptroller of the United States for purposes of auditing the expenditures by the applicant of the grant.

(f) REPORTS TO SECRETARY.—The Secretary may not make a grant under subsection (a) unless the applicant involved agrees to submit to the Secretary such reports as the Secretary may require with respect to the grant.

(g) DESCRIPTION OF INTENDED USES OF GRANT.—The Secretary may not make a grant under subsection (a) unless—

(1) the applicant involved submits to the Secretary a description of the purposes for which the applicant intends to expend the grant;

(2) the description identifies the populations, areas, and localities in the applicant[12] with a need for the services or activities described in subsection (a);

(3) the description provides information relating to the services and activities to be provided, including a description of the manner in which the services and activities will be coordinated with any similar services or activities of public or nonprivate entities; and

(4) the description provides assurances that the grant funds will be used in the most cost-effective manner.

(h) REQUIREMENT OF SUBMISSION OF APPLICATION.—The Secretary may not make a grant under subsection (a) unless an application for the grant is submitted to the Secretary, the application contains the description of intended uses required in subsection (g), and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(i) METHOD AND AMOUNT OF PAYMENT.—The Secretary shall determine the amount of a grant made under subsection (a). Payments under such grants may be made in advance on the basis of estimates or by way of reimbursement, with necessary adjustments on account of the underpayments or overpayments, and in such in-

[12] So in law.

stallments and on such terms and conditions as the Secretary finds necessary to carry out the purposes of such grants.

(j) TECHNICAL ASSISTANCE AND PROVISION OF SUPPLIES AND SERVICES IN LIEU OF GRANT FUNDS.—

(1) TECHNICAL ASSISTANCE.—The Secretary may provide training and technical assistance with respect to the planning, development, and operation of any program or service carried out pursuant to subsection (a). The Secretary may provide such technical assistance directly or through grants to, or contracts with, public and private entities.

(2) PROVISION OF SUPPLIES AND SERVICES IN LIEU OF GRANT FUNDS.—

(A) Upon the request of an applicant receiving a grant under subsection (a), the Secretary may, subject to subparagraph (B), provide supplies, equipment, and services for the purpose of aiding the applicant in carrying out such section and, for such purpose, may detail to the applicant any officer or employee of the Department of Health and Human Services.

(B) With respect to a request described in subparagraph (A), the Secretary shall reduce the amount of payments under the grant under subsection (a) to the applicant involved by an amount equal to the costs of detailing personnel (including pay, allowances, and travel expenses) and the fair market value of any supplies, equipment, or services provided by the Secretary. The Secretary shall, for the payment of expenses incurred in complying with such request, expend the amounts withheld.

(k) DEFINITION.—For purposes of this section, the term "units of local government" includes Indian tribes.

(l) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—For the purpose of carrying out this section, there are authorized to be appropriated $20,000,000 for fiscal year 1993, and such sums as may be necessary for each of the fiscal years 1994 through 2004.

(2) ALLOCATION FOR TECHNICAL ASSISTANCE.—Of the amounts appropriated under paragraph (1) for a fiscal year, the Secretary shall reserve not more than 20 percent for carrying out subsection (j)(1).

NATIONAL STRATEGY FOR COMBATING AND ELIMINATING TUBERCULOSIS.

SEC. 317E.[247b–6] (a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make grants to States, political subdivisions, and other public entities for preventive health service programs for the prevention, control, and elimination of tuberculosis.

(b) RESEARCH AND DEVELOPMENT; DEMONSTRATION PROJECTS; EDUCATION AND TRAINING.—With respect to the prevention, treatment, control, and elimination of tuberculosis, the Secretary may, directly or through grants to public or nonprofit private entities, carry out the following:

(1) Research, with priority given to research and development concerning latent tuberculosis infection, strains of tuberculosis resistant to drugs, and research concerning cases of tuberculosis that affect certain populations at risk for tuberculosis.

(2) Research and development and related activities to develop new tools for the elimination of tuberculosis, including drugs, diagnostics, vaccines, and public health interventions, such as directly observed therapy and non-pharmaceutical intervention, and methods to enhance detection and response to outbreaks of tuberculosis, including multidrug resistant tuberculosis. The Secretary is encouraged to give priority to programmatically relevant research so that new tools can be utilized in public health practice.

(3) Demonstration projects for—

(A) the development of regional capabilities to prevent, control, and eliminate tuberculosis and prevent multidrug resistant and extensively drug resistant strains of tuberculosis;

(B) the intensification of efforts to reduce health disparities in the incidence of tuberculosis;

(C) the intensification of efforts to control tuberculosis along the United States-Mexico border and among United States-Mexico binational populations, including through expansion of the scope and number of programs that—

(i) detect and treat binational cases of tuberculosis; and

(ii) treat high-risk cases of tuberculosis referred from Mexican health departments;

(D) the intensification of efforts to prevent, detect, and treat tuberculosis among foreign-born persons who are in the United States;

(E) the intensification of efforts to prevent, detect, and treat tuberculosis among populations and settings documented as having a high risk for tuberculosis; and

(F) tuberculosis detection, control, and prevention.

(4) Public information and education activities.

(5) Education, training, clinical skills improvement activities, and workplace exposure prevention for health professionals, including allied health personnel and emergency response employees.

(6) Support of Centers to carry out activities under paragraphs (1) through (4).

(7) Collaboration with international organizations and foreign countries in carrying out such activities.

(8) Develop, enhance, and expand information technologies that support tuberculosis control including surveillance and database management systems with cross-jurisdictional capabilities, which shall conform to the standards and implementation specifications for such information technologies as recommended by the Secretary.

(c) COOPERATION WITH PROVIDERS OF PRIMARY HEALTH SERVICES.—The Secretary may make a grant under subsection (a) or (b) only if the applicant for the grant agrees that, in carrying out ac-

tivities under the grant, the applicant will cooperate with public and nonprofit private providers of primary health services or substance abuse services, including entities receiving assistance under section 329, 330, or 340A or under title V or XIX.

(d) APPLICATION FOR GRANT.—

(1) IN GENERAL.—The Secretary may make a grant under subsection (a) or (b) only if an application for the grant is submitted to the Secretary and the application, subject to paragraph (2), is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out the subsection involved.

(2) PLAN FOR PREVENTION, CONTROL, AND ELIMINATION.—The Secretary may make a grant under subsection (a) only if the application under paragraph (1) contains a plan regarding the prevention, control, and elimination of tuberculosis in the geographic area with respect to which the grant is sought.

(3) DETERMINATION OF AMOUNT OF NONFEDERAL CONTRIBUTIONS.—

(A) PRIORITY.—In awarding grants under subsection (a) or (b), the Secretary shall give highest priority to an applicant that provides assurances that the applicant will contribute non-Federal funds to carry out activities under this section, which may be provided directly or through donations from public or private entities and may be in cash or in kind, including equipment or services.

(B) FEDERAL AMOUNTS NOT TO BE INCLUDED AS CONTRIBUTIONS.—Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of non-Federal contributions as described in subparagraph (A).

(e) SUPPLIES AND SERVICES IN LIEU OF GRANT FUNDS.—

(1) IN GENERAL.—Upon the request of a grantee under subsection (a) or (b), the Secretary may, subject to paragraph (2), provide supplies, equipment, and services for the purpose of aiding the grantee in carrying out the subsection involved and, for such purpose, may detail to the State any officer or employee of the Department of Health and Human Services.

(2) CORRESPONDING REDUCTION IN PAYMENTS.—With respect to a request described in paragraph (1), the Secretary shall reduce the amount of payments under the grant involved by an amount equal to the costs of detailing personnel and the fair market value of any supplies, equipment, or services provided by the Secretary. The Secretary shall, for the payment of expenses incurred in complying with such request, expend the amounts withheld.

(f) ADVISORY COUNCIL.—

(1) IN GENERAL.—The Secretary shall establish an advisory council to be known as the Advisory Council for the Elimination of Tuberculosis (in this subsection referred to as the "Council").

(2) DUTIES.—The Council shall provide advice and recommendations regarding the elimination of tuberculosis to the

Secretary. In addition, the Council shall, with respect to eliminating such disease, provide to the Secretary and other appropriate Federal officials advice on—

(A) coordinating the activities of the Department of Health and Human Services and other Federal agencies that relate to the disease, including activities under subsection (b);

(B) responding rapidly and effectively to emerging issues in tuberculosis; and

(C) efficiently utilizing the Federal resources involved.

(3) COMPREHENSIVE PLAN.—

(A) IN GENERAL.—In carrying out paragraph (2), the Council shall make or update recommendations on the development, revision, and implementation of a comprehensive plan to eliminate tuberculosis in the United States.

(B) CONSULTATION.—In carrying out subparagraph (A), the Council may consult with appropriate public and private entities, which may, subject to the direction or discretion of the Secretary, include—

(i) individuals who are scientists, physicians, laboratorians, and other health professionals, who are not officers or employees of the Federal Government and who represent the disciplines relevant to tuberculosis elimination;

(ii) members of public-private partnerships or private entities established to address the elimination of tuberculosis;

(iii) members of national and international nongovernmental organizations whose purpose is to eliminate tuberculosis;

(iv) members from the general public who are knowledgeable with respect to tuberculosis elimination including individuals who have or have had tuberculosis; and

(v) scientists, physicians, laboratorians, and other health professionals who reside in a foreign country with a substantial incidence or prevalence of tuberculosis, and who represent the specialties and disciplines relevant to the research under consideration.

(C) CERTAIN COMPONENTS OF PLAN.—In carrying out subparagraph (A), the Council shall, subject to the direction or discretion of the Secretary—

(i) consider recommendations for the involvement of the United States in continuing global and cross-border tuberculosis control activities in countries where a high incidence of tuberculosis directly affects the United States; and

(ii) review the extent to which progress has been made toward eliminating tuberculosis.

(4) BIENNIAL REPORT.—

(A) IN GENERAL.—The Council shall submit a biennial report to the Secretary, as determined necessary by the Secretary, on the activities carried under this section. Each such report shall include the opinion of the Council

on the extent to which its recommendations regarding the elimination of tuberculosis have been implemented, including with respect to—

(i) activities under subsection (b); and

(ii) the national plan referred to in paragraph (3).

(B) PUBLIC.—The Secretary shall make a report submitted under subparagraph (A) public.

(5) COMPOSITION.—The Council shall be composed of—

(A) ex officio representatives from the Centers for Disease Control and Prevention, the National Institutes of Health, the United States Agency for International Development, the Agency for Healthcare Research and Quality, the Health Resources and Services Administration, the United States-Mexico Border Health Commission, and other Federal departments and agencies that carry out significant activities related to tuberculosis;

(B) State and local tuberculosis control and public health officials;

(C) individuals who are scientists, physicians, laboratorians, and other health professionals who represent disciplines relevant to tuberculosis elimination; and

(D) members of national and international nongovernmental organizations established to address the elimination of tuberculosis.

(6) STAFF, INFORMATION, AND OTHER ASSISTANCE.—The Secretary shall provide to the Council such staff, information, and other assistance as may be necessary to carry out the duties of the Council.

(g) FEDERAL TUBERCULOSIS TASK FORCE.—

(1) DUTIES.—The Federal Tuberculosis Task Force (in this subsection referred to as the "Task Force") shall provide to the Secretary and other appropriate Federal officials advice on research into new tools under subsection (b)(2), including advice regarding the efficient utilization of the Federal resources involved.

(2) COMPREHENSIVE PLAN FOR NEW TOOLS DEVELOPMENT.—In carrying out paragraph (1), the Task Force shall make recommendations on the development of a comprehensive plan for the creation of new tools for the elimination of tuberculosis, including drugs, diagnostics, and vaccines.

(3) CONSULTATION.—In developing the comprehensive plan under paragraph (1), the Task Force shall consult with external parties including representatives from groups such as—

(A) scientists, physicians, laboratorians, and other health professionals who represent the specialties and disciplines relevant to the research under consideration;

(B) members from public-private partnerships, private entities, or foundations (or both) engaged in activities relevant to research under consideration;

(C) members of national and international nongovernmental organizations established to address tuberculosis elimination;

(D) members from the general public who are knowledgeable with respect to tuberculosis including individuals who have or have had tuberculosis; and

(E) scientists, physicians, laboratorians, and other health professionals who reside in a foreign country with a substantial incidence or prevalence of tuberculosis, and who represent the specialties and disciplines relevant to the research under consideration.

(h) AUTHORIZATION OF APPROPRIATIONS.—

(1) GENERAL PROGRAM.—

(A) IN GENERAL.—For the purpose of carrying out this section, there are authorized to be appropriated $200,000,000 for fiscal year 2009, $210,000,000 for fiscal year 2010, $220,500,000 for fiscal year 2011, $231,525,000 for fiscal year 2012, and $243,101,250 for fiscal year 2013.

(B) RESERVATION FOR EMERGENCY GRANTS.—Of the amounts appropriated under subparagraph (A) for a fiscal year, the Secretary may reserve not more than 25 percent for emergency grants under subsection (a) for any geographic area, State, political subdivision of a State, or other public entity in which there is, relative to other areas, a substantial number of cases of tuberculosis, multidrug resistant tuberculosis, or extensively drug resistant tuberculosis or a substantial rate of increase in such cases.

(C) PRIORITY.—In allocating amounts appropriated under subparagraph (A), the Secretary shall give priority to allocating such amounts for grants under subsection (a).

(D) ALLOCATION OF FUNDS.—

(i) REQUIREMENT OF FORMULA.—Of the amounts appropriated under subparagraph (A), not reserved under subparagraph (B), and allocated by the Secretary for grants under subsection (a), the Secretary shall distribute a portion of such amounts to grantees under subsection (a) on the basis of a formula.

(ii) RELEVANT FACTORS.—The formula developed by the Secretary under clause (i) shall take into account the level of tuberculosis morbidity and case complexity in the respective geographic area and may consider other factors relevant to tuberculosis in such area.

(iii) NO CHANGE TO FORMULA REQUIRED.—This subparagraph does not require the Secretary to modify the formula that was used by the Secretary to distribute funds to grantees under subsection (a) for fiscal year 2009.

(2) LIMITATION.—The authorization of appropriations established in paragraph (1) for a fiscal year is effective only if the amount appropriated under such paragraph for such year equals or exceeds the amount appropriated to carry out this section for fiscal year 2009.

LOAN REPAYMENT PROGRAM.

SEC. 317F.[247b–7] (a) IN GENERAL.—

(1) AUTHORITY.—Subject to paragraph (2), the Secretary may carry out a program of entering into contracts with appropriately qualified health professionals under which such health professionals agree to conduct prevention activities, as employees of the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry, in consideration of the Federal Government agreeing to repay, for each year of such service, not more than $35,000 of the principal and interest of the educational loans of such health professionals.

(2) LIMITATION.—The Secretary may not enter into an agreement with a health professional pursuant to paragraph (1) unless such professional—

(A) has a substantial amount of educational loans relative to income; and

(B) agrees to serve as an employee of the Centers for Disease Control and Prevention or the Agency for Toxic Substances and Disease Registry for purposes of paragraph (1) for a period of not less than 3 years.

(b) APPLICABILITY OF CERTAIN PROVISIONS.—With respect to the National Health Service Corps Loan Repayment Program established in subpart III of part D of title III of this Act, the provisions of such subpart shall, except as inconsistent with subsection (a), apply to the program established in this section in the same manner and to the same extent as such provisions apply to the National Health Service Corps Loan Repayment Program.

(c) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $500,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 through 2002.

(d) AVAILABILITY OF APPROPRIATIONS.—Amounts appropriated for a fiscal year for contracts under subsection (a) shall remain available until the expiration of the second fiscal year beginning after the fiscal year for which the amounts were appropriated.

SEC. 317G.[247b–8] FELLOWSHIP AND TRAINING PROGRAMS.

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish fellowship and training programs to be conducted by such Centers to train individuals to develop skills in epidemiology, surveillance, laboratory analysis, and other disease detection and prevention methods. Such programs shall be designed to enable health professionals and health personnel trained under such programs to work, after receiving such training, in local, State, national, and international efforts toward the prevention and control of diseases, injuries, and disabilities. Such fellowships and training may be administered through the use of either appointment or nonappointment procedures.

DIABETES IN CHILDREN AND YOUTH.

SEC. 317H.[247b–9] (a) SURVEILLANCE ON JUVENILE DIABETES.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall develop a sentinel system to collect data on juvenile diabetes, including with respect to incidence and prevalence, and shall establish a national database for such data.

(b) TYPE 2 DIABETES IN YOUTH.—The Secretary shall implement a national public health effort to address type 2 diabetes in youth, including—

(1) enhancing surveillance systems and expanding research to better assess the prevalence and incidence of type 2 diabetes in youth and determine the extent to which type 2 diabetes is incorrectly diagnosed as type 1 diabetes among children; and

(2) developing and improving laboratory methods to assist in diagnosis, treatment, and prevention of diabetes including, but not limited to, developing noninvasive ways to monitor blood glucose to prevent hypoglycemia and improving existing glucometers that measure blood glucose.

(c) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005.

COMPILATION OF DATA ON ASTHMA.

SEC. 317I.[247b–10] (a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall—

(1) conduct local asthma surveillance activities to collect data on the prevalence and severity of asthma and the quality of asthma management;

(2) compile and annually publish data on the prevalence of children suffering from asthma in each State; and

(3) to the extent practicable, compile and publish data on the childhood mortality rate associated with asthma nationally.

(b) SURVEILLANCE ACTIVITIES.—The Director of the Centers for Disease Control and Prevention, acting through the representative of the Director on the National Asthma Education Prevention Program Coordinating Committee, shall, in carrying out subsection (a), provide an update on surveillance activities at each Committee meeting.

(c) COLLABORATIVE EFFORTS.—The activities described in subsection (a)(1) may be conducted in collaboration with eligible entities awarded a grant under section 399L.

(d) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005.

EFFECTS OF FOLIC ACID IN PREVENTION OF BIRTH DEFECTS.

SEC. 317J.[247b–11] (a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall expand and intensify programs (directly or through grants or contracts) for the following purposes:

(1) To provide education and training for health professionals and the general public for purposes of explaining the effects of folic acid in preventing birth defects and for purposes of encouraging each woman of reproductive capacity (whether or not planning a pregnancy) to consume on a daily basis a dietary supplement that provides an appropriate level of folic acid.

(2) To conduct research with respect to such education and training, including identifying effective strategies for increasing the rate of consumption of folic acid by women of reproductive capacity.

(3) To conduct research to increase the understanding of the effects of folic acid in preventing birth defects, including understanding with respect to cleft lip, cleft palate, and heart defects.

(4) To provide for appropriate epidemiological activities regarding folic acid and birth defects, including epidemiological activities regarding neural tube defects.

(b) CONSULTATIONS WITH STATES AND PRIVATE ENTITIES.—In carrying out subsection (a), the Secretary shall consult with the States and with other appropriate public or private entities, including national nonprofit private organizations, health professionals, and providers of health insurance and health plans.

(c) TECHNICAL ASSISTANCE.—The Secretary may (directly or through grants or contracts) provide technical assistance to public and nonprofit private entities in carrying out the activities described in subsection (a).

(d) EVALUATIONS.—The Secretary shall (directly or through grants or contracts) provide for the evaluation of activities under subsection (a) in order to determine the extent to which such activities have been effective in carrying out the purposes of the program under such subsection, including the effects on various demographic populations. Methods of evaluation under the preceding sentence may include surveys of knowledge and attitudes on the consumption of folic acid and on blood folate levels. Such methods may include complete and timely monitoring of infants who are born with neural tube defects.

(e) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005.

SAFE MOTHERHOOD.

SEC. 317K.[247b–12] (a) SURVEILLANCE.—

(1) PURPOSE.—The purpose of this subsection is to develop surveillance systems at the local, State, and national level to better understand the burden of maternal complications and

mortality and to decrease the disparities among population at risk of death and complications from pregnancy.

(2) ACTIVITIES.—For the purpose described in paragraph (1), the Secretary, acting through the Director of the Centers for Disease Control and Prevention, may carry out the following activities:

(A) The Secretary may establish and implement a national surveillance program to identify and promote the investigation of deaths and severe complications that occur during pregnancy.

(B) The Secretary may expand the Pregnancy Risk Assessment Monitoring System to provide surveillance and collect data in each State.

(C) The Secretary may expand the Maternal and Child Health Epidemiology Program to provide technical support, financial assistance, or the time-limited assignment of senior epidemiologists to maternal and child health programs in each State.

(b) PREVENTION RESEARCH.—

(1) PURPOSE.—The purpose of this subsection is to provide the Secretary with the authority to further expand research concerning risk factors, prevention strategies, and the roles of the family, health care providers and the community in safe motherhood.

(2) RESEARCH.—The Secretary may carry out activities to expand research relating to—

(A) encouraging preconception counseling, especially for at risk populations such as diabetics;

(B) the identification of critical components of prenatal delivery and postpartum care;

(C) the identification of outreach and support services, such as folic acid education, that are available for pregnant women;

(D) the identification of women who are at high risk for complications;

(E) preventing preterm delivery;

(F) preventing urinary tract infections;

(G) preventing unnecessary caesarean sections;

(H) an examination of the higher rates of maternal mortality among African American women;

(I) an examination of the relationship between domestic violence and maternal complications and mortality;

(J) preventing and reducing adverse health consequences that may result from smoking, alcohol and illegal drug use before, during and after pregnancy;

(K) preventing infections that cause maternal and infant complications; and

(L) other areas determined appropriate by the Secretary.

(c) PREVENTION PROGRAMS.—

(1)[13] IN GENERAL.—The Secretary may carry out activities to promote safe motherhood, including—

(A) public education campaigns on healthy pregnancies and the building of partnerships with outside organizations concerned about safe motherhood;

(B) education programs for physicians, nurses and other health care providers; and

(C) activities to promote community support services for pregnant women.

(d) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005.

PRENATAL AND POSTNATAL HEALTH.

SEC. 317L.[247b–13] (a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall carry out programs—

(1) to collect, analyze, and make available data on prenatal smoking, alcohol and illegal drug use, including data on the implications of such activities and on the incidence and prevalence of such activities and their implications;

(2) to conduct applied epidemiological research on the prevention of prenatal and postnatal smoking, alcohol and illegal drug use;

(3) to support, conduct, and evaluate the effectiveness of educational and cessation programs; and

(4) to provide information and education to the public on the prevention and implications of prenatal and postnatal smoking, alcohol and illegal drug use.

(b) GRANTS.—In carrying out subsection (a), the Secretary may award grants to and enter into contracts with States, local governments, scientific and academic institutions, federally qualified health centers, and other public and nonprofit entities, and may provide technical and consultative assistance to such entities.

(c) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005.

ORAL HEALTH PROMOTION AND DISEASE PREVENTION.

SEC. 317M.[247b–14] (a) GRANTS TO INCREASE RESOURCES FOR COMMUNITY WATER FLUORIDATION.—

(1) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make grants to States and Indian tribes for the purpose of increasing the resources available for community water fluoridation.

(2) USE OF FUNDS.—A State shall use amounts provided under a grant under paragraph (1)—

[13] So in law. Subsection (c) does not contain a paragraph (2). See section 901 of Public Law 106–310 (114 Stat. 1126).

(A) to purchase fluoridation equipment;

(B) to train fluoridation engineers;

(C) to develop educational materials on the benefits of fluoridation; or

(D) to support the infrastructure necessary to monitor and maintain the quality of water fluoridation.

(b) COMMUNITY WATER FLUORIDATION.—

(1) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention and in collaboration with the Director of the Indian Health Service, shall establish a demonstration project that is designed to assist rural water systems in successfully implementing the water fluoridation guidelines of the Centers for Disease Control and Prevention that are entitled "Engineering and Administrative Recommendations for Water Fluoridation, 1995" (referred to in this subsection as the "EARWF").

(2) REQUIREMENTS.—

(A) COLLABORATION.—In collaborating under paragraph (1), the Directors referred to in such paragraph shall ensure that technical assistance and training are provided to tribal programs located in each of the 12 areas of the Indian Health Service. The Director of the Indian Health Service shall provide coordination and administrative support to tribes under this section.

(B) GENERAL USE OF FUNDS.—Amounts made available under paragraph (1) shall be used to assist small water systems in improving the effectiveness of water fluoridation and to meet the recommendations of the EARWF.

(C) FLUORIDATION SPECIALISTS.—

(i) IN GENERAL.—In carrying out this subsection, the Secretary shall provide for the establishment of fluoridation specialist engineering positions in each of the Dental Clinical and Preventive Support Centers through which technical assistance and training will be provided to tribal water operators, tribal utility operators and other Indian Health Service personnel working directly with fluoridation projects.

(ii) LIAISON.—A fluoridation specialist shall serve as the principal technical liaison between the Indian Health Service and the Centers for Disease Control and Prevention with respect to engineering and fluoridation issues.

(iii) CDC.—The Director of the Centers for Disease Control and Prevention shall appoint individuals to serve as the fluoridation specialists.

(D) IMPLEMENTATION.—The project established under this subsection shall be planned, implemented and evaluated over the 5-year period beginning on the date on which funds are appropriated under this section and shall be designed to serve as a model for improving the effectiveness of water fluoridation systems of small rural communities.

(3) EVALUATION.—In conducting the ongoing evaluation as provided for in paragraph (2)(D), the Secretary shall ensure that such evaluation includes—

(A) the measurement of changes in water fluoridation compliance levels resulting from assistance provided under this section;

(B) the identification of the administrative, technical and operational challenges that are unique to the fluoridation of small water systems;

(C) the development of a practical model that may be easily utilized by other tribal, State, county or local governments in improving the quality of water fluoridation with emphasis on small water systems; and

(D) the measurement of any increased percentage of Native Americans or Alaskan Natives who receive the benefits of optimally fluoridated water.

(c) SCHOOL-BASED DENTAL SEALANT PROGRAM.—

(1) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention and in collaboration with the Administrator of the Health Resources and Services Administration, shall award a grant to each of the 50 States and territories and to Indians, Indian tribes, tribal organizations and urban Indian organizations (as such terms are defined in section 4 of the Indian Health Care Improvement Act) to provide for the development of school-based dental sealant programs to improve the access of children to sealants.

(2) USE OF FUNDS.—A State shall use amounts received under a grant under paragraph (1) to provide funds to eligible school-based entities or to public elementary or secondary schools to enable such entities or schools to provide children with access to dental care and dental sealant services. Such services shall be provided by licensed dental health professionals in accordance with State practice licensing laws.

(3) ELIGIBILITY.—To be eligible to receive funds under paragraph (1), an entity shall—

(A) prepare and submit to the State an application at such time, in such manner and containing such information as the State may require; and

(B) be a public elementary or secondary school—

(i) that is located in an urban area in which and more than 50 percent of the student population is participating in Federal or State free or reduced meal programs; or

(ii) that is located in a rural area and, with respect to the school district in which the school is located, the district involved has a median income that is at or below 235 percent of the poverty line, as defined in section 673(2) of the Community Services Block Grant Act (42 U.S.C. 9902(2)).

(d) ORAL HEALTH INFRASTRUCTURE.—

(1) COOPERATIVE AGREEMENTS.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall enter into cooperative agreements with State, territorial, and Indian tribes or tribal organizations (as those terms are defined in section 4 of the Indian Health Care Improvement Act) to establish oral health leadership and pro-

gram guidance, oral health data collection and interpretation, (including determinants of poor oral health among vulnerable populations), a multi-dimensional delivery system for oral health, and to implement science-based programs (including dental sealants and community water fluoridation) to improve oral health.

(2) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated such sums as necessary to carry out this subsection for fiscal years 2010 through 2014.

(e) DEFINITIONS.—For purposes of this section, the term "Indian tribe" means an Indian tribe or tribal organization as defined in section 4(b) and section 4(c) of the Indian Self-Determination and Education Assistance Act.

(f) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005.

SURVEILLANCE AND EDUCATION REGARDING HEPATITIS C VIRUS.

SEC. 317N.[247b–15] (a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may (directly and through grants to public and nonprofit private entities) provide for programs to carry out the following:

(1) To cooperate with the States in implementing a national system to determine the incidence of hepatitis C virus infection (in this section referred to as "HCV infection") and to assist the States in determining the prevalence of such infection, including the reporting of chronic HCV cases.

(2) To identify, counsel, and offer testing to individuals who are at risk of HCV infection as a result of receiving blood transfusions prior to July 1992, or as a result of other risk factors.

(3) To provide appropriate referrals for counseling, testing, and medical treatment of individuals identified under paragraph (2) and to ensure, to the extent practicable, the provision of appropriate follow-up services.

(4) To develop and disseminate public information and education programs for the detection and control of HCV infection, with priority given to high risk populations as determined by the Secretary.

(5) To improve the education, training, and skills of health professionals in the detection and control of HCV infection, with priority given to pediatricians and other primary care physicians, and obstetricians and gynecologists.

(b) LABORATORY PROCEDURES.—The Secretary may (directly and through grants to public and nonprofit private entities) carry out programs to provide for improvements in the quality of clinical-laboratory procedures regarding hepatitis C, including reducing variability in laboratory results on hepatitis C antibody and PCR testing.

(c) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated

such sums as may be necessary for each of the fiscal years 2001 through 2005.

GRANTS FOR LEAD POISONING RELATED ACTIVITIES.

SEC. 317O.[247b–16] (a) AUTHORITY TO MAKE GRANTS.—

(1) IN GENERAL.—The Secretary shall make grants to States to support public health activities in States and localities where data suggests that at least 5 percent of preschool-age children have an elevated blood lead level through—

(A) effective, ongoing outreach and community education targeted to families most likely to be at risk for lead poisoning;

(B) individual family education activities that are designed to reduce ongoing exposures to lead for children with elevated blood lead levels, including through home visits and coordination with other programs designed to identify and treat children at risk for lead poisoning; and

(C) the development, coordination and implementation of community-based approaches for comprehensive lead poisoning prevention from surveillance to lead hazard control.

(2) STATE MATCH.—A State is not eligible for a grant under this section unless the State agrees to expend (through State or local funds) $1 for every $2 provided under the grant to carry out the activities described in paragraph (1).

(3) APPLICATION.—To be eligible to receive a grant under this section, a State shall submit an application to the Secretary in such form and manner and containing such information as the Secretary may require.

(b) COORDINATION WITH OTHER CHILDREN'S PROGRAMS.—A State shall identify in the application for a grant under this section how the State will coordinate operations and activities under the grant with—

(1) other programs operated in the State that serve children with elevated blood lead levels, including any such programs operated under title V, XIX, or XXI of the Social Security Act; and

(2) one or more of the following—

(A) the child welfare and foster care and adoption assistance programs under parts B and E of title IV of such Act;

(B) the head start program established under the Head Start Act (42 U.S.C. 9831 et seq.);

(C) the program of assistance under the special supplemental nutrition program for women, infants and children (WIC) under section 17 of the Child Nutrition Act of 1966 (42 U.S.C. 1786);

(D) local public and private elementary or secondary schools; or

(E) public housing agencies, as defined in section 3 of the United States Housing Act of 1937 (42 U.S.C. 1437a).

(c) PERFORMANCE MEASURES.—The Secretary shall establish needs indicators and performance measures to evaluate the activi-

ties carried out under grants awarded under this section. Such indicators shall be commensurate with national measures of maternal and child health programs and shall be developed in consultation with the Director of the Centers for Disease Control and Prevention.

(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section such sums as may be necessary for each of the fiscal years 2001 through 2005.

HUMAN PAPILLOMAVIRUS (JOHANNA'S LAW [14]).

SEC. 317P.[247b–17]

(1) IN GENERAL.—The Secretary, acting through the Centers for Disease Control and Prevention, shall—

(A) enter into cooperative agreements with States and other entities to conduct sentinel surveillance or other special studies that would determine the prevalence in various age groups and populations of specific types of human papillomavirus (referred to in this section as "HPV") in different sites in various regions of the United States, through collection of special specimens for HPV using a variety of laboratory-based testing and diagnostic tools; and

(B) develop and analyze data from the HPV sentinel surveillance system described in subparagraph (A).

(2) REPORT.—The Secretary shall make a progress report to the Congress with respect to paragraph (1) no later than 1 year after the effective date of this section.

(b) PREVENTION ACTIVITIES; EDUCATION PROGRAM.—

(1) IN GENERAL.—The Secretary, acting through the Centers for Disease Control and Prevention, shall conduct prevention research on HPV, including—

(A) behavioral and other research on the impact of HPV-related diagnosis on individuals;

(B) formative research to assist with the development of educational messages and information for the public, for patients, and for their partners about HPV;

(C) surveys of physician and public knowledge, attitudes, and practices about genital HPV infection; and

(D) upon the completion of and based on the findings under subparagraphs (A) through (C), develop and disseminate educational materials for the public and health care providers regarding HPV and its impact and prevention.

(2) REPORT; FINAL PROPOSAL.—The Secretary shall make a progress report to the Congress with respect to paragraph (1) not later than 1 year after the effective date of this section, and shall develop a final report not later than 3 years after such effective date, including a detailed summary of the significant findings and problems and the best strategies to prevent future infections, based on available science.

(c) HPV EDUCATION AND PREVENTION.—

[14] The typeface and casing of the parenthetical matter in the section heading appears in law with all letter cased in lowercase and in bold face type; however, it is reflect here as it should appear in light face and all small caps. (a) SURVEILLANCE.—

(1) IN GENERAL.—The Secretary shall prepare and distribute educational materials for health care providers and the public that include information on HPV. Such materials shall address—

(A) modes of transmission;

(B) consequences of infection, including the link between HPV and cervical cancer;

(C) the available scientific evidence on the effectiveness or lack of effectiveness of condoms in preventing infection with HPV; and

(D) the importance of regular Pap smears, and other diagnostics for early intervention and prevention of cervical cancer purposes in preventing cervical cancer.

(2) MEDICALLY ACCURATE INFORMATION.—Educational material under paragraph (1), and all other relevant educational and prevention materials prepared and printed from this date forward for the public and health care providers by the Secretary (including materials prepared through the Food and Drug Administration, the Centers for Disease Control and Prevention, and the Health Resources and Services Administration), or by contractors, grantees, or subgrantees thereof, that are specifically designed to address STDs including HPV shall contain medically accurate information regarding the effectiveness or lack of effectiveness of condoms in preventing the STD the materials are designed to address. Such requirement only applies to materials mass produced for the public and health care providers, and not to routine communications.

(d) JOHANNA'S LAW.—

(1) NATIONAL PUBLIC AWARENESS CAMPAIGN.—

(A) IN GENERAL.—The Secretary shall carry out a national campaign to increase the awareness and knowledge of health care providers and women with respect to gynecologic cancers.

(B) WRITTEN MATERIALS.—Activities under the national campaign under subparagraph (A) shall include—

(i) maintaining a supply of written materials that provide information to the public on gynecologic cancers; and

(ii) distributing the materials to members of the public upon request.

(C) PUBLIC SERVICE ANNOUNCEMENTS.—Activities under the national campaign under subparagraph (A) shall, in accordance with applicable law and regulations, include developing and placing, in telecommunications media, public service announcements intended to encourage women to discuss with their physicians their risks of gynecologic cancers. Such announcements shall inform the public on the manner in which the written materials referred to in subparagraph (B) can be obtained upon request, and shall call attention to early warning signs and risk factors based on the best available medical information.

(2) REPORT AND STRATEGY.—

(A) REPORT.—Not later than 6 months after the date of the enactment of this subsection, the Secretary shall submit to the Congress a report including the following:

(i) A description of the past and present activities of the Department of Health and Human Services to increase awareness and knowledge of the public with respect to different types of cancer, including gynecologic cancers.

(ii) A description of the past and present activities of the Department of Health and Human Services to increase awareness and knowledge of health care providers with respect to different types of cancer, including gynecologic cancers.

(iii) For each activity described pursuant to clause (i) or (ii), a description of the following:

(I) The funding for such activity for fiscal year 2006 and the cumulative funding for such activity for previous fiscal years.

(II) The background and history of such activity, including—

(aa) the goals of such activity;

(bb) the communications objectives of such activity;

(cc) the identity of each agency within the Department of Health and Human Services responsible for any aspect of the activity; and

(dd) how such activity is or was expected to result in change.

(III) How long the activity lasted or is expected to last.

(IV) The outcomes observed and the evaluation methods, if any, that have been, are being, or will be used with respect to such activity.

(V) For each such outcome or evaluation method, a description of the associated results, analyses, and conclusions.

(B) STRATEGY.—

(i) DEVELOPMENT; SUBMISSION TO CONGRESS.—Not later than 3 months after submitting the report required by subparagraph (A), the Secretary shall develop and submit to the Congress a strategy for improving efforts to increase awareness and knowledge of the public and health care providers with respect to different types of cancer, including gynecological cancers.

(ii) CONSULTATION.—In developing the strategy under clause (i), the Secretary should consult with qualified private sector groups, including nonprofit organizations.

(3) FULL COMPLIANCE.—

(A) IN GENERAL.—Not later than March 1, 2008, the Secretary shall ensure that all provisions of this section, including activities directed to be carried out by the Centers for Disease Control and Prevention and the Food and

Drug Administration, are fully implemented and being complied with. Not later than April 30, 2008, the Secretary shall submit to Congress a report that certifies compliance with the preceding sentence and that contains a description of all activities undertaken to achieve such compliance.

(B) If the Secretary fails to submit the certification as provided for under subparagraph (A), the Secretary shall, not later than 3 months after the date on which the report is to be submitted under subparagraph (A), and every 3 months thereafter, submit to Congress an explanation as to why the Secretary has not yet complied with the first sentence of subparagraph (A), a detailed description of all actions undertaken within the month for which the report is being submitted to bring the Secretary into compliance with such sentence, and the anticipated date the Secretary expects to be in full compliance with such sentence.

(4) CONSULTATION WITH NONPROFIT GYNECOLOGIC CANCER ORGANIZATIONS.—In carrying out the national campaign under this subsection, the Secretary shall consult with nonprofit gynecologic cancer organizations, with a mission both to conquer ovarian or other gynecologic cancer and to provide outreach to State and local governments and communities, for the purpose of determining the best practices for providing gynecologic cancer information and outreach services to varied populations.

(6)[15] AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this subsection, there is authorized to be appropriated $16,500,000 for the period of fiscal years 2007 through 2009 and $18,000,000 for the period of fiscal years 2012 through 2014.

SEC. 317Q.[247b–18] SURVEILLANCE AND RESEARCH REGARDING MUSCULAR DYSTROPHY.

(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may award grants and cooperative agreements to public or nonprofit private entities (including health departments of States and political subdivisions of States, and including universities and other educational entities) for the collection, analysis, and reporting of data on Duchenne and other forms of muscular dystrophy. In making such awards, the Secretary may provide direct technical assistance in lieu of cash.

(b) NATIONAL MUSCULAR DYSTROPHY EPIDEMIOLOGY PROGRAM.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may award grants to public or nonprofit private entities (including health departments of States and political subdivisions of States, and including universities and other educational entities) for the purpose of carrying out epidemiological activities regarding Duchenne and other forms of muscular dystrophies, including collecting and analyzing information on the number, incidence, correlates, and symptoms of cases. In carrying out the preceding sentence, the Secretary shall provide for a national surveillance program. In making awards under this sub-

[15] So in law. There is no paragraph (5).

section, the Secretary may provide direct technical assistance in lieu of cash.

(c) COORDINATION WITH CENTERS OF EXCELLENCE.—The Secretary shall ensure that epidemiological information under subsections (a) and (b) is made available to centers of excellence supported under section 404E(b) by the Director of the National Institutes of Health.

(d) DATA.—In carrying out this section, the Secretary may ensure that any data on patients that is collected as part of the Muscular Dystrophy STARnet (under a grant under this section) is regularly updated to reflect changes in patient condition over time.

(e) REPORTS AND STUDY.—

(1) ANNUAL REPORT.—Not later than 18 months after the date of the enactment of the Paul D. Wellstone Muscular Dystrophy Community Assistance, Research, and Education Amendments of 2008, and annually thereafter, the Director of the Centers for Disease Control and Prevention shall submit to the appropriate committees of the Congress a report—

(A) concerning the activities carried out by MD STARnet site [16] funded under this section during the year for which the report is prepared;

(B) containing the data collected and findings derived from the MD STARnet sites each fiscal year (as funded under a grant under this section during fiscal years 2008 through 2012); and

(C) that every 2 years outlines prospective data collection objectives and strategies.

(2) TRACKING HEALTH OUTCOMES.—The Secretary may provide health outcome data on the health and survival of people with muscular dystrophy.

(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary to carry out this section.

SEC. 317R.[247b–20] FOOD SAFETY GRANTS.

(a) IN GENERAL.—The Secretary may award grants to States and Indian tribes (as defined in section 4(e) of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450b(e))) to expand participation in networks to enhance Federal, State, and local food safety efforts, including meeting the costs of establishing and maintaining the food safety surveillance, technical, and laboratory capacity needed for such participation.

(b) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $19,500,000 for fiscal year 2010, and such sums as may be necessary for each of the fiscal years 2011 through 2015.

SEC. 317S.[247b–21] MOSQUITO-BORNE DISEASES; COORDINATION GRANTS TO STATES; ASSESSMENT AND CONTROL GRANTS TO POLITICAL SUBDIVISIONS.

(a) COORDINATION GRANTS TO STATES; ASSESSMENT GRANTS TO POLITICAL SUBDIVISIONS.—

(1) IN GENERAL.—With respect to mosquito control programs to prevent and control mosquito-borne diseases (referred

[16] So in law. The term "site" probably should be "sites".

to in this section as "control programs"), the Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make grants to States for the purpose of—

(A) coordinating control programs in the State involved; and

(B) assisting such State in making grants to political subdivisions of the State to conduct assessments to determine the immediate needs in such subdivisions for control programs, and to develop, on the basis of such assessments, plans for carrying out control programs in the subdivisions.

(2) PREFERENCE IN MAKING GRANTS.—In making grants under paragraph (1), the Secretary shall give preference to States that have one or more political subdivisions with an incidence, prevalence, or high risk of mosquito-borne disease, or a population of infected mosquitoes, that is substantial relative to political subdivisions in other States.

(3) CERTAIN REQUIREMENTS.—A grant may be made under paragraph (1) only if—

(A) the State involved has developed, or agrees to develop, a plan for coordinating control programs in the State, and the plan takes into account any assessments or plans described in subsection (b)(3) that have been conducted or developed, respectively, by political subdivisions in the State;

(B) in developing such plan, the State consulted or will consult (as the case may be under subparagraph (A)) with political subdivisions in the State that are carrying out or planning to carry out control programs;

(C) the State agrees to monitor control programs in the State in order to ensure that the programs are carried out in accordance with such plan, with priority given to coordination of control programs in political subdivisions described in paragraph (2) that are contiguous;

(D) the State agrees that the State will make grants to political subdivisions as described in paragraph (1)(B), and that such a grant will not exceed $10,000; and

(E) the State agrees that the grant will be used to supplement, and not supplant, State and local funds available for the purpose described in paragraph (1).

(4) REPORTS TO SECRETARY.—A grant may be made under paragraph (1) only if the State involved agrees that, promptly after the end of the fiscal year for which the grant is made, the State will submit to the Secretary a report that—

(A) describes the activities of the State under the grant; and

(B) contains an evaluation of whether the control programs of political subdivisions in the State were effectively coordinated with each other, which evaluation takes into account any reports that the State received under subsection (b)(5) from such subdivisions.

(5) NUMBER OF GRANTS.—A State may not receive more than one grant under paragraph (1).

(b) PREVENTION AND CONTROL GRANTS TO POLITICAL SUBDIVISIONS.—

(1) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make grants to political subdivisions of States or consortia of political subdivisions of States, for the operation of control programs.

(2) PREFERENCE IN MAKING GRANTS.—In making grants under paragraph (1), the Secretary shall give preference to a political subdivision or consortium of political subdivisions that—

(A) has—

(i) a history of elevated incidence or prevalence of mosquito-borne disease;

(ii) a population of infected mosquitoes; or

(iii) met criteria determined by the Secretary to suggest an increased risk of elevated incidence or prevalence of mosquito-borne disease in the pending fiscal year;

(B) demonstrates to the Secretary that such political subdivision or consortium of political subdivisions will, if appropriate to the mosquito circumstances involved, effectively coordinate the activities of the control programs with contiguous political subdivisions;

(C) demonstrates to the Secretary (directly or through State officials) that the State in which such a political subdivision or consortium of political subdivisions is located has identified or will identify geographic areas in such State that have a significant need for control programs and will effectively coordinate such programs in such areas; and

(D) is located in a State that has received a grant under subsection (a).

(3) REQUIREMENT OF ASSESSMENT AND PLAN.—A grant may be made under paragraph (1) only if the political subdivision or consortium of political subdivisions involved—

(A) has conducted an assessment to determine the immediate needs in such subdivision or consortium for a control program, including an entomological survey of potential mosquito breeding areas; and

(B) has, on the basis of such assessment, developed a plan for carrying out such a program.

(4) REQUIREMENT OF MATCHING FUNDS.—

(A) IN GENERAL.—With respect to the costs of a control program to be carried out under paragraph (1) by a political subdivision or consortium of political subdivisions, a grant under such paragraph may be made only if the subdivision or consortium agrees to make available (directly or through donations from public or private entities) non-Federal contributions toward such costs in an amount that is not less than ⅓ of such costs ($1 for each $2 of Federal funds provided in the grant).

(B) DETERMINATION OF AMOUNT CONTRIBUTED.—Non-Federal contributions required in subparagraph (A) may be

in cash or in kind, fairly evaluated, including plant, equipment, or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

(C) WAIVER.—The Secretary may waive the requirement established in subparagraph (A) if the Secretary determines that extraordinary economic conditions in the political subdivision or consortium of political subdivisions involved justify the waiver.

(5) REPORTS TO SECRETARY.—A grant may be made under paragraph (1) only if the political subdivision or consortium of political subdivisions involved agrees that, promptly after the end of the fiscal year for which the grant is made, the subdivision or consortium will submit to the Secretary, and to the State within which the subdivision or consortium is located, a report that describes the control program and contains an evaluation of whether the program was effective.

(6) AMOUNT OF GRANT; NUMBER OF GRANTS.—

(A) AMOUNT OF GRANT.—

(i) SINGLE POLITICAL SUBDIVISION.—A grant under paragraph (1) awarded to a political subdivision for a fiscal year may not exceed $100,000.

(ii) CONSORTIUM.—A grant under paragraph (1) awarded to a consortium of 2 or more political subdivisions may not exceed $110,000 for each political subdivision. A consortium is not required to provide matching funds under paragraph (4) for any amounts received by such consortium in excess of amounts each political subdivision would have received separately.

(iii) WAIVER OF REQUIREMENT.—A grant may exceed the maximum amount in clause (i) or (ii) if the Secretary determines that the geographical area covered by a political subdivision or consortium awarded a grant under paragraph (1) has an extreme need due to the size or density of—

(I) the human population in such geographical area; or

(II) the mosquito population in such geographical area.

(B) NUMBER OF GRANTS.—A political subdivision or a consortium of political subdivisions may not receive more than one grant under paragraph (1).

(c) APPLICATIONS FOR GRANTS.—A grant may be made under subsection (a) or (b) only if an application for the grant is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(d) TECHNICAL ASSISTANCE.—Amounts appropriated under subsection (f) may be used by the Secretary to provide training and technical assistance with respect to the planning, development, and operation of assessments and plans under subsection (a) and con-

trol programs under subsection (b). The Secretary may provide such technical assistance directly or through awards of grants or contracts to public and private entities.

(e) DEFINITION OF POLITICAL SUBDIVISION.—In this section, the term "political subdivision" means the local political jurisdiction immediately below the level of State government, including counties, parishes, and boroughs. If State law recognizes an entity of general government that functions in lieu of, and is not within, a county, parish, or borough, the Secretary may recognize an area under the jurisdiction of such other entities of general government as a political subdivision for purposes of this section.

(f) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—For the purpose of carrying out this section, there are authorized to be appropriated $100,000,000 for fiscal year 2003, and such sums as may be necessary for each of fiscal years 2004 through 2007.

(2) PUBLIC HEALTH EMERGENCIES.—In the case of control programs carried out in response to a mosquito-borne disease that constitutes a public health emergency, the authorization of appropriations under paragraph (1) is in addition to applicable authorizations of appropriations under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

(3) FISCAL YEAR 2004 APPROPRIATIONS.—For fiscal year 2004, 50 percent or more of the funds appropriated under paragraph (1) shall be used to award grants to political subdivisions or consortia of political subdivisions under subsection (b).

SEC. 317T.[247b–22] MICROBICIDE RESEARCH.

(a) IN GENERAL.—The Director of the Centers for Disease Control and Prevention is strongly encouraged to fully implement the Centers' microbicide agenda to support research and development of microbicides for use to prevent the transmission of the human immunodeficiency virus.

(b) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary for each of fiscal years 2009 through 2013 to carry out this section.

PROJECTS AND PROGRAMS FOR THE PREVENTION AND CONTROL OF SEXUALLY TRANSMITTED DISEASES [17].

SEC. 318.[247c] (a) The Secretary may provide technical assistance to appropriate public and non-profit private entities and to scientific institutions for their research in, and training and public health programs for the prevention and control of sexually transmitted diseases.

[17] Title II of Public Law 103–333, an appropriations Act, provides (under the heading relating to the Centers for Disease Control and Prevention; see 108 Stat. 2550) in part as follows: "That funds appropriated under this heading for fiscal year 1995 and subsequent fiscal years shall be available for payment of the costs of medical care, related expenses, and burial expenses hereafter incurred by or on behalf of any person who had participated in the study of untreated syphilis initiated in Tuskegee, Alabama, in 1932, in such amounts and subject to such terms and conditions as prescribed by the Secretary of Health and Human Services and for payment, in such amounts and subject to such terms and conditions, of such costs and expenses hereafter incurred by or on behalf of such person's wife or offspring determined by the Secretary to have suffered injury or disease from syphilis contracted from such person".

(b) The Secretary may make grants to States, political subdivisions of States, and any other public and nonprofit private entity for—

(1) research into the prevention and control of sexually transmitted diseases;

(2) demonstration projects for the prevention and control of sexually transmitted diseases;

(3) public information and education programs for the prevention and control of such diseases; and

(4) education, training, and clinical skills improvement activities in the prevention and control of such diseases for health professionals (including allied health personnel).

(c) The Secretary is also authorized to make project grants to States and, in consultation with the State health authority, to political subdivisions of States, for—

(1) sexually transmitted diseases surveillance activities, including the reporting, screening, and followup of diagnostic tests for, and diagnosed cases of, sexually transmitted diseases;

(2) casefinding and case followup activities respecting sexually transmitted diseases, including contact tracing of infectious cases of sexually transmitted diseases and routine testing, including laboratory tests and followup systems;

(3) interstate epidemiologic referral and followup activities respecting sexually transmitted diseases; and

(4) such special studies or demonstrations to evaluate or test sexually transmitted diseases prevention and control strategies and activities as may be prescribed by the Secretary.

(d) The Secretary may make grants to States and political subdivisions of States for the development, implementation, and evaluation of innovative, interdisciplinary approaches to the prevention and control of sexually transmitted diseases.

(e)(1) For the purpose of making grants under subsections (b) through (d), there are authorized to be appropriated $85,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 through 1998.

(2) Each recipient of a grant under this section shall keep such records as the Secretary shall prescribe including records which fully disclose the amount and disposition by such recipient of the proceeds of such grant, the total cost of the project or undertaking in connection with which such grant was given or used and the amount of that portion of the cost of the project or undertaking supplied by other sources, and such other records as will facilitate an effective audit.

(3) The Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of the recipients of grants under this section that are pertinent to such grants.

(4) The Secretary, at the request of a recipient of a grant under this section, may reduce such grant by the fair market value of any supplies or equipment furnished to such recipient and by the amount of pay, allowances, travel expenses, and any other costs in connection with the detail of an officer or employee of the United States to the recipient when the furnishing of such supplies or

equipment or the detail of such an officer or employee is for the convenience of and at the request of such recipient and for the purpose of carrying out the program with respect to which the grant under this section is made. The amount by which any such grant is so reduced shall be available for payment by the Secretary of the costs incurred in furnishing the supplies, equipment, or personal services on which the reduction of such grant is based.

(5) All information obtained in connection with the examination, care, or treatment of any individual under any program which is being carried out with a grant made under this section shall not, without such individual's consent, be disclosed except as may be necessary to provide service to him or as may be required by a law of a State or political subdivision of a State. Information derived from any such program may be disclosed—

(A) in summary, statistical, or other form; or

(B) for clinical or research purposes;

but only if the identity of the individuals diagnosed or provided care or treatment under such program is not disclosed.

(f) Nothing in this section shall be construed to require any State or any political subdivision of a State to have a sexually transmitted diseases program which would require any person, who objects to any treatment provided under such a program, to be treated under such a program.

INFERTILITY AND SEXUALLY TRANSMITTED DISEASES.

SEC. 318A.[247c–1] (a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make grants to States, political subdivisions of States, and other public or nonprofit private entities for the purpose of carrying out the activities described in subsection (c) regarding any treatable sexually transmitted disease that can cause infertility in women if treatment is not received for the disease.

(b) AUTHORITY REGARDING INDIVIDUAL DISEASES.—With respect to diseases described in subsection (a), the Secretary shall, in making a grant under such subsection, specify the particular disease or diseases with respect to which the grant is to be made. The Secretary may not make the grant unless the applicant involved agrees to carry out this section only with respect to the disease or diseases so specified.

(c) AUTHORIZED ACTIVITIES.—With respect to any sexually transmitted disease described in subsection (a), the activities referred to in such subsection are—

(1) screening women for the disease and for secondary conditions resulting from the disease, subject to compliance with criteria issued under subsection (f);

(2) providing treatment to women for the disease;

(3) providing counseling to women on the prevention and control of the disease (including, in the case of a woman with the disease, counseling on the benefits of locating and providing such counseling to any individual from whom the woman may have contracted the disease and any individual whom the woman may have exposed to the disease);

(4) providing follow-up services;

(5) referrals for necessary medical services for women screened pursuant to paragraph (1), including referrals for evaluation and treatment with respect to acquired immune deficiency syndrome and other sexually transmitted diseases;

(6) in the case of any woman receiving services pursuant to any of paragraphs (1) through (5), providing to the partner of the woman the services described in such paragraphs, as appropriate;

(7) providing outreach services to inform women of the availability of the services described in paragraphs (1) through (6);

(8) providing to the public information and education on the prevention and control of the disease, including disseminating such information; and

(9) providing training to health care providers in carrying out the screenings and counseling described in paragraphs (1) and (3).

(d) REQUIREMENT OF AVAILABILITY OF ALL SERVICES THROUGH EACH GRANTEE.—The Secretary may make a grant under subsection (a) only if the applicant involved agrees that each activity authorized in subsection (c) will be available through the applicant. With respect to compliance with such agreement, the applicant may expend the grant to carry out any of the activities directly, and may expend the grant to enter into agreements with other public or nonprofit private entities under which the entities carry out the activities.

(e) REQUIRED PROVIDERS REGARDING CERTAIN SERVICES.—The Secretary may make a grant under subsection (a) only if the applicant involved agrees that, in expending the grant to carry out activities authorized in subsection (c), the services described in paragraphs (1) through (7) of such subsection will be provided only through entities that are State or local health departments, grantees under section 329, 330, 340A, or 1001, or are other public or nonprofit private entities that provide health services to a significant number of low-income women.

(f) QUALITY ASSURANCE REGARDING SCREENING FOR DISEASES.—For purposes of this section, the Secretary shall establish criteria for ensuring the quality of screening procedures for diseases described in subsection (a).

(g) CONFIDENTIALITY.—The Secretary may make a grant under subsection (a) only if the applicant involved agrees, subject to applicable law, to maintain the confidentiality of information on individuals with respect to activities carried out under subsection (c).

(h) LIMITATION ON IMPOSITION OF FEES FOR SERVICES.—The Secretary may make a grant under subsection (a) only if the applicant involved agrees that, if a charge is imposed for the provision of services or activities under the grant, such charge—

(1) will be made according to a schedule of charges that is made available to the public;

(2) will be adjusted to reflect the income of the individual involved; and

(3) will not be imposed on any individual with an income of less than 150 percent of the official poverty line, as established by the Director of the Office of Management and Budget

and revised by the Secretary in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1981.

(i) LIMITATIONS ON CERTAIN EXPENDITURES.—The Secretary may make a grant under subsection (a) only if the applicant involved agrees that not less than 80 percent of the grant will be expended for the purpose of carrying out paragraphs (1) through (7) of subsection (c).

(j) REPORTS TO SECRETARY.—

(1) COLLECTION OF DATA.—The Secretary may make a grant under subsection (a) only if the applicant involved agrees, with respect to any disease selected under subsection (b) for the applicant, to submit to the Secretary, for each fiscal year for which the applicant receives such a grant, a report providing—

(A) the incidence of the disease among the population of individuals served by the applicant;

(B) the number and demographic characteristics of individuals in such population;

(C) the types of interventions and treatments provided by the applicant, and the health conditions with respect to which referrals have been made pursuant to subsection (c)(5);

(D) an assessment of the extent to which the activities carried pursuant to subsection (a) have reduced the incidence of infertility in the geographic area involved; and

(E) such other information as the Secretary may require with respect to the project carried out with the grant.

(2) UTILITY AND COMPARABILITY OF DATA.—The Secretary shall carry out activities for the purpose of ensuring the utility and comparability of data collected pursuant to paragraph (1).

(k) MAINTENANCE OF EFFORT.—With respect to activities for which a grant under subsection (a) is authorized to be expended, the Secretary may make such a grant only if the applicant involved agrees to maintain expenditures of non-Federal amounts for such activities at a level that is not less than the average level of such expenditures maintained by the applicant for the 2-year period preceding the fiscal year for which the applicant is applying to receive such a grant.

(l) REQUIREMENT OF APPLICATION.—

(1) IN GENERAL.—The Secretary may make a grant under subsection (a) only if an application for the grant is submitted to the Secretary, the application contains the plan required in paragraph (2), and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(2) SUBMISSION OF PLAN FOR PROGRAM OF GRANTEE.—

(A) IN GENERAL.—The Secretary may make a grant under subsection (a) only if the applicant involved submits to the Secretary a plan describing the manner in which the applicant will comply with the agreements required as a condition of receiving such a grant, including a specifica-

tion of the entities through which activities authorized in subsection (c) will be provided.

(B) PARTICIPATION OF CERTAIN ENTITIES.—The Secretary may make a grant under subsection (a) only if the applicant provides assurances satisfactory to the Secretary that the plan submitted under subparagraph (A) has been prepared in consultation with an appropriate number and variety of—

(i) representatives of entities in the geographic area involved that provide services for the prevention and control of sexually transmitted diseases, including programs to provide to the public information and education regarding such diseases; and

(ii) representatives of entities in such area that provide family planning services.

(m) DURATION OF GRANT.—The period during which payments are made to an entity from a grant under subsection (a) may not exceed 3 years. The provision of such payments shall be subject to annual approval by the Secretary of the payments and subject to the availability of appropriations for the fiscal year involved to make the payments in such year. The preceding sentence may not be construed to establish a limitation on the number of grants under such subsection that may be made to an entity.

(n) TECHNICAL ASSISTANCE, AND SUPPLIES AND SERVICES IN LIEU OF GRANT FUNDS.—

(1) TECHNICAL ASSISTANCE.—The Secretary may provide training and technical assistance to grantees under subsection (a) with respect to the planning, development, and operation of any program or service carried out under such subsection. The Secretary may provide such technical assistance directly or through grants or contracts.

(2) SUPPLIES, EQUIPMENT, AND EMPLOYEE DETAIL.—The Secretary, at the request of a recipient of a grant under subsection (a), may reduce the amount of such grant by—

(A) the fair market value of any supplies or equipment furnished the grant recipient; and

(B) the amount of the pay, allowances, and travel expenses of any officer or employee of the Government when detailed to the grant recipient and the amount of any other costs incurred in connection with the detail of such officer or employee;

when the furnishing of such supplies or equipment or the detail of such an officer or employee is for the convenience of and at the request of such grant recipient and for the purpose of carrying out a program with respect to which the grant under subsection (a) is made. The amount by which any such grant is so reduced shall be available for payment by the Secretary of the costs incurred in furnishing the supplies or equipment, or in detailing the personnel, on which the reduction of such grant is based, and such amount shall be deemed as part of the grant and shall be deemed to have been paid to the grant recipient.

(o) EVALUATIONS AND REPORTS BY SECRETARY.—

(1) EVALUATIONS.—The Secretary shall, directly or through contracts with public or private entities, provide for annual evaluations of programs carried out pursuant to subsection (a) in order to determine the quality and effectiveness of the programs.

(2) REPORT TO CONGRESS.—Not later than 1 year after the date on which amounts are first appropriated pursuant to subsection (q), and biennially thereafter, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report—

(A) summarizing the information provided to the Secretary in reports made pursuant to subsection (j)(1), including information on the incidence of sexually transmitted diseases described in subsection (a); and

(B) summarizing evaluations carried out pursuant to paragraph (1) during the preceding fiscal year.

(p) COORDINATION OF FEDERAL PROGRAMS.—The Secretary shall coordinate the program carried out under this section with any similar programs administered by the Secretary (including coordination between the Director of the Centers for Disease Control and Prevention and the Director of the National Institutes of Health).

(q) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, other than subsections (o) and (r), there are authorized to be appropriated $25,000,000 for fiscal year 1993, and such sums as may be necessary for each of the fiscal years 1994 through 1998.

(r) SEPARATE GRANTS FOR RESEARCH ON DELIVERY OF SERVICES.—

(1) IN GENERAL.—The Secretary may make grants for the purpose of conducting research on the manner in which the delivery of services under subsection (a) may be improved. The Secretary may make such grants only to grantees under such subsection and to public and nonprofit private entities that are carrying out programs substantially similar to programs carried out under such subsection.

(2) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out paragraph (1), there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1993 through 1998.

DATA COLLECTION REGARDING PROGRAMS UNDER TITLE XXVI.

SEC. 318B.[247c–2] For the purpose of collecting and providing data for program planning and evaluation activities under title XXVI, there are authorized to be appropriated to the Secretary (acting through the Director of the Centers for Disease Control and Prevention) such sums as may be necessary for each of the fiscal years 2001 through 2005. Such authorization of appropriations is in addition to other authorizations of appropriations that are available for such purpose.

SEC. 319.[247d] PUBLIC HEALTH EMERGENCIES.

(a) EMERGENCIES.—If the Secretary determines, after consultation with such public health officials as may be necessary, that—

(1) a disease or disorder presents a public health emergency; or

(2) a public health emergency, including significant outbreaks of infectious diseases or bioterrorist attacks, otherwise exists,

the Secretary may take such action as may be appropriate to respond to the public health emergency, including making grants, providing awards for expenses, and entering into contracts and conducting and supporting investigations into the cause, treatment, or prevention of a disease or disorder as described in paragraphs (1) and (2). Any such determination of a public health emergency terminates upon the Secretary declaring that the emergency no longer exists, or upon the expiration of the 90-day period beginning on the date on which the determination is made by the Secretary, whichever occurs first. Determinations that terminate under the preceding sentence may be renewed by the Secretary (on the basis of the same or additional facts), and the preceding sentence applies to each such renewal. Not later than 48 hours after making a determination under this subsection of a public health emergency (including a renewal), the Secretary shall submit to the Congress written notification of the determination.

(b) PUBLIC HEALTH EMERGENCY FUND.—

(1) IN GENERAL.—There is established in the Treasury a fund to be designated as the "Public Health Emergency Fund" to be made available to the Secretary without fiscal year limitation to carry out subsection (a) only if a public health emergency has been declared by the Secretary under such subsection. There is authorized to be appropriated to the Fund such sums as may be necessary.

(2) REPORT.—Not later than 90 days after the end of each fiscal year, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Commerce and the Committee on Appropriations of the House of Representatives a report describing—

(A) the expenditures made from the Public Health Emergency Fund in such fiscal year; and

(B) each public health emergency for which the expenditures were made and the activities undertaken with respect to each emergency which was conducted or supported by expenditures from the Fund.

(c) SUPPLEMENT NOT SUPPLANT.—Funds appropriated under this section shall be used to supplement and not supplant other Federal, State, and local public funds provided for activities under this section.

(d) DATA SUBMITTAL AND REPORTING DEADLINES.—In any case in which the Secretary determines that, wholly or partially as a result of a public health emergency that has been determined pursuant to subsection (a), individuals or public or private entities are unable to comply with deadlines for the submission to the Secretary of data or reports required under any law administered by

the Secretary, the Secretary may, notwithstanding any other provision of law, grant such extensions of such deadlines as the circumstances reasonably require, and may waive, wholly or partially, any sanctions otherwise applicable to such failure to comply. Before or promptly after granting such an extension or waiver, the Secretary shall notify the Congress of such action and publish in the Federal Register a notice of the extension or waiver.

(e) TEMPORARY REASSIGNMENT OF STATE AND LOCAL PERSONNEL DURING A PUBLIC HEALTH EMERGENCY.—

(1) EMERGENCY REASSIGNMENT OF FEDERALLY FUNDED PERSONNEL.—Notwithstanding any other provision of law, and subject to paragraph (2), upon request by the Governor of a State or a tribal organization or such Governor or tribal organization's designee, the Secretary may authorize the requesting State or Indian tribe to temporarily reassign, for purposes of immediately addressing a public health emergency in the State or Indian tribe, State and local public health department or agency personnel funded in whole or in part through programs authorized under this Act, as appropriate.

(2) ACTIVATION OF EMERGENCY REASSIGNMENT.—

(A) PUBLIC HEALTH EMERGENCY.—The Secretary may authorize a temporary reassignment of personnel under paragraph (1) only during the period of a public health emergency determined pursuant to subsection (a).

(B) CONTENTS OF REQUEST.—To seek authority for a temporary reassignment of personnel under paragraph (1), the Governor of a State or a tribal organization shall submit to the Secretary a request for such reassignment flexibility and shall include in the request each of the following:

(i) An assurance that the public health emergency in the geographic area of the requesting State or Indian tribe cannot be adequately and appropriately addressed by the public health workforce otherwise available.

(ii) An assurance that the public health emergency would be addressed more efficiently and effectively through the requested temporary reassignment of State and local personnel described in paragraph (1).

(iii) An assurance that the requested temporary reassignment of personnel is consistent with any applicable All-Hazards Public Health Emergency Preparedness and Response Plan under section 319C–1.

(iv) An identification of—

(I) each Federal program from which personnel would be temporarily reassigned pursuant to the requested authority; and

(II) the number of personnel who would be so reassigned from each such program.

(v) Such other information and assurances upon which the Secretary and Governor of a State or tribal organization agree.

(C) CONSIDERATION.—In reviewing a request for temporary reassignment under paragraph (1), the Secretary

shall consider the degree to which the program or programs funded in whole or in part by programs authorized under this Act would be adversely affected by the reassignment.

(D) TERMINATION AND EXTENSION.—

(i) TERMINATION.—A State or Indian tribe's temporary reassignment of personnel under paragraph (1) shall terminate upon the earlier of the following:

(I) The Secretary's determination that the public health emergency no longer exists.

(II) Subject to clause (ii), the expiration of the 30-day period following the date on which the Secretary approved the State or Indian tribe's request for such reassignment flexibility.

(ii) EXTENSION OF REASSIGNMENT FLEXIBILITY.—The Secretary may extend reassignment flexibility of personnel under paragraph (1) beyond the date otherwise applicable under clause (i)(II) if the public health emergency still exists as of such date, but only if—

(I) the State or Indian tribe that submitted the initial request for a temporary reassignment of personnel submits a request for an extension of such temporary reassignment; and

(II) the request for an extension contains the same information and assurances necessary for the approval of an initial request for such temporary reassignment pursuant to subparagraph (B).

(3) VOLUNTARY NATURE OF TEMPORARY REASSIGNMENT OF STATE AND LOCAL PERSONNEL.—

(A) IN GENERAL.—Unless otherwise provided under the law or regulation of the State or Indian tribe that receives authorization for temporary reassignment of personnel under paragraph (1), personnel eligible for reassignment pursuant to such authorization—

(i) shall have the opportunity to volunteer for temporary reassignment; and

(ii) shall not be required to agree to a temporary reassignment.

(B) PROHIBITION ON CONDITIONING FEDERAL AWARDS.—The Secretary may not condition the award of a grant, contract, or cooperative agreement under this Act on the requirement that a State or Indian tribe require that personnel eligible for reassignment pursuant to an authorization under paragraph (1) agree to such reassignment.

(4) NOTICE TO CONGRESS.—The Secretary shall give notice to the Congress in conjunction with the approval under this subsection of—

(A) any initial request for temporary reassignment of personnel; and

(B) any request for an extension of such temporary reassignment.

(5) GUIDANCE.—The Secretary shall—

(A) not later than 6 months after the enactment of this subsection, issue proposed guidance on the temporary reassignment of personnel under this subsection; and

(B) after providing notice and a 60-day period for public comment, finalize such guidance.

(6) REPORT TO CONGRESS.—Not later than 4 years after the date of enactment of the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013, the Comptroller General of the United States shall conduct an independent evaluation, and submit to the appropriate committees of the Congress a report, on temporary reassignment under this subsection, including—

(A) a description of how, and under what circumstances, such temporary reassignment has been used by States and Indian tribes;

(B) an analysis of how such temporary reassignment has assisted States and Indian tribes in responding to public health emergencies;

(C) an evaluation of how such temporary reassignment has improved operational efficiencies in responding to public health emergencies;

(D) an analysis of the extent to which, if any, Federal programs from which personnel have been temporarily reassigned have been adversely affected by the reassignment; and

(E) recommendations on how medical surge capacity could be improved in responding to public health emergencies and the impact of the reassignment flexibility under this section on such surge capacity.

(7) DEFINITIONS.—In this subsection—

(A) the terms "Indian tribe" and "tribal organization" have the meanings given such terms in section 4 of the Indian Self-Determination and Education Assistance Act; and

(B) the term "State" includes, in addition to the entities listed in the definition of such term in section 2, the Freely Associated States.

(8) SUNSET.—This subsection shall terminate on September 30, 2018.

SEC. 319A.[247d–1] VACCINE TRACKING AND DISTRIBUTION.

(a) TRACKING.—The Secretary, together with relevant manufacturers, wholesalers, and distributors as may agree to cooperate, may track the initial distribution of federally purchased influenza vaccine in an influenza pandemic. Such tracking information shall be used to inform Federal, State, local, and tribal decision makers during an influenza pandemic.

(b) DISTRIBUTION.—The Secretary shall promote communication between State, local, and tribal public health officials and such manufacturers, wholesalers, and distributors as agree to participate, regarding the effective distribution of seasonal influenza vaccine. Such communication shall include estimates of high priority populations, as determined by the Secretary, in State, local, and tribal jurisdictions in order to inform Federal, State, local, and trib-

al decision makers during vaccine shortages and supply disruptions.

(c) CONFIDENTIALITY.—The information submitted to the Secretary or its contractors, if any, under this section or under any other section of this Act related to vaccine distribution information shall remain confidential in accordance with the exception from the public disclosure of trade secrets, commercial or financial information, and information obtained from an individual that is privileged and confidential, as provided for in section 552(b)(4) of title 5, United States Code, and subject to the penalties and exceptions under sections 1832 and 1833 of title 18, United States Code, relating to the protection and theft of trade secrets, and subject to privacy protections that are consistent with the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996. None of such information provided by a manufacturer, wholesaler, or distributor shall be disclosed without its consent to another manufacturer, wholesaler, or distributor, or shall be used in any manner to give a manufacturer, wholesaler, or distributor a proprietary advantage.

(d) GUIDELINES.—The Secretary, in order to maintain the confidentiality of relevant information and ensure that none of the information contained in the systems involved may be used to provide proprietary advantage within the vaccine market, while allowing State, local, and tribal health officials access to such information to maximize the delivery and availability of vaccines to high priority populations, during times of influenza pandemics, vaccine shortages, and supply disruptions, in consultation with manufacturers, distributors, wholesalers and State, local, and tribal health departments, shall develop guidelines for subsections (a) and (b).

(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, $30,800,000 for each of fiscal years 2014 through 2018.

(f) REPORT TO CONGRESS.—As part of the National Health Security Strategy described in section 2802, the Secretary shall provide an update on the implementation of subsections (a) through (d).

SEC. 319C–1.[247d–3a] IMPROVING STATE AND LOCAL PUBLIC HEALTH SECURITY.[18].

(a) IN GENERAL.—To enhance the security of the United States with respect to public health emergencies, the Secretary shall award cooperative agreements to eligible entities to enable such entities to conduct the activities described in subsection (d).

(b) ELIGIBLE ENTITIES.—To be eligible to receive an award under subsection (a), an entity shall—

(1)(A) be a State;

(B) be a political subdivision determined by the Secretary to be eligible for an award under this section (based on criteria described in subsection (h)(4)); or

(C) be a consortium of States; and

[18] Former sections 319B and 319C were repealed by section 204(b)(1) of Public Law 109–417 (120 Stat. 2951).

(2) prepare and submit to the Secretary an application at such time, and in such manner, and containing such information as the Secretary may require, including—

(A) an All-Hazards Public Health Emergency Preparedness and Response Plan which shall include—

(i) a description of the activities such entity will carry out under the agreement to meet the goals identified under section 2802, including with respect to chemical, biological, radiological, or nuclear threats, whether naturally occurring, unintentional, or deliberate;

(ii) a description of the activities such entity will carry out with respect to pandemic influenza, as a component of the activities carried out under clause (i), and consistent with the requirements of paragraphs (2) and (5) of subsection (g);

(iii) preparedness and response strategies and capabilities that take into account the medical and public health needs of at-risk individuals in the event of a public health emergency;

(iv) a description of the mechanism the entity will implement to utilize the Emergency Management Assistance Compact or other mutual aid agreements for medical and public health mutual aid;

(v) a description of how the entity will include the State Unit on Aging in public health emergency preparedness;

(vi) a description of how, as appropriate, the entity may partner with relevant public and private stakeholders in public health emergency preparedness and response;

(vii) a description of how the entity, as applicable and appropriate, will coordinate with State emergency preparedness and response plans in public health emergency preparedness, including State educational agencies (as defined in section 9101(41) of the Elementary and Secondary Education Act of 1965) and State child care lead agencies (designated under section 658D of the Child Care and Development Block Grant Act of 1990);

(viii) in the case of entities that operate on the United States-Mexico border or the United States-Canada border, a description of the activities such entity will carry out under the agreement that are specific to the border area including disease detection, identification, investigation, and preparedness and response activities related to emerging diseases and infectious disease outbreaks whether naturally occurring or due to bioterrorism, consistent with the requirements of this section; and

(ix) a description of any activities that such entity will use to analyze real-time clinical specimens for pathogens of public health or bioterrorism significance, including any utilization of poison control centers;

(B) an assurance that the entity will report to the Secretary on an annual basis (or more frequently as determined by the Secretary) on the evidence-based benchmarks and objective standards established by the Secretary to evaluate the preparedness and response capabilities of such entity under subsection (g);

(C) an assurance that the entity will conduct, on at least an annual basis, an exercise or drill that meets any criteria established by the Secretary to test the preparedness and response capabilities of such entity, including addressing the needs of at-risk individuals,,[19] and that the entity will report back to the Secretary within the application of the following year on the strengths and weaknesses identified through such exercise or drill, and corrective actions taken to address material weaknesses;

(D) an assurance that the entity will provide to the Secretary the data described under section 319D(c)(3) as determined feasible by the Secretary;

(E) an assurance that the entity will conduct activities to inform and educate the hospitals within the jurisdiction of such entity on the role of such hospitals in the plan required under subparagraph (A);

(F) an assurance that the entity, with respect to the plan described under subparagraph (A), has developed and will implement an accountability system to ensure that such entity make satisfactory annual improvement and describe such system in the plan under subparagraph (A);

(G) a description of the means by which to obtain public comment and input on the plan described in subparagraph (A) and on the implementation of such plan, that shall include an advisory committee or other similar mechanism for obtaining comment from the public and from other State, local, and tribal stakeholders; and

(H) as relevant, a description of the process used by the entity to consult with local departments of public health to reach consensus, approval, or concurrence on the relative distribution of amounts received under this section.

(c) LIMITATION.—Beginning in fiscal year 2009, the Secretary may not award a cooperative agreement to a State unless such State is a participant in the Emergency System for Advance Registration of Volunteer Health Professionals described in section 319I.

(d) USE OF FUNDS.—

(1) IN GENERAL.—An award under subsection (a) shall be expended for activities to achieve the preparedness goals described under paragraphs (1), (2), (4), (5), and (6) of section 2802(b).

(2) EFFECT OF SECTION.—Nothing in this subsection may be construed as establishing new regulatory authority or as modifying any existing regulatory authority.

[19] Two commas so in law.

(e) COORDINATION WITH LOCAL RESPONSE CAPABILITIES.—An entity shall, to the extent practicable, ensure that activities carried out under an award under subsection (a) are coordinated with activities of relevant Metropolitan Medical Response Systems, local public health departments, the Cities Readiness Initiative, and local emergency plans.

(f) CONSULTATION WITH HOMELAND SECURITY.—In making awards under subsection (a), the Secretary shall consult with the Secretary of Homeland Security to—

(1) ensure maximum coordination of public health and medical preparedness and response activities with the Metropolitan Medical Response System, and other relevant activities;

(2) minimize duplicative funding of programs and activities; and

(3) analyze activities, including exercises and drills, conducted under this section to develop recommendations and guidance on best practices for such activities.

(g) ACHIEVEMENT OF MEASURABLE EVIDENCE-BASED BENCHMARKS AND OBJECTIVE STANDARDS.—

(1) IN GENERAL.—Not later than 180 days after the date of enactment of the Pandemic and All-Hazards Preparedness Act, the Secretary shall develop or where appropriate adopt, and require the application of, measurable evidence-based benchmarks and objective standards that measure levels of preparedness with respect to the activities described in this section and with respect to activities described in section 319C–2. In developing such benchmarks and standards, the Secretary shall consult with and seek comments from State, local, and tribal officials and private entities, as appropriate. Where appropriate, the Secretary shall incorporate existing objective standards. Such benchmarks and standards shall—

(A) include outcome goals representing operational achievements of the National Preparedness Goals developed under section 2802(b) with respect to all-hazards, including chemical, biological, radiological, or nuclear threats; and

(B) at a minimum, require entities to—

(i) measure progress toward achieving the outcome goals; and

(ii) at least annually, test, exercise, and rigorously evaluate the public health and medical emergency preparedness and response capabilities of the entity, and report to the Secretary on such measured and tested capabilities and measured and tested progress toward achieving outcome goals, based on criteria established by the Secretary.

(2) CRITERIA FOR PANDEMIC INFLUENZA PLANS.—

(A) IN GENERAL.—Not later than 180 days after the date of enactment of the Pandemic and All-Hazards Preparedness Act, the Secretary shall develop and disseminate to the chief executive officer of each State criteria for an effective State plan for responding to pandemic influenza. The Secretary shall periodically update, as necessary and appropriate, such pandemic influenza plan criteria

and shall require the integration of such criteria into the benchmarks and standards described in paragraph (1).

(B) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to require the duplication of Federal efforts with respect to the development of criteria or standards, without regard to whether such efforts were carried out prior to or after the date of enactment of this section.

(3) TECHNICAL ASSISTANCE.—The Secretary shall, as determined appropriate by the Secretary, provide to a State, upon request, technical assistance in meeting the requirements of this section, including the provision of advice by experts in the development of high-quality assessments, the setting of State objectives and assessment methods, the development of measures of satisfactory annual improvement that are valid and reliable, and other relevant areas.

(4) NOTIFICATION OF FAILURES.—The Secretary shall develop and implement a process to notify entities that are determined by the Secretary to have failed to meet the requirements of paragraph (1) or (2). Such process shall provide such entities with the opportunity to correct such noncompliance. An entity that fails to correct such noncompliance shall be subject to paragraph (5).

(5) WITHHOLDING OF AMOUNTS FROM ENTITIES THAT FAIL TO ACHIEVE BENCHMARKS OR SUBMIT INFLUENZA PLAN.—Beginning with fiscal year 2009, and in each succeeding fiscal year, the Secretary shall—

(A) withhold from each entity that has failed substantially to meet the benchmarks and performance measures described in paragraph (1) for the immediately preceding fiscal year (beginning with fiscal year 2008), pursuant to the process developed under paragraph (4), the amount described in paragraph (6); and

(B) withhold from each entity that has failed to submit to the Secretary a plan for responding to pandemic influenza that meets the criteria developed under paragraph (2), the amount described in paragraph (6).

(6) AMOUNTS DESCRIBED.—

(A) IN GENERAL.—The amounts described in this paragraph are the following amounts that are payable to an entity for activities described in section 319C–1 or 319C–2:

(i) For the fiscal year immediately following a fiscal year in which an entity experienced a failure described in subparagraph (A) or (B) of paragraph (5) by the entity, an amount equal to 10 percent of the amount the entity was eligible to receive for such fiscal year.

(ii) For the fiscal year immediately following two consecutive fiscal years in which an entity experienced such a failure, an amount equal to 15 percent of the amount the entity was eligible to receive for such fiscal year, taking into account the withholding of funds for the immediately preceding fiscal year under clause (i).

(iii) For the fiscal year immediately following three consecutive fiscal years in which an entity experienced such a failure, an amount equal to 20 percent of the amount the entity was eligible to receive for such fiscal year, taking into account the withholding of funds for the immediately preceding fiscal years under clauses (i) and (ii).

(iv) For the fiscal year immediately following four consecutive fiscal years in which an entity experienced such a failure, an amount equal to 25 percent of the amount the entity was eligible to receive for such a fiscal year, taking into account the withholding of funds for the immediately preceding fiscal years under clauses (i), (ii), and (iii).

(B) SEPARATE ACCOUNTING.—Each failure described in subparagraph (A) or (B) of paragraph (5) shall be treated as a separate failure for purposes of calculating amounts withheld under subparagraph (A).

(7) REALLOCATION OF AMOUNTS WITHHELD.—

(A) IN GENERAL.—The Secretary shall make amounts withheld under paragraph (6) available for making awards under section 319C–2 to entities described in subsection (b)(1) of such section.

(B) PREFERENCE IN REALLOCATION.—In making awards under section 319C–2 with amounts described in subparagraph (A), the Secretary shall give preference to eligible entities (as described in section 319C–2(b)(1)) that are located in whole or in part in States from which amounts have been withheld under paragraph (6).

(8) WAIVE OR REDUCE WITHHOLDING.—The Secretary may waive or reduce the withholding described in paragraph (6), for a single entity or for all entities in a fiscal year, if the Secretary determines that mitigating conditions exist that justify the waiver or reduction.

(h) FUNDING.—

(1) AUTHORIZATION OF APPROPRIATIONS.—

(A) IN GENERAL.—For the purpose of carrying out this section, there is authorized to be appropriated $641,900,000 for fiscal year 2014 for awards pursuant to paragraph (3) (subject to the authority of the Secretary to make awards pursuant to paragraphs (4) and (5)), and $641,900,000 for each of fiscal years 2015 through 2018.

(B) REQUIREMENT FOR STATE MATCHING FUNDS.—Beginning in fiscal year 2009, in the case of any State or consortium of two or more States, the Secretary may not award a cooperative agreement under this section unless the State or consortium of States agree that, with respect to the amount of the cooperative agreement awarded by the Secretary, the State or consortium of States will make available (directly or through donations from public or private entities) non-Federal contributions in an amount equal to—

(i) for the first fiscal year of the cooperative agreement, not less than 5 percent of such costs ($1 for each

$20 of Federal funds provided in the cooperative agreement); and

(ii) for any second fiscal year of the cooperative agreement, and for any subsequent fiscal year of such cooperative agreement, not less than 10 percent of such costs ($1 for each $10 of Federal funds provided in the cooperative agreement).

(C) DETERMINATION OF AMOUNT OF NON-FEDERAL CONTRIBUTIONS.—As determined by the Secretary, non-Federal contributions required in subparagraph (B) may be provided directly or through donations from public or private entities and may be in cash or in kind, fairly evaluated, including plant, equipment or services. Amounts provided by the Federal government, or services assisted or subsidized to any significant extent by the Federal government, may not be included in determining the amount of such non-Federal contributions.

(2) MAINTAINING STATE FUNDING.—

(A) IN GENERAL.—An entity that receives an award under this section shall maintain expenditures for public health security at a level that is not less than the average level of such expenditures maintained by the entity for the preceding 2 year period.

(B) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to prohibit the use of awards under this section to pay salary and related expenses of public health and other professionals employed by State, local, or tribal public health agencies who are carrying out activities supported by such awards (regardless of whether the primary assignment of such personnel is to carry out such activities).

(3) DETERMINATION OF AMOUNT.—

(A) IN GENERAL.—The Secretary shall award cooperative agreements under subsection (a) to each State or consortium of 2 or more States that submits to the Secretary an application that meets the criteria of the Secretary for the receipt of such an award and that meets other implementation conditions established by the Secretary for such awards

(B) BASE AMOUNT.—In determining the amount of an award pursuant to subparagraph (A) for a State, the Secretary shall first determine an amount the Secretary considers appropriate for the State (referred to in this paragraph as the "base amount"), except that such amount may not be greater than the minimum amount determined under subparagraph (D).

(C) INCREASE ON BASIS OF POPULATION.—After determining the base amount for a State under subparagraph (B), the Secretary shall increase the base amount by an amount equal to the product of—

(i) the amount appropriated under paragraph (1)(A) for the fiscal year, less an amount equal to the sum of all base amounts determined for the States under subparagraph (B), and less the amount, if any,

reserved by the Secretary under paragraphs (4) and (5); and

(ii) subject to paragraph (4)(C), the percentage constituted by the ratio of an amount equal to the population of the State over an amount equal to the total population of the States (as indicated by the most recent data collected by the Bureau of the Census).

(D) MINIMUM AMOUNT.—Subject to the amount appropriated under paragraph (1)(A), an award pursuant to subparagraph (A) for a State shall be the greater of the base amount as increased under subparagraph (C), or the minimum amount under this subparagraph. The minimum amount under this subparagraph is—

(i) in the case of each of the several States, the District of Columbia, and the Commonwealth of Puerto Rico, an amount equal to the lesser of—

(I) $5,000,000; or

(II) if the amount appropriated under paragraph (1)(A) is less than $667,000,000, an amount equal to 0.75 percent of the amount appropriated under such paragraph, less the amount, if any, reserved by the Secretary under paragraphs (4) and (5); or

(ii) in the case of each of American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, and the Virgin Islands, an amount determined by the Secretary to be appropriate, except that such amount may not exceed the amount determined under clause (i).

(4) CERTAIN POLITICAL SUBDIVISIONS.—

(A) IN GENERAL.—For fiscal year 2007, the Secretary may, before making awards pursuant to paragraph (3) for such year, reserve from the amount appropriated under paragraph (1) for the year an amount determined necessary by the Secretary to make awards under subsection (a) to political subdivisions that have a substantial number of residents, have a substantial local infrastructure for responding to public health emergencies, and face a high degree of risk from bioterrorist attacks or other public health emergencies. Not more than three political subdivisions may receive awards pursuant to this subparagraph.

(B) COORDINATION WITH STATEWIDE PLANS.—An award pursuant to subparagraph (A) may not be made unless the application of the political subdivision involved is in coordination with, and consistent with, applicable Statewide plans described in subsection (b).

(C) RELATIONSHIP TO FORMULA GRANTS.—In the case of a State that will receive an award pursuant to paragraph (3), and in which there is located a political subdivision that will receive an award pursuant to subparagraph (A), the Secretary shall, in determining the amount under paragraph (3)(C) for the State, subtract from the population of the State an amount equal to the population of such political subdivision.

(D) CONTINUITY OF FUNDING.—In determining whether to make an award pursuant to subparagraph (A) to a political subdivision, the Secretary may consider, as a factor indicating that the award should be made, that the political subdivision received public health funding from the Secretary for fiscal year 2006.

(5) SIGNIFICANT UNMET NEEDS; DEGREE OF RISK.—

(A) IN GENERAL.—For fiscal year 2007, the Secretary may, before making awards pursuant to paragraph (3) for such year, reserve from the amount appropriated under paragraph (1) for the year an amount determined necessary by the Secretary to make awards under subsection (a) to eligible entities that—

(i) have a significant need for funds to build capacity to identify, detect, monitor, and respond to a bioterrorist or other threat to the public health, which need will not be met by awards pursuant to paragraph (3); and

(ii) face a particularly high degree of risk of such a threat.

(B) RECIPIENTS OF GRANTS.—Awards pursuant to subparagraph (A) may be supplemental awards to States that receive awards pursuant to paragraph (3), or may be awards to eligible entities described in subsection (b)(1)(B) within such States.

(C) FINDING WITH RESPECT TO DISTRICT OF COLUMBIA.—The Secretary shall consider the District of Columbia to have a significant unmet need for purposes of subparagraph (A), and to face a particularly high degree of risk for such purposes, on the basis of the concentration of entities of national significance located within the District.

(6) FUNDING OF LOCAL ENTITIES.—The Secretary shall, in making awards under this section, ensure that with respect to the cooperative agreement awarded, the entity make available appropriate portions of such award to political subdivisions and local departments of public health through a process involving the consensus, approval or concurrence with such local entities.

(7) AVAILABILITY OF COOPERATIVE AGREEMENT FUNDS.—

(A) IN GENERAL.—Amounts provided to an eligible entity under a cooperative agreement under subsection (a) for a fiscal year and remaining unobligated at the end of such year shall remain available to such entity for the next fiscal year for the purposes for which such funds were provided.

(B) FUNDS CONTINGENT ON ACHIEVING BENCHMARKS.—The continued availability of funds under subparagraph (A) with respect to an entity shall be contingent upon such entity achieving the benchmarks and submitting the pandemic influenza plan as described in subsection (g).

(i) ADMINISTRATIVE AND FISCAL RESPONSIBILITY.—

(1) ANNUAL REPORTING REQUIREMENTS.—Each entity shall prepare and submit to the Secretary annual reports on its activities under this section and section 319C–2. Each such re-

port shall be prepared by, or in consultation with, the health department. In order to properly evaluate and compare the performance of different entities assisted under this section and section 319C–2 and to assure the proper expenditure of funds under this section and section 319C–2, such reports shall be in such standardized form and contain such information as the Secretary determines and describes within 180 days of the date of enactment of the Pandemic and All-Hazards Preparedness Act (after consultation with the States) to be necessary to—

(A) secure an accurate description of those activities;

(B) secure a complete record of the purposes for which funds were spent, and of the recipients of such funds;

(C) describe the extent to which the entity has met the goals and objectives it set forth under this section or section 319C–2;

(D) determine the extent to which funds were expended consistent with the entity's application transmitted under this section or section 319C–2; and

(E) publish such information on a Federal Internet website consistent with subsection (j).

(2) AUDITS; IMPLEMENTATION.—

(A) IN GENERAL.—Each entity receiving funds under this section or section 319C–2 shall, not less often than once every 2 years, audit its expenditures from amounts received under this section or section 319C–2. Such audits shall be conducted by an entity independent of the agency administering a program funded under this section or section 319C–2 in accordance with the Comptroller General's standards for auditing governmental organizations, programs, activities, and functions and generally accepted auditing standards. Within 30 days following the completion of each audit report, the entity shall submit a copy of that audit report to the Secretary.

(B) REPAYMENT.—Each entity shall repay to the United States amounts found by the Secretary, after notice and opportunity for a hearing to the entity, not to have been expended in accordance with this section or section 319C–2 and, if such repayment is not made, the Secretary may offset such amounts against the amount of any allotment to which the entity is or may become entitled under this section or section 319C–2 or may otherwise recover such amounts.

(C) WITHHOLDING OF PAYMENT.—The Secretary may, after notice and opportunity for a hearing, withhold payment of funds to any entity which is not using its allotment under this section or section 319C–2 in accordance with such section. The Secretary may withhold such funds until the Secretary finds that the reason for the withholding has been removed and there is reasonable assurance that it will not recur.

(j) COMPILATION AND AVAILABILITY OF DATA.—The Secretary shall compile the data submitted under this section and make such data available in a timely manner on an appropriate Internet

website in a format that is useful to the public and to other entities and that provides information on what activities are best contributing to the achievement of the outcome goals described in subsection (g).

SEC. 319C–2.[247d–3b] PARTNERSHIPS FOR STATE AND REGIONAL HOSPITAL PREPAREDNESS TO IMPROVE SURGE CAPACITY.

(a) IN GENERAL.—The Secretary shall award competitive grants or cooperative agreements to eligible entities to enable such entities to improve surge capacity and enhance community and hospital preparedness for public health emergencies, including, as appropriate, capacity and preparedness to address the needs of children and other at-risk individuals.

(b) ELIGIBILITY.—To be eligible for an award under subsection (a), an entity shall—

(1)(A) be a partnership consisting of—

(i) one or more hospitals, at least one of which shall be a designated trauma center, consistent with section 1213(c);

(ii) one or more other local health care facilities, including clinics, health centers, community health centers, primary care facilities, mental health centers, mobile medical assets, or nursing homes; and

(iii)(I) one or more political subdivisions;

(II) one or more States; or

(III) one or more States and one or more political subdivisions; and

(B) prepare, in consultation with the Chief Executive Officer and the lead health officials of the State, District, or territory in which the hospital and health care facilities described in subparagraph (A) are located, and submit to the Secretary, an application at such time, in such manner, and containing such information as the Secretary may require; or

(2)(A) be an entity described in section 319C–1(b)(1); and

(B) submit an application at such time, in such manner, and containing such information as the Secretary may require, including the information or assurances required under section 319C–1(b)(2) and an assurance that the State will adhere to any applicable guidelines established by the Secretary.

(c) USE OF FUNDS.—An award under subsection (a) shall be expended for activities to achieve the preparedness goals described under paragraphs (1), (3), (4), (5), and (6) of section 2802(b) with respect to all-hazards, including chemical, biological, radiological, or nuclear threats.

(d) PREFERENCES.—

(1) REGIONAL COORDINATION.—In making awards under subsection (a), the Secretary shall give preference to eligible entities that submit applications that, in the determination of the Secretary—

(A) will enhance coordination—

(i) among the entities described in subsection (b)(1)(A)(i); and

(ii) between such entities and the entities described in subsection (b)(1)(A)(ii); and

(B) include, in the partnership described in subsection (b)(1)(A), a significant percentage of the hospitals and health care facilities within the geographic area served by such partnership.

(2) OTHER PREFERENCES.—In making awards under subsection (a), the Secretary shall give preference to eligible entities that, in the determination of the Secretary—

(A) include one or more hospitals that are participants in the National Disaster Medical System;

(B) are located in a geographic area that faces a high degree of risk, as determined by the Secretary in consultation with the Secretary of Homeland Security; or

(C) have a significant need for funds to achieve the medical preparedness goals described in section 2802(b)(3).

(e) CONSISTENCY OF PLANNED ACTIVITIES.—The Secretary may not award a cooperative agreement to an eligible entity described in subsection (b)(1) unless the application submitted by the entity is coordinated and consistent with an applicable State All-Hazards Public Health Emergency Preparedness and Response Plan and relevant local plans, as determined by the Secretary in consultation with relevant State health officials.

(f) LIMITATION ON AWARDS.—A political subdivision shall not participate in more than one partnership described in subsection (b)(1).

(g) COORDINATION.—

(1) LOCAL RESPONSE CAPABILITIES.—An eligible entity shall, to the extent practicable, ensure that activities carried out under an award under subsection (a) are coordinated with activities of relevant local Metropolitan Medical Response Systems, local Medical Reserve Corps, the local Cities Readiness Initiative, and local emergency plans.

(2) NATIONAL COLLABORATION.—Partnerships consisting of one or more eligible entities under this section may, to the extent practicable, collaborate with other partnerships consisting of one or more eligible entities under this section for purposes of national coordination and collaboration with respect to activities to achieve the preparedness goals described under paragraphs (1), (3), (4), (5), and (6) of section 2802(b).

(h) MAINTENANCE OF FUNDING.—

(1) IN GENERAL.—An entity that receives an award under this section shall maintain expenditures for health care preparedness at a level that is not less than the average level of such expenditures maintained by the entity for the preceding 2 year period.

(2) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to prohibit the use of awards under this section to pay salary and related expenses of public health and other professionals employed by State, local, or tribal agencies who are carrying out activities supported by such awards (regardless of whether the primary assignment of such personnel is to carry out such activities).

(i) PERFORMANCE AND ACCOUNTABILITY.—

(1) IN GENERAL.—The requirements of section 319C–1(g), (i), and (j) shall apply to entities receiving awards under this

section (regardless of whether such entities are described under subsection (b)(1)(A) or (b)(2)(A)) in the same manner as such requirements apply to entities under section 319C–1. An entity described in subsection (b)(1)(A) shall make such reports available to the lead health official of the State in which such partnership is located.

(2) MEETING GOALS OF NATIONAL HEALTH SECURITY STRATEGY.—The Secretary shall implement objective, evidence-based metrics to ensure that entities receiving awards under this section are meeting, to the extent practicable, the applicable goals of the National Health Security Strategy under section 2802.

(j) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—For purposes of carrying out this section, there is authorized to be appropriated $374,700,000 for each of fiscal years 2014 through 2018.

(2) RESERVATION OF AMOUNTS FOR PARTNERSHIPS.—Prior to making awards described in paragraph (3), the Secretary may reserve from the amount appropriated under paragraph (1) for a fiscal year, an amount determined appropriate by the Secretary for making awards to entities described in subsection (b)(1)(A).

(3) AWARDS TO STATES AND POLITICAL SUBDIVISIONS.—

(A) IN GENERAL.—From amounts appropriated for a fiscal year under paragraph (1) and not reserved under paragraph (2), the Secretary shall make awards to entities described in subsection (b)(2)(A) that have completed an application as described in subsection (b)(2)(B).

(B) AMOUNT.—The Secretary shall determine the amount of an award to each entity described in subparagraph (A) in the same manner as such amounts are determined under section 319C–1(h).

(4) AVAILABILITY OF COOPERATIVE AGREEMENT FUNDS.—

(A) IN GENERAL.—Amounts provided to an eligible entity under a cooperative agreement under subsection (a) for a fiscal year and remaining unobligated at the end of such year shall remain available to such entity for the next fiscal year for the purposes for which such funds were provided.

(B) FUNDS CONTINGENT ON ACHIEVING BENCHMARKS.—The continued availability of funds under subparagraph (A) with respect to an entity shall be contingent upon such entity achieving the benchmarks and submitting the pandemic influenza plan as required under subsection (i).

SEC. 319D.[247d–4] REVITALIZING THE CENTERS FOR DISEASE CONTROL AND PREVENTION.

(a) FACILITIES; CAPACITIES.—

(1) FINDINGS.—Congress finds that the Centers for Disease Control and Prevention has an essential role in defending against and combatting public health threats domestically and abroad and requires secure and modern facilities, and expanded and improved capabilities related to bioterrorism and other public health emergencies, sufficient to enable such Centers to conduct this important mission.

(2) FACILITIES.—

(A) IN GENERAL.—The Director of the Centers for Disease Control and Prevention may design, construct, and equip new facilities, renovate existing facilities (including laboratories, laboratory support buildings, scientific communication facilities, transshipment complexes, secured and isolated parking structures, office buildings, and other facilities and infrastructure), and upgrade security of such facilities, in order to better conduct the capacities described in section 319A, and for supporting public health activities.

(B) MULTIYEAR CONTRACTING AUTHORITY.—For any project of designing, constructing, equipping, or renovating any facility under subparagraph (A), the Director of the Centers for Disease Control and Prevention may enter into a single contract or related contracts that collectively include the full scope of the project, and the solicitation and contract shall contain the clause "availability of funds" found at section 52.232–18 of title 48, Code of Federal Regulations.

(3) IMPROVING THE CAPACITIES OF THE CENTERS FOR DISEASE CONTROL AND PREVENTION.—The Secretary shall expand, enhance, and improve the capabilities of the Centers for Disease Control and Prevention relating to preparedness for and responding effectively to bioterrorism and other public health emergencies. Activities that may be carried out under the preceding sentence include—

(A) expanding or enhancing the training of personnel;

(B) improving communications facilities and networks, including delivery of necessary information to rural areas;

(C) improving capabilities for public health surveillance and reporting activities, taking into account the integrated system or systems of public health alert communications and surveillance networks under subsection (b); and

(D) improving laboratory facilities related to bioterrorism and other public health emergencies, including increasing the security of such facilities.

(b) NATIONAL COMMUNICATIONS AND SURVEILLANCE NETWORKS.—

(1) IN GENERAL.—The Secretary, directly or through awards of grants, contracts, or cooperative agreements, shall provide for the establishment of an integrated system or systems of public health alert communications and surveillance networks between and among—

(A) Federal, State, and local public health officials;

(B) public and private health-related laboratories, hospitals, poison control centers, and other health care facilities; and

(C) any other entities determined appropriate by the Secretary.

(2) REQUIREMENTS.—The Secretary shall ensure that networks under paragraph (1) allow for the timely sharing and discussion, in a secure manner, of essential information concerning bioterrorism or another public health emergency, or

recommended methods for responding to such an attack or emergency, allowing for coordination to maximize all-hazards medical and public health preparedness and response and to minimize duplication of effort.

(3) STANDARDS.—Not later than one year after the date of the enactment of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, the Secretary, in cooperation with health care providers and State and local public health officials, shall establish any additional technical and reporting standards (including standards for interoperability) for networks under paragraph (1) and update such standards as necessary.

(c) MODERNIZING PUBLIC HEALTH SITUATIONAL AWARENESS AND BIOSURVEILLANCE.—

(1) IN GENERAL.—Not later than 2 years after the date of enactment of the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013, the Secretary, in collaboration with State, local, and tribal public health officials, shall establish a near real-time electronic nationwide public health situational awareness capability through an interoperable network of systems to share data and information to enhance early detection of rapid response to, and management of, potentially catastrophic infectious disease outbreaks, novel emerging threats, and other public health emergencies that originate domestically or abroad. Such network shall be built on existing State situational awareness systems or enhanced systems that enable such connectivity.

(2) STRATEGY AND IMPLEMENTATION PLAN.—Not later than 180 days after the date of enactment of the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013, the Secretary shall submit to the appropriate committees of Congress a coordinated strategy and an accompanying implementation plan that identifies and demonstrates the measurable steps the Secretary will carry out to—

(A) develop, implement, and evaluate the network described in paragraph (1), utilizing the elements described in paragraph (3);

(B) modernize and enhance biosurveillance activities; and

(C) improve information sharing, coordination, and communication among disparate biosurveillance systems supported by the Department of Health and Human Services.

(3) ELEMENTS.—The network described in paragraph (1) shall include data and information transmitted in a standardized format from—

(A) State, local, and tribal public health entities, including public health laboratories;

(B) Federal health agencies;

(C) zoonotic disease monitoring systems;

(D) public and private sector health care entities, hospitals, pharmacies, poison control centers or professional organizations in the field of poison control, community health centers, health centers and clinical laboratories, to

the extent practicable and provided that such data are voluntarily provided simultaneously to the Secretary and appropriate State, local, and tribal public health agencies; and

(E) such other sources as the Secretary may deem appropriate.

(4) RULE OF CONSTRUCTION.—Paragraph (3) shall not be construed as requiring separate reporting of data and information from each source listed.

(5) REQUIRED ACTIVITIES.—In establishing and operating the network described in paragraph (1), the Secretary shall—

(A) utilize applicable interoperability standards as determined by the Secretary, and in consultation with the Office of the National Coordinator for Health Information Technology, through a joint public and private sector process;

(B) define minimal data elements for such network;

(C) in collaboration with State, local, and tribal public health officials, integrate and build upon existing State, local, and tribal capabilities, ensuring simultaneous sharing of data, information, and analyses from the network described in paragraph (1) with State, local, and tribal public health agencies; and

(D) in collaboration with State, local, and tribal public health officials, develop procedures and standards for the collection, analysis, and interpretation of data that States, regions, or other entities collect and report to the network described in paragraph (1).

(6) CONSULTATION WITH THE NATIONAL BIODEFENSE SCIENCE BOARD.—In carrying out this section and consistent with section 319M, the National Biodefense Science Board shall provide expert advice and guidance, including recommendations, regarding the measurable steps the Secretary should take to modernize and enhance biosurveillance activities pursuant to the efforts of the Department of Health and Human Services to ensure comprehensive, real-time, all-hazards biosurveillance capabilities. In complying with the preceding sentence, the National Biodefense Science Board shall—

(A) identify the steps necessary to achieve a national biosurveillance system for human health, with international connectivity, where appropriate, that is predicated on State, regional, and community level capabilities and creates a networked system to allow for two-way information flow between and among Federal, State, and local government public health authorities and clinical health care providers;

(B) identify any duplicative surveillance programs under the authority of the Secretary, or changes that are necessary to existing programs, in order to enhance and modernize such activities, minimize duplication, strengthen and streamline such activities under the authority of the Secretary, and achieve real-time and appropriate data that relate to disease activity, both human and zoonotic; and

(C) coordinate with applicable existing advisory committees of the Director of the Centers for Disease Control and Prevention, including such advisory committees consisting of representatives from State, local, and tribal public health authorities and appropriate public and private sector health care entities and academic institutions, in order to provide guidance on public health surveillance activities.

(d) STATE AND REGIONAL SYSTEMS TO ENHANCE SITUATIONAL AWARENESS IN PUBLIC HEALTH EMERGENCIES.—

(1) IN GENERAL.—To implement the network described in subsection (c), the Secretary may award grants to States or consortia of States to enhance the ability of such States or consortia of States to establish or operate a coordinated public health situational awareness system for regional or Statewide early detection of, rapid response to, and management of potentially catastrophic infectious disease outbreaks and public health emergencies, in collaboration with appropriate public health agencies, sentinel hospitals, clinical laboratories, pharmacies, poison control centers, other health care organizations, and animal health organizations within such States.

(2) ELIGIBILITY.—To be eligible to receive a grant under paragraph (1), the State or consortium of States shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require, including an assurance that the State or consortium of States will submit to the Secretary—

(A) reports of such data, information, and metrics as the Secretary may require;

(B) a report on the effectiveness of the systems funded under the grant; and

(C) a description of the manner in which grant funds will be used to enhance the timelines and comprehensiveness of efforts to detect, respond to, and manage potentially catastrophic infectious disease outbreaks and public health emergencies.

(3) USE OF FUNDS.—A State or consortium of States that receives an award under this subsection—

(A) shall establish, enhance, or operate a coordinated public health situational awareness system for regional or Statewide early detection of, rapid response to, and management of potentially catastrophic infectious disease outbreaks and public health emergencies;

(B) may award grants or contracts to entities described in paragraph (1) within or serving such State to assist such entities in improving the operation of information technology systems, facilitating the secure exchange of data and information, and training personnel to enhance the operation of the system described in subparagraph (A); and

(C) may conduct a pilot program for the development of multi-State telehealth network test beds that build on, enhance, and securely link existing State and local telehealth programs to prepare for, monitor, respond to, and

manage the events of public health emergencies, facilitate coordination and communication among medical, public health, and emergency response agencies, and provide medical services through telehealth initiatives within the States that are involved in such a multi-State telehealth network test bed.

(4) LIMITATION.—Information technology systems acquired or implemented using grants awarded under this section must be compliant with—

(A) interoperability and other technological standards, as determined by the Secretary; and

(B) data collection and reporting requirements for the network described in subsection (c).

(5) INDEPENDENT EVALUATION.—Not later than 3 years after the date of enactment of the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013, the Government Accountability Office shall conduct an independent evaluation, and submit to the Secretary and the appropriate committees of Congress a report concerning the activities conducted under this subsection and subsection (c).

(e) TELEHEALTH ENHANCEMENTS FOR EMERGENCY RESPONSE.—

(1) EVALUATION.—The Secretary, in consultation with the Federal Communications Commission and other relevant Federal agencies, shall—

(A) conduct an inventory of telehealth initiatives in existence on the date of enactment of the Pandemic and All-Hazards Preparedness Act, including—

(i) the specific location of network components;

(ii) the medical, technological, and communications capabilities of such components;

(iii) the functionality of such components; and

(iv) the capacity and ability of such components to handle increased volume during the response to a public health emergency;

(B) identify methods to expand and interconnect the regional health information networks funded by the Secretary, the State and regional broadband networks funded through the rural health care support mechanism pilot program funded by the Federal Communications Commission, and other telehealth networks;

(C) evaluate ways to prepare for, monitor, respond rapidly to, or manage the events of, a public health emergency through the enhanced use of telehealth technologies, including mechanisms for payment or reimbursement for use of such technologies and personnel during public health emergencies;

(D) identify methods for reducing legal barriers that deter health care professionals from providing telemedicine services, such as by utilizing State emergency health care professional credentialing verification systems, encouraging States to establish and implement mechanisms to improve interstate medical licensure cooperation, facilitating the exchange of information among States regarding investigations and adverse actions, and encouraging States

to waive the application of licensing requirements during a public health emergency;

(E) evaluate ways to integrate the practice of telemedicine within the National Disaster Medical System; and

(F) promote greater coordination among existing Federal interagency telemedicine and health information technology initiatives.

(2) REPORT.—Not later than 12 months after the date of enactment of the Pandemic and All-Hazards Preparedness Act, the Secretary shall prepare and submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives regarding the findings and recommendations pursuant to subparagraphs (A) through (F) of paragraph (1).

(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, $138,300,000 for each of fiscal years 2014 through 2018.

(g) DEFINITION.—For purposes of this section the term "biosurveillance" means the process of gathering near real-time biological data that relates to human and zoonotic disease activity and threats to human or animal health, in order to achieve early warning and identification of such health threats, early detection and prompt ongoing tracking of health events, and overall situational awareness of disease activity.

SEC. 319E.[247d–5] COMBATING ANTIMICROBIAL RESISTANCE.

(a) TASK FORCE.—

(1) IN GENERAL.—The Secretary shall establish an Antimicrobial Resistance Task Force to provide advice and recommendations to the Secretary and coordinate Federal programs relating to antimicrobial resistance. The Secretary may appoint or select a committee, or other organization in existence as of the date of the enactment of this section, to serve as such a task force, if such committee, or other organization meets the requirements of this section.

(2) MEMBERS OF TASK FORCE.—The task force described in paragraph (1) shall be composed of representatives from such Federal agencies, and shall seek input from public health constituencies, manufacturers, veterinary and medical professional societies and others, as determined to be necessary by the Secretary, to develop and implement a comprehensive plan to address the public health threat of antimicrobial resistance.

(3) AGENDA.—

(A) IN GENERAL.—The task force described in paragraph (1) shall consider factors the Secretary considers appropriate, including—

(i) public health factors contributing to increasing antimicrobial resistance;

(ii) public health needs to detect and monitor antimicrobial resistance;

(iii) detection, prevention, and control strategies for resistant pathogens;

(iv) the need for improved information and data collection;

(v) the assessment of the risk imposed by pathogens presenting a threat to the public health; and

(vi) any other issues which the Secretary determines are relevant to antimicrobial resistance.

(B) DETECTION AND CONTROL.—The Secretary, in consultation with the task force described in paragraph (1) and State and local public health officials, shall—

(i) develop, improve, coordinate or enhance participation in a surveillance plan to detect and monitor emerging antimicrobial resistance; and

(ii) develop, improve, coordinate or enhance participation in an integrated information system to assimilate, analyze, and exchange antimicrobial resistance data between public health departments.

(4) MEETINGS.—The task force described under paragraph (1) shall convene not less than twice a year, or more frequently as the Secretary determines to be appropriate.

(b) RESEARCH AND DEVELOPMENT OF NEW ANTIMICROBIAL DRUGS AND DIAGNOSTICS.—The Secretary and the Director of Agricultural Research Services, consistent with the recommendations of the task force established under subsection (a), shall directly or through awards of grants or cooperative agreements to public or private entities provide for the conduct of research, investigations, experiments, demonstrations, and studies in the health sciences that are related to—

(1) the development of new therapeutics, including vaccines and antimicrobials, against resistant pathogens;

(2) the development or testing of medical diagnostics to detect pathogens resistant to antimicrobials;

(3) the epidemiology, mechanisms, and pathogenesis of antimicrobial resistance;

(4) the sequencing of the genomes, or other DNA analysis, or other comparative analysis, of priority pathogens (as determined by the Director of the National Institutes of Health in consultation with the task force established under subsection (a)), in collaboration and coordination with the activities of the Department of Defense and the Joint Genome Institute of the Department of Energy; and

(5) other relevant research areas.

(c) EDUCATION OF MEDICAL AND PUBLIC HEALTH PERSONNEL.—The Secretary, after consultation with the Assistant Secretary for Health, the Surgeon General, the Director of the Centers for Disease Control and Prevention, the Administrator of the Health Resources and Services Administration, the Director of the Agency for Healthcare Research and Quality, members of the task force described in subsection (a), professional organizations and societies, and such other public health officials as may be necessary, shall—

(1) develop and implement educational programs to increase the awareness of the general public with respect to the public health threat of antimicrobial resistance and the appropriate use of antibiotics;

(2) develop and implement educational programs to instruct health care professionals in the prudent use of antibiotics; and

(3) develop and implement programs to train laboratory personnel in the recognition or identification of resistance in pathogens.

(d) GRANTS.—

(1) IN GENERAL.—The Secretary shall award competitive grants to eligible entities to enable such entities to increase the capacity to detect, monitor, and combat antimicrobial resistance.

(2) ELIGIBLE ENTITIES.—Eligible entities for grants under paragraph (1) shall be State or local public health agencies, Indian tribes or tribal organizations, or other public or private nonprofit entities.

(3) USE OF FUNDS.—An eligible entity receiving a grant under paragraph (1) shall use funds from such grant for activities that are consistent with the factors identified by the task force under subsection (a)(3), which may include activities that—

(A) provide training to enable such entity to identify patterns of resistance rapidly and accurately;

(B) develop, improve, coordinate or enhance participation in information systems by which data on resistant infections can be shared rapidly among relevant national, State, and local health agencies and health care providers; and

(C) develop and implement policies to control the spread of antimicrobial resistance.

(e) GRANTS FOR DEMONSTRATION PROGRAMS.—

(1) IN GENERAL.—The Secretary shall award competitive grants to eligible entities to establish demonstration programs to promote judicious use of antimicrobial drugs or control the spread of antimicrobial-resistant pathogens.

(2) ELIGIBLE ENTITIES.—Eligible entities for grants under paragraph (1) may include hospitals, clinics, institutions of long-term care, professional medical societies, schools or programs that train medical laboratory personnel, or other public or private nonprofit entities.

(3) TECHNICAL ASSISTANCE.—The Secretary shall provide appropriate technical assistance to eligible entities that receive grants under paragraph (1).

(f) SUPPLEMENT NOT SUPPLANT.—Funds appropriated under this section shall be used to supplement and not supplant other Federal, State, and local public funds provided for activities under this section.

(g) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, $40,000,000 for fiscal year 2001, $25,000,000 for each of the fiscal years 2002 and 2003, and such sums as may be necessary for each of the fiscal years 2004 through 2006.

SEC. 319F.[247d–6] PUBLIC HEALTH COUNTERMEASURES TO A BIOTERRORIST ATTACK.

(a) ALL-HAZARDS PUBLIC HEALTH AND MEDICAL RESPONSE CURRICULA AND TRAINING.—

(1) IN GENERAL.—The Secretary, in collaboration with the Secretary of Defense, and in consultation with relevant public and private entities, shall develop core health and medical response curricula and trainings by adapting applicable existing curricula and training programs to improve responses to public health emergencies.

(2) CURRICULUM.—The public health and medical response training program may include course work related to—

(A) medical management of casualties, taking into account the needs of at-risk individuals;

(B) public health aspects of public health emergencies;

(C) mental health aspects of public health emergencies;

(D) national incident management, including coordination among Federal, State, local, tribal, international agencies, and other entities; and

(E) protecting health care workers and health care first responders from workplace exposures during a public health emergency.

(3) PEER REVIEW.—On a periodic basis, products prepared as part of the program shall be rigorously tested and peer-reviewed by experts in the relevant fields.

(4) CREDIT.—The Secretary and the Secretary of Defense shall—

(A) take into account continuing professional education requirements of public health and healthcare professions; and

(B) cooperate with State, local, and tribal accrediting agencies and with professional associations in arranging for students enrolled in the program to obtain continuing professional education credit for program courses.

(5) DISSEMINATION AND TRAINING.—

(A) IN GENERAL.—The Secretary may provide for the dissemination and teaching of the materials described in paragraphs (1) and (2) by appropriate means, as determined by the Secretary.

(B) CERTAIN ENTITIES.—The education and training activities described in subparagraph (A) may be carried out by Federal public health, medical, or dental entities, appropriate educational entities, professional organizations and societies, private accrediting organizations, and other nonprofit institutions or entities meeting criteria established by the Secretary.

(C) GRANTS AND CONTRACTS.—In carrying out this subsection, the Secretary may carry out activities directly or through the award of grants and contracts, and may enter into interagency agreements with other Federal agencies.

(b) ADVICE TO THE FEDERAL GOVERNMENT.—

(1) REQUIRED ADVISORY COMMITTEES.—In coordination with the working group under subsection (a), the Secretary

shall establish advisory committees in accordance with paragraphs (2) and (3) to provide expert recommendations to assist such working groups in carrying out their respective responsibilities under subsections (a) and (b)[20].

(2) NATIONAL ADVISORY COMMITTEE ON CHILDREN AND TERRORISM[21].—

(A) IN GENERAL.—For purposes of paragraph (1), the Secretary shall establish an advisory committee to be known as the National Advisory Committee on At-Risk Individuals and Public Health Emergencies (referred to in this paragraph as the "Advisory Committee").

(B) DUTIES.—The Advisory Committee shall provide recommendations regarding—

(i) the preparedness of the health care (including mental health care) system to respond to public health emergencies as they relate to at-risk individuals;

(ii) needed changes to the health care and emergency medical service systems and emergency medical services protocols to meet the special needs of at-risk individuals; and

(iii) changes, if necessary, to the national stockpile under section 121 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 to meet the emergency health security of at-risk individuals.

(C) COMPOSITION.—The Advisory Committee shall be composed of such Federal officials as may be appropriate to address the special needs of the diverse population groups of at-risk populations.

(D) TERMINATION.—The Advisory Committee terminates six years after the date of the enactment of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

(3) EMERGENCY PUBLIC INFORMATION AND COMMUNICATIONS ADVISORY COMMITTEE.—

(A) IN GENERAL.—For purposes of paragraph (1), the Secretary shall establish an advisory committee to be known as the Emergency Public Information and Communications Advisory Committee (referred to in this paragraph as the "EPIC Advisory Committee").

(B) DUTIES.—The EPIC Advisory Committee shall make recommendations to the Secretary and report on appropriate ways to communicate public health information regarding bioterrorism and other public health emergencies to the public.

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[20] Probably should be "to assist such working group in carrying out its responsibilities under subsection (a)". Formerly there were two working groups, one under subsection (a) and one under subsection (b). Now there is only the working group under subsection (a). See the amendments made by sections 104(a) and 108 of Public Law 107–188 (116 Stat. 605, 609).

[21] The heading for subsection (b)(2) probably should read "NATIONAL ADVISORY COMMITTEE ON AT-RISK INDIVIDUALS AND PUBLIC HEALTH EMERGENCIES". The amendment made by section 301(d)(1) of Public Law 109–417 (120 Stat. 2854) to strike "CHILDREN AND TERRORISM" and insert "AT-RISK INDIVIDUALS AND PUBLIC HEALTH EMERGENCIES" could not be executed due to incorrect capitalization of the word "Children" in the matter to be struck. Also the letter "A" in the word "At-risk" in the inserted text probably should be lowercase type.

(C) COMPOSITION.—The EPIC Advisory Committee shall be composed of individuals representing a diverse group of experts in public health, medicine, communications, behavioral psychology, and other areas determined appropriate by the Secretary.

(D) DISSEMINATION.—The Secretary shall review the recommendations of the EPIC Advisory Committee and ensure that appropriate information is disseminated to the public.

(E) TERMINATION.—The EPIC Advisory Committee terminates one year after the date of the enactment of Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

(c) EXPANSION OF EPIDEMIC INTELLIGENCE SERVICE PROGRAM.—The Secretary may establish 20 officer positions in the Epidemic Intelligence Service Program, in addition to the number of the officer positions offered under such Program in 2006, for individuals who agree to participate, for a period of not less than 2 years, in the Career Epidemiology Field Officer program in a State, local, or tribal health department that serves a health professional shortage area (as defined under section 332(a)), a medically underserved population (as defined under section 330(b)(3)), or a medically underserved area or area at high risk of a public health emergency as designated by the Secretary.

(d) CENTERS FOR PUBLIC HEALTH PREPAREDNESS; CORE CURRICULA AND TRAINING.—

(1) IN GENERAL.—The Secretary may establish at accredited schools of public health, Centers for Public Health Preparedness (hereafter referred to in this section as the "Centers").

(2) ELIGIBILITY.—To be eligible to receive an award under this subsection to establish a Center, an accredited school of public health shall agree to conduct activities consistent with the requirements of this subsection.

(3) CORE CURRICULA.—The Secretary, in collaboration with the Centers and other public or private entities shall establish core curricula based on established competencies leading to a 4-year bachelor's degree, a graduate degree, a combined bachelor and master's degree, or a certificate program, for use by each Center. The Secretary shall disseminate such curricula to other accredited schools of public health and other health professions schools determined appropriate by the Secretary, for voluntary use by such schools.

(4) CORE COMPETENCY-BASED TRAINING PROGRAM.—The Secretary, in collaboration with the Centers and other public or private entities shall facilitate the development of a competency-based training program to train public health practitioners. The Centers shall use such training program to train public health practitioners. The Secretary shall disseminate such training program to other accredited schools of public health, health professions schools, and other public or private entities as determined by the Secretary, for voluntary use by such entities.

(5) CONTENT OF CORE CURRICULA AND TRAINING PROGRAM.—The Secretary shall ensure that the core curricula and training program established pursuant to this subsection respond to the needs of State, local, and tribal public health authorities and integrate and emphasize essential public health security capabilities consistent with section 2802(b)(2).

(6) ACADEMIC-WORKFORCE COMMUNICATION.—As a condition of receiving funding from the Secretary under this subsection, a Center shall collaborate with a State, local, or tribal public health department to—

(A) define the public health preparedness and response needs of the community involved;

(B) assess the extent to which such needs are fulfilled by existing preparedness and response activities of such school or health department, and how such activities may be improved;

(C) prior to developing new materials or trainings, evaluate and utilize relevant materials and trainings developed by others Centers; and

(D) evaluate community impact and the effectiveness of any newly developed materials or trainings.

(7) PUBLIC HEALTH SYSTEMS RESEARCH.—In consultation with relevant public and private entities, the Secretary shall define the existing knowledge base for public health preparedness and response systems, and establish a research agenda based on Federal, State, local, and tribal public health preparedness priorities. As a condition of receiving funding from the Secretary under this subsection, a Center shall conduct public health systems research that is consistent with the agenda described under this paragraph.

(e) ACCELERATED RESEARCH AND DEVELOPMENT ON PRIORITY PATHOGENS AND COUNTERMEASURES.—

(1) IN GENERAL.—With respect to pathogens of potential use in a bioterrorist attack, and other agents that may cause a public health emergency, the Secretary, taking into consideration any recommendations of the working group under subsection (a), shall conduct, and award grants, contracts, or cooperative agreements for, research, investigations, experiments, demonstrations, and studies in the health sciences relating to—

(A) the epidemiology and pathogenesis of such pathogens;

(B) the sequencing of the genomes, or other DNA analysis, or other comparative analysis, of priority pathogens (as determined by the Director of the National Institutes of Health in consultation with the working group established in subsection (a)), in collaboration and coordination with the activities of the Department of Defense and the Joint Genome Institute of the Department of Energy;

(C) the development of priority countermeasures; and

(D) other relevant areas of research;

with consideration given to the needs of children and other vulnerable populations.

(2) PRIORITY.—The Secretary shall give priority under this section to the funding of research and other studies related to priority countermeasures.

(3) ROLE OF DEPARTMENT OF VETERANS AFFAIRS.—In carrying out paragraph (1), the Secretary shall consider using the biomedical research and development capabilities of the Department of Veterans Affairs, in conjunction with that Department's affiliations with health-professions universities. When advantageous to the Government in furtherance of the purposes of such paragraph, the Secretary may enter into cooperative agreements with the Secretary of Veterans Affairs to achieve such purposes.

(4) PRIORITY COUNTERMEASURES.—For purposes of this section, the term "priority countermeasure" means a drug, biological product, device, vaccine, vaccine adjuvant, antiviral, or diagnostic test that the Secretary determines to be—

(A) a priority to treat, identify, or prevent infection by a biological agent or toxin listed pursuant to section 351A(a)(1), or harm from any other agent that may cause a public health emergency; or

(B) a priority to treat, identify, or prevent conditions that may result in adverse health consequences or death and may be caused by the administering of a drug, biological product, device, vaccine, vaccine adjuvant, antiviral, or diagnostic test that is a priority under subparagraph (A).

(f) AUTHORIZATION OF APPROPRIATIONS.—

(1) FISCAL YEAR 2007.—There are authorized to be appropriated to carry out this section for fiscal year 2007—

(A) to carry out subsection (a)—

(i) $5,000,000 to carry out paragraphs (1) through (4); and

(ii) $7,000,000 to carry out paragraph (5);

(B) to carry out subsection (c), $3,000,000; and

(C) to carry out subsection (d), $31,000,000, of which $5,000,000 shall be used to carry out paragraphs (3) through (5) of such subsection.

(2) SUBSEQUENT FISCAL YEARS.—There are authorized to be appropriated such sums as may be necessary to carry out this section for fiscal year 2008 and each subsequent fiscal year.

SEC. 319F–1.[247d–6a] AUTHORITY FOR USE OF CERTAIN PROCEDURES REGARDING QUALIFIED COUNTERMEASURE RESEARCH AND DEVELOPMENT ACTIVITIES.[22].

(a) IN GENERAL.—

(1) AUTHORITY.—In conducting and supporting research and development activities regarding countermeasures under section 319F(h), the Secretary may conduct and support such activities in accordance with this section and, in consultation with the Director of the National Institutes of Health, as part of the program under section 446, if the activities concern qualified countermeasures.

(2) DEFINITIONS.—In this section:

[22] Section 5 of Public Law 108–276 (118 Stat. 860) requires various reports regarding section 319F–1 and related provisions of law. Section 5 is included in the appendix to this compilation.

(A) QUALIFIED COUNTERMEASURE.—The term "qualified countermeasure" means a drug (as that term is defined by section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1))), biological product (as that term is defined by section 351(i) of this Act (42 U.S.C. 262(i))), or device (as that term is defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h))), that the Secretary determines to be a priority (consistent with sections 302(2) and 304(a) of the Homeland Security Act of 2002)—

(i) to diagnose, mitigate, prevent, or treat harm from any biological agent (including organisms that cause an infectious disease) or toxin, chemical, radiological, or nuclear agent that may cause a public health emergency affecting national security;

(ii) to diagnose, mitigate, prevent, or treat harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, biological product, or device that is used as described in this subparagraph; or

(iii) is a product or technology intended to enhance the use or effect of a drug, biological product, or device described in clause (i) or (ii).

(B) INFECTIOUS DISEASE.—The term "infectious disease" means a disease potentially caused by a pathogenic organism (including a bacteria, virus, fungus, or parasite) that is acquired by a person and that reproduces in that person.

(3) INTERAGENCY COOPERATION.—

(A) IN GENERAL.—In carrying out activities under this section, the Secretary is authorized, subject to subparagraph (B), to enter into interagency agreements and other collaborative undertakings with other agencies of the United States Government.

(B) LIMITATION.—An agreement or undertaking under this paragraph shall not authorize another agency to exercise the authorities provided by this section.

(4) AVAILABILITY OF FACILITIES TO THE SECRETARY.—In any grant, contract, or cooperative agreement entered into under the authority provided in this section with respect to a biocontainment laboratory or other related or ancillary specialized research facility that the Secretary determines necessary for the purpose of performing, administering, or supporting qualified countermeasure research and development, the Secretary may provide that the facility that is the object of such grant, contract, or cooperative agreement shall be available as needed to the Secretary to respond to public health emergencies affecting national security.

(5) TRANSFERS OF QUALIFIED COUNTERMEASURES.—Each agreement for an award of a grant, contract, or cooperative agreement under section 319F(h) for the development of a qualified countermeasure shall provide that the recipient of the award will comply with all applicable export-related controls with respect to such countermeasure.

(b) EXPEDITED PROCUREMENT AUTHORITY.—

(1) INCREASED SIMPLIFIED ACQUISITION THRESHOLD FOR QUALIFIED COUNTERMEASURE PROCUREMENTS.—

(A) IN GENERAL.—For any procurement by the Secretary of property or services for use (as determined by the Secretary) in performing, administering, or supporting qualified countermeasure research or development activities under this section that the Secretary determines necessary to respond to pressing research and development needs under this section, the amount specified in section 4(11) of the Office of Federal Procurement Policy Act (41 U.S.C. 403(11)), as applicable pursuant to section 302A(a) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 252a(a)), shall be deemed to be $25,000,000 in the administration, with respect to such procurement, of—

(i) section 303(g)(1)(A) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(g)(1)(A)) and its implementing regulations; and

(ii) section 302A(b) of such Act (41 U.S.C. 252a(b)) and its implementing regulations.

(B) APPLICATION OF CERTAIN PROVISIONS.—Notwithstanding subparagraph (A) and the provision of law and regulations referred to in such subparagraph, each of the following provisions shall apply to procurements described in this paragraph to the same extent that such provisions would apply to such procurements in the absence of subparagraph (A):

(i) Chapter 37 of title 40, United States Code (relating to contract work hours and safety standards).

(ii) Subsections (a) and (b) of section 7 of the Anti-Kickback Act of 1986 (41 U.S.C. 57(a) and (b)).

(iii) Section 304C of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 254d) (relating to the examination of contractor records).

(iv) Section 3131 of title 40, United States Code (relating to bonds of contractors of public buildings or works).

(v) Subsection (a) of section 304 of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 254(a)) (relating to contingent fees to middlemen).

(vi) Section 6002 of the Solid Waste Disposal Act (42 U.S.C. 6962).

(vii) Section 1354 of title 31, United States Code (relating to the limitation on the use of appropriated funds for contracts with entities not meeting veterans employment reporting requirements).

(C) INTERNAL CONTROLS TO BE INSTITUTED.—The Secretary shall institute appropriate internal controls for procurements that are under this paragraph, including requirements with regard to documenting the justification for use of the authority in this paragraph with respect to the procurement involved.

(D) AUTHORITY TO LIMIT COMPETITION.—In conducting a procurement under this paragraph, the Secretary may not use the authority provided for under subparagraph (A) to conduct a procurement on a basis other than full and open competition unless the Secretary determines that the mission of the BioShield Program under the Project BioShield Act of 2004 would be seriously impaired without such a limitation.

(2) PROCEDURES OTHER THAN FULL AND OPEN COMPETITION.—

(A) IN GENERAL.—In using the authority provided in section 303(c)(1) of title III of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(c)(1)) to use procedures other than competitive procedures in the case of a procurement described in paragraph (1) of this subsection, the phrase "available from only one responsible source" in such section 303(c)(1) shall be deemed to mean "available from only one responsible source or only from a limited number of responsible sources".

(B) RELATION TO OTHER AUTHORITIES.—The authority under subparagraph (A) is in addition to any other authority to use procedures other than competitive procedures.

(C) APPLICABLE GOVERNMENT-WIDE REGULATIONS.—The Secretary shall implement this paragraph in accordance with government-wide regulations implementing such section 303(c)(1) (including requirements that offers be solicited from as many potential sources as is practicable under the circumstances, that required notices be published, and that submitted offers be considered), as such regulations apply to procurements for which an agency has authority to use procedures other than competitive procedures when the property or services needed by the agency are available from only one responsible source or only from a limited number of responsible sources and no other type of property or services will satisfy the needs of the agency.

(3) INCREASED MICROPURCHASE THRESHOLD.—

(A) IN GENERAL.—For a procurement described by paragraph (1), the amount specified in subsections (c), (d), and (f) of section 32 of the Office of Federal Procurement Policy Act (41 U.S.C. 428) shall be deemed to be $15,000 in the administration of that section with respect to such procurement.

(B) INTERNAL CONTROLS TO BE INSTITUTED.—The Secretary shall institute appropriate internal controls for purchases that are under this paragraph and that are greater than $2,500.

(C) EXCEPTION TO PREFERENCE FOR PURCHASE CARD MECHANISM.—No provision of law establishing a preference for using a Government purchase card method for purchases shall apply to purchases that are under this paragraph and that are greater than $2,500.

(4) REVIEW.—

(A) REVIEW ALLOWED.—Notwithstanding subsection (f), section 1491 of title 28, United States Code, and section

3556 of title 31 of such Code, review of a contracting agency decision relating to a procurement described in paragraph (1) may be had only by filing a protest—

(i) with a contracting agency; or

(ii) with the Comptroller General under subchapter V of chapter 35 of title 31, United States Code.

(B) OVERRIDE OF STAY OF CONTRACT AWARD OR PERFORMANCE COMMITTED TO AGENCY DISCRETION.—Notwithstanding section 1491 of title 28, United States Code, and section 3553 of title 31 of such Code, the following authorizations by the head of a procuring activity are committed to agency discretion:

(i) An authorization under section 3553(c)(2) of title 31, United States Code, to award a contract for a procurement described in paragraph (1) of this subsection.

(ii) An authorization under section 3553(d)(3)(C) of such title to perform a contract for a procurement described in paragraph (1) of this subsection.

(c) AUTHORITY TO EXPEDITE PEER REVIEW.—

(1) IN GENERAL.—The Secretary may, as the Secretary determines necessary to respond to pressing qualified countermeasure research and development needs under this section, employ such expedited peer review procedures (including consultation with appropriate scientific experts) as the Secretary, in consultation with the Director of NIH, deems appropriate to obtain assessment of scientific and technical merit and likely contribution to the field of qualified countermeasure research, in place of the peer review and advisory council review procedures that would be required under sections 301(a)(3), 405(b)(1)(B), 405(b)(2), 406(a)(3)(A), 492, and 494, as applicable to a grant, contract, or cooperative agreement—

(A) that is for performing, administering, or supporting qualified countermeasure research and development activities; and

(B) the amount of which is not greater than $1,500,000.

(2) SUBSEQUENT PHASES OF RESEARCH.—The Secretary's determination of whether to employ expedited peer review with respect to any subsequent phases of a research grant, contract, or cooperative agreement under this section shall be determined without regard to the peer review procedures used for any prior peer review of that same grant, contract, or cooperative agreement. Nothing in the preceding sentence may be construed to impose any requirement with respect to peer review not otherwise required under any other law or regulation.

(d) AUTHORITY FOR PERSONAL SERVICES CONTRACTS.—

(1) IN GENERAL.—For the purpose of performing, administering, or supporting qualified countermeasure research and development activities, the Secretary may, as the Secretary determines necessary to respond to pressing qualified countermeasure research and development needs under this section, obtain by contract (in accordance with section 3109 of title 5,

United States Code, but without regard to the limitations in such section on the period of service and on pay) the personal services of experts or consultants who have scientific or other professional qualifications, except that in no case shall the compensation provided to any such expert or consultant exceed the daily equivalent of the annual rate of compensation for the President.

(2) FEDERAL TORT CLAIMS ACT COVERAGE.—

(A) IN GENERAL.—A person carrying out a contract under paragraph (1), and an officer, employee, or governing board member of such person, shall, subject to a determination by the Secretary, be deemed to be an employee of the Department of Health and Human Services for purposes of claims under sections 1346(b) and 2672 of title 28, United States Code, for money damages for personal injury, including death, resulting from performance of functions under such contract.

(B) EXCLUSIVITY OF REMEDY.—The remedy provided by subparagraph (A) shall be exclusive of any other civil action or proceeding by reason of the same subject matter against the entity involved (person, officer, employee, or governing board member) for any act or omission within the scope of the Federal Tort Claims Act.

(C) RECOURSE IN CASE OF GROSS MISCONDUCT OR CONTRACT VIOLATION.—

(i) IN GENERAL.—Should payment be made by the United States to any claimant bringing a claim under this paragraph, either by way of administrative determination, settlement, or court judgment, the United States shall have, notwithstanding any provision of State law, the right to recover against any entity identified in subparagraph (B) for that portion of the damages so awarded or paid, as well as interest and any costs of litigation, resulting from the failure of any such entity to carry out any obligation or responsibility assumed by such entity under a contract with the United States or from any grossly negligent or reckless conduct or intentional or willful misconduct on the part of such entity.

(ii) VENUE.—The United States may maintain an action under this subparagraph against such entity in the district court of the United States in which such entity resides or has its principal place of business.

(3) INTERNAL CONTROLS TO BE INSTITUTED.—

(A) IN GENERAL.—The Secretary shall institute appropriate internal controls for contracts under this subsection, including procedures for the Secretary to make a determination of whether a person, or an officer, employee, or governing board member of a person, is deemed to be an employee of the Department of Health and Human Services pursuant to paragraph (2).

(B) DETERMINATION OF EMPLOYEE STATUS TO BE FINAL.—A determination by the Secretary under subparagraph (A) that a person, or an officer, employee, or gov-

erning board member of a person, is or is not deemed to be an employee of the Department of Health and Human Services shall be final and binding on the Secretary and the Attorney General and other parties to any civil action or proceeding.

(4) NUMBER OF PERSONAL SERVICES CONTRACTS LIMITED.—The number of experts and consultants whose personal services are obtained under paragraph (1) shall not exceed 30 at any time.

(e) STREAMLINED PERSONNEL AUTHORITY.—

(1) IN GENERAL.—In addition to any other personnel authorities, the Secretary may, as the Secretary determines necessary to respond to pressing qualified countermeasure research and development needs under this section, without regard to those provisions of title 5, United States Code, governing appointments in the competitive service, and without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates, appoint professional and technical employees, not to exceed 30 such employees at any time, to positions in the National Institutes of Health to perform, administer, or support qualified countermeasure research and development activities in carrying out this section.

(2) LIMITATIONS.—The authority provided for under paragraph (1) shall be exercised in a manner that—

(A) recruits and appoints individuals based solely on their abilities, knowledge, and skills;

(B) does not discriminate for or against any applicant for employment on any basis described in section 2302(b)(1) of title 5, United States Code;

(C) does not allow an official to appoint an individual who is a relative (as defined in section 3110(a)(3) of such title) of such official;

(D) does not discriminate for or against an individual because of the exercise of any activity described in paragraph (9) or (10) of section 2302(b) of such title; and

(E) accords a preference, among equally qualified persons, to persons who are preference eligibles (as defined in section 2108(3) of such title).

(3) INTERNAL CONTROLS TO BE INSTITUTED.—The Secretary shall institute appropriate internal controls for appointments under this subsection.

(f) ACTIONS COMMITTED TO AGENCY DISCRETION.—Actions by the Secretary under the authority of this section are committed to agency discretion.

SEC. 319F–2.[247d–6b] STRATEGIC NATIONAL STOCKPILE AND SECURITY COUNTERMEASURE PROCUREMENTS.[23].

(a) STRATEGIC NATIONAL STOCKPILE.—

(1) IN GENERAL.—The Secretary, in collaboration with the Director of the Centers for Disease Control and Prevention, and in coordination with the Secretary of Homeland Security

[23] Section 5 of Public Law 108–276 (118 Stat. 860) requires various reports regarding section 319F–2 and related provisions of law. Section 5 is included in the appendix to this compilation.

(referred to in this section as the "Homeland Security Secretary"), shall maintain a stockpile or stockpiles of drugs, vaccines and other biological products, medical devices, and other supplies in such numbers, types, and amounts as are determined consistent with section 2811 by the Secretary to be appropriate and practicable, taking into account other available sources, to provide for the emergency health security of the United States, including the emergency health security of children and other vulnerable populations, in the event of a bioterrorist attack or other public health emergency. The Secretary shall conduct an annual review (taking into account at-risk individuals) of the contents of the stockpile, including non-pharmaceutical supplies, and make necessary additions or modifications to the contents based on such review and shall submit such review annually to the appropriate congressional committees of jurisdiction to the extent that disclosure of such information does not compromise national security.

(2) PROCEDURES.—The Secretary, in managing the stockpile under paragraph (1), shall—

(A) consult with the working group under section 319F(a);

(B) ensure that adequate procedures are followed with respect to such stockpile for inventory management and accounting, and for the physical security of the stockpile;

(C) in consultation with Federal, State, and local officials, take into consideration the timing and location of special events;

(D) review and revise, as appropriate, the contents of the stockpile on a regular basis to ensure that emerging threats, advanced technologies, and new countermeasures are adequately considered and that the potential depletion of countermeasures currently in the stockpile is identified and appropriately addressed, including through necessary replenishment;

(E) devise plans for the effective and timely supply-chain management of the stockpile, in consultation with appropriate Federal, State and local agencies, and the public and private health care infrastructure;

(F) deploy the stockpile as required by the Secretary of Homeland Security to respond to an actual or potential emergency;

(G) deploy the stockpile at the discretion of the Secretary to respond to an actual or potential public health emergency or other situation in which deployment is necessary to protect the public health or safety; and

(H) ensure the adequate physical security of the stockpile.

(b) SMALLPOX VACCINE DEVELOPMENT.—

(1) IN GENERAL.—The Secretary shall award contracts, enter into cooperative agreements, or carry out such other activities as may reasonably be required in order to ensure that the stockpile under subsection (a) includes an amount of vaccine against smallpox as determined by such Secretary to be

sufficient to meet the health security needs of the United States.

(2) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to limit the private distribution, purchase, or sale of vaccines from sources other than the stockpile described in subsection (a).

(c) ADDITIONAL AUTHORITY REGARDING PROCUREMENT OF CERTAIN COUNTERMEASURES; AVAILABILITY OF SPECIAL RESERVE FUND.—

(1) IN GENERAL.—

(A) USE OF FUND.—A security countermeasure may, in accordance with this subsection, be procured with amounts in the special reserve fund as defined in subsection (h).

(B) SECURITY COUNTERMEASURE.—For purposes of this subsection, the term "security countermeasure" means a drug (as that term is defined by section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1))), biological product (as that term is defined by section 351(i) of this Act (42 U.S.C. 262(i))), or device (as that term is defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h))) that—

(i)(I) the Secretary determines to be a priority (consistent with sections 302(2) and 304(a) of the Homeland Security Act of 2002) to diagnose, mitigate, prevent, or treat harm from any biological, chemical, radiological, or nuclear agent identified as a material threat under paragraph (2)(A)(ii), or to diagnose, mitigate, prevent, or treat harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, biological product, or device against such an agent;

(II) the Secretary determines under paragraph (2)(B)(ii) to be a necessary countermeasure; and

(III)(aa) is approved or cleared under chapter V of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of this Act; or

(bb) is a countermeasure for which the Secretary determines that sufficient and satisfactory clinical experience or research data (including data, if available, from pre-clinical and clinical trials) support a reasonable conclusion that the countermeasure will qualify for approval or licensing within 10 years after the date of a determination under paragraph (5); or

(ii) is authorized for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act.

(2) DETERMINATION OF MATERIAL THREATS.—

(A) MATERIAL THREAT.—The Homeland Security Secretary, in consultation with the Secretary and the heads of other agencies as appropriate, shall on an ongoing basis—

(i) assess current and emerging threats of chemical, biological, radiological, and nuclear agents; and

(ii) determine which of such agents present a material threat against the United States population sufficient to affect national security.

(B) PUBLIC HEALTH IMPACT; NECESSARY COUNTERMEASURES.—The Secretary shall on an ongoing basis—

(i) assess the potential public health consequences for the United States population of exposure to agents identified under subparagraph (A)(ii); and

(ii) determine, on the basis of such assessment, the agents identified under subparagraph (A)(ii) for which countermeasures are necessary to protect the public health.

(C) NOTICE TO CONGRESS.—The Secretary and the Homeland Security Secretary shall promptly notify the appropriate committees of Congress that a determination has been made pursuant to subparagraph (A) or (B).

(D) ASSURING ACCESS TO THREAT INFORMATION.—In making the assessment and determination required under subparagraph (A), the Homeland Security Secretary shall use all relevant information to which such Secretary is entitled under section 202 of the Homeland Security Act of 2002, including but not limited to information, regardless of its level of classification, relating to current and emerging threats of chemical, biological, radiological, and nuclear agents.

(3) ASSESSMENT OF AVAILABILITY AND APPROPRIATENESS OF COUNTERMEASURES.—

(A) IN GENERAL.—The Secretary, in consultation with the Homeland Security Secretary, shall assess on an ongoing basis the availability and appropriateness of specific countermeasures to address specific threats identified under paragraph (2).

(B) INFORMATION.—The Secretary shall institute a process for making publicly available the results of assessments under subparagraph (A) while withholding such information as—

(i) would, in the judgment of the Secretary, tend to reveal public health vulnerabilities; or

(ii) would otherwise be exempt from disclosure under section 552 of title 5, United States Code.

(4) CALL FOR DEVELOPMENT OF COUNTERMEASURES; COMMITMENT FOR RECOMMENDATION FOR PROCUREMENT.—

(A) PROPOSAL TO THE PRESIDENT.—If, pursuant to an assessment under paragraph (3), the Homeland Security Secretary and the Secretary make a determination that a countermeasure would be appropriate but is either currently not developed or unavailable for procurement as a security countermeasure or is approved, licensed, or cleared only for alternative uses, such Secretaries may jointly submit to the President a proposal to—

(i) issue a call for the development of such countermeasure; and

(ii) make a commitment that, upon the first development of such countermeasure that meets the conditions for procurement under paragraph (5), the Secretaries will, based in part on information obtained pursuant to such call, make a recommendation under

paragraph (6) that the special reserve fund as defined in subsection (h) be made available for the procurement of such countermeasure.

(B) COUNTERMEASURE SPECIFICATIONS.—The Homeland Security Secretary and the Secretary shall, to the extent practicable, include in the proposal under subparagraph (A)—

(i) estimated quantity of purchase (in the form of number of doses or number of effective courses of treatments regardless of dosage form);

(ii) necessary measures of minimum safety and effectiveness;

(iii) estimated price for each dose or effective course of treatment regardless of dosage form; and

(iv) other information that may be necessary to encourage and facilitate research, development, and manufacture of the countermeasure or to provide specifications for the countermeasure.

(C) PRESIDENTIAL APPROVAL.—If the President approves a proposal under subparagraph (A), the Homeland Security Secretary and the Secretary shall make known to persons who may respond to a call for the countermeasure involved—

(i) the call for the countermeasure;

(ii) specifications for the countermeasure under subparagraph (B); and

(iii) the commitment described in subparagraph (A)(ii).

(5) SECRETARY'S DETERMINATION OF COUNTERMEASURES APPROPRIATE FOR FUNDING FROM SPECIAL RESERVE FUND.—

(A) IN GENERAL.—The Secretary, in accordance with the provisions of this paragraph, shall identify specific security countermeasures that the Secretary determines, in consultation with the Homeland Security Secretary, to be appropriate for inclusion in the stockpile under subsection (a) pursuant to procurements made with amounts in the special reserve fund as defined in subsection (h) (referred to in this subsection individually as a "procurement under this subsection").

(B) REQUIREMENTS.—In making a determination under subparagraph (A) with respect to a security countermeasure, the Secretary shall determine and consider the following:

(i) The quantities of the product that will be needed to meet the stockpile needs.

(ii) The feasibility of production and delivery within 10 years of sufficient quantities of the product.

(iii) Whether there is a lack of a significant commercial market for the product at the time of procurement, other than as a security countermeasure.

(6) RECOMMENDATION FOR PRESIDENT'S APPROVAL.—

(A) RECOMMENDATION FOR PROCUREMENT.—In the case of a security countermeasure that the Secretary has, in accordance with paragraphs (3) and (5), determined to be ap-

propriate for procurement under this subsection, the Homeland Security Secretary and the Secretary shall jointly submit to the President, in coordination with the Director of the Office of Management and Budget, a recommendation that the special reserve fund as defined in subsection (h) be made available for the procurement of such countermeasure.

(B) PRESIDENTIAL APPROVAL.—The special reserve fund as defined in subsection (h) is available for a procurement of a security countermeasure only if the President has approved a recommendation under subparagraph (A) regarding the countermeasure.

(C) NOTICE TO APPROPRIATE CONGRESSIONAL COMMITTEES.—The Secretary and the Homeland Security Secretary shall notify the appropriate congressional committees of each decision of the President to approve a recommendation under subparagraph (A). Such notice shall include an explanation of the decision to make available the special reserve fund as defined in subsection (h) for procurement of such a countermeasure, including, where available, the number of, nature of, and other information concerning potential suppliers of such countermeasure, and whether other potential suppliers of the same or similar countermeasures were considered and rejected for procurement under this section and the reasons therefor.

(D) SUBSEQUENT SPECIFIC COUNTERMEASURES.—Procurement under this subsection of a security countermeasure for a particular purpose does not preclude the subsequent procurement under this subsection of any other security countermeasure for such purpose if the Secretary has determined under paragraph (5)(A) that such countermeasure is appropriate for inclusion in the stockpile and if, as determined by the Secretary, such countermeasure provides improved safety or effectiveness, or for other reasons enhances preparedness to respond to threats of use of a biological, chemical, radiological, or nuclear agent. Such a determination by the Secretary is committed to agency discretion.

(E) RULE OF CONSTRUCTION.—Recommendations and approvals under this paragraph apply solely to determinations that the special reserve fund as defined in subsection (h) will be made available for a procurement of a security countermeasure, and not to the substance of contracts for such procurement or other matters relating to awards of such contracts.

(7) PROCUREMENT.—

(A) IN GENERAL.—For purposes of a procurement under this subsection that is approved by the President under paragraph (6), the Homeland Security Secretary and the Secretary shall have responsibilities in accordance with subparagraphs (B) and (C).

(B) INTERAGENCY AGREEMENT; COST.—The Homeland Security Secretary shall enter into an agreement with the Secretary for procurement of a security countermeasure in

accordance with the provisions of this paragraph. The special reserve fund as defined in subsection (h) shall be available for payments made by the Secretary to a vendor for such procurement.

(C) PROCUREMENT.—

(i) IN GENERAL.—The Secretary shall be responsible for—

(I) arranging for procurement of a security countermeasure, including negotiating terms (including quantity, production schedule, and price) of, and entering into, contracts and cooperative agreements, and for carrying out such other activities as may reasonably be required, including advanced research and development, in accordance with the provisions of this subparagraph; and

(II) promulgating such regulations as the Secretary determines necessary to implement the provisions of this subsection.

(ii) CONTRACT TERMS.—A contract for procurements under this subsection shall (or, as specified below, may) include the following terms:

(I) PAYMENT CONDITIONED ON DELIVERY.—The contract shall provide that no payment may be made until delivery of a portion, acceptable to the Secretary, of the total number of units contracted for, except that, notwithstanding any other provision of law, the contract may provide that, if the Secretary determines (in the Secretary's discretion) that an advance payment, partial payment for significant milestones, or payment to increase manufacturing capacity is necessary to ensure success of a project, the Secretary shall pay an amount, not to exceed 10 percent of the contract amount, in advance of delivery. The Secretary shall, to the extent practicable, make the determination of advance payment at the same time as the issuance of a solicitation. The contract shall provide that such advance payment is required to be repaid if there is a failure to perform by the vendor under the contract. The contract may also provide for additional advance payments of 5 percent each for meeting the milestones specified in such contract, except that such payments shall not exceed 50 percent of the total contract amount. If the specified milestones are reached, the advanced payments of 5 percent shall not be required to be repaid. Nothing in this subclause shall be construed as affecting the rights of vendors under provisions of law or regulation (including the Federal Acquisition Regulation) relating to the termination of contracts for the convenience of the Government.

(II) DISCOUNTED PAYMENT.—The contract may provide for a discounted price per unit of a product that is not licensed, cleared, or approved as described in paragraph (1)(B)(i)(III)(aa) at the time of delivery, and may provide for payment of an additional amount per unit if the product becomes so licensed, cleared, or approved before the expiration date of the contract (including an additional amount per unit of product delivered before the effective date of such licensing, clearance, or approval).

(III) CONTRACT DURATION.—The contract shall be for a period not to exceed five years, except that, in first awarding the contract, the Secretary may provide for a longer duration, not exceeding 10 years, if the Secretary determines that complexities or other difficulties in performance under the contract justify such a period. The contract shall be renewable for additional periods, none of which shall exceed five years.

(IV) STORAGE BY VENDOR.—The contract may provide that the vendor will provide storage for stocks of a product delivered to the ownership of the Federal Government under the contract, for such period and under such terms and conditions as the Secretary may specify, and in such case amounts from the special reserve fund as defined in subsection (h) shall be available for costs of shipping, handling, storage, and related costs for such product.

(V) PRODUCT APPROVAL.—The contract shall provide that the vendor seek approval, clearance, or licensing of the product from the Secretary; for a timetable for the development of data and other information to support such approval, clearance, or licensing; and that the Secretary may waive part or all of this contract term on request of the vendor or on the initiative of the Secretary.

(VI) NON-STOCKPILE TRANSFERS OF SECURITY COUNTERMEASURES.—The contract shall provide that the vendor will comply with all applicable export-related controls with respect to such countermeasure.

(VII) SALES EXCLUSIVITY.—The contract may provide that the vendor is the exclusive supplier of the product to the Federal Government for a specified period of time, not to exceed the term of the contract, on the condition that the vendor is able to satisfy the needs of the Government. During the agreed period of sales exclusivity, the vendor shall not assign its rights of sales exclusivity to another entity or entities without approval by the Secretary. Such a sales exclusivity provision in such a contract shall constitute a valid basis for

a sole source procurement under section 303(c)(1) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(c)(1)).

(VIII) WARM BASED SURGE CAPACITY.—The contract may provide that the vendor establish domestic manufacturing capacity of the product to ensure that additional production of the product is available in the event that the Secretary determines that there is a need to quickly purchase additional quantities of the product. Such contract may provide a fee to the vendor for establishing and maintaining such capacity in excess of the initial requirement for the purchase of the product. Additionally, the cost of maintaining the domestic manufacturing capacity shall be an allowable and allocable direct cost of the contract.

(IX) CONTRACT TERMS.—The Secretary, in any contract for procurement under this section—

(aa) may specify—

(AA) the dosing and administration requirements for the countermeasure to be developed and procured;

(BB) the amount of funding that will be dedicated by the Secretary for advanced research, development, and procurement of the countermeasure; and

(CC) the specifications the countermeasure must meet to qualify for procurement under a contract under this section; and

(bb) shall provide a clear statement of defined Government purpose limited to uses related to a security countermeasure, as defined in paragraph (1)(B).

(iii) AVAILABILITY OF SIMPLIFIED ACQUISITION PROCEDURES.—

(I) IN GENERAL.—If the Secretary determines that there is a pressing need for a procurement of a specific countermeasure, the amount of the procurement under this subsection shall be deemed to be below the threshold amount specified in section 4(11) of the Office of Federal Procurement Policy Act (41 U.S.C. 403(11)), for purposes of application to such procurement, pursuant to section 302A(a) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 252a(a)), of—

(aa) section 303(g)(1)(A) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(g)(1)(A)) and its implementing regulations; and

(bb) section 302A(b) of such Act (41 U.S.C. 252a(b)) and its implementing regulations.

(II) APPLICATION OF CERTAIN PROVISIONS.—Notwithstanding subclause (I) and the provision of law and regulations referred to in such clause, each of the following provisions shall apply to procurements described in this clause to the same extent that such provisions would apply to such procurements in the absence of subclause (I):

(aa) Chapter 37 of title 40, United States Code (relating to contract work hours and safety standards).

(bb) Subsections (a) and (b) of section 7 of the Anti-Kickback Act of 1986 (41 U.S.C. 57(a) and (b)).

(cc) Section 304C of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 254d) (relating to the examination of contractor records).

(dd) Section 3131 of title 40, United States Code (relating to bonds of contractors of public buildings or works).

(ee) Subsection (a) of section 304 of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 254(a)) (relating to contingent fees to middlemen).

(ff) Section 6002 of the Solid Waste Disposal Act (42 U.S.C. 6962).

(gg) Section 1354 of title 31, United States Code (relating to the limitation on the use of appropriated funds for contracts with entities not meeting veterans employment reporting requirements).

(III) INTERNAL CONTROLS TO BE ESTABLISHED.—The Secretary shall establish appropriate internal controls for procurements made under this clause, including requirements with respect to documentation of the justification for the use of the authority provided under this paragraph with respect to the procurement involved.

(IV) AUTHORITY TO LIMIT COMPETITION.—In conducting a procurement under this subparagraph, the Secretary may not use the authority provided for under subclause (I) to conduct a procurement on a basis other than full and open competition unless the Secretary determines that the mission of the BioShield Program under the Project BioShield Act of 2004 would be seriously impaired without such a limitation.

(iv) PROCEDURES OTHER THAN FULL AND OPEN COMPETITION.—

(I) IN GENERAL.—In using the authority provided in section 303(c)(1) of title III of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(c)(1)) to use procedures other than competitive procedures in the case of a procure-

ment under this subsection, the phrase "available from only one responsible source" in such section 303(c)(1) shall be deemed to mean "available from only one responsible source or only from a limited number of responsible sources".

(II) RELATION TO OTHER AUTHORITIES.—The authority under subclause (I) is in addition to any other authority to use procedures other than competitive procedures.

(III) APPLICABLE GOVERNMENT-WIDE REGULATIONS.—The Secretary shall implement this clause in accordance with government-wide regulations implementing such section 303(c)(1) (including requirements that offers be solicited from as many potential sources as is practicable under the circumstances, that required notices be published, and that submitted offers be considered), as such regulations apply to procurements for which an agency has authority to use procedures other than competitive procedures when the property or services needed by the agency are available from only one responsible source or only from a limited number of responsible sources and no other type of property or services will satisfy the needs of the agency.

(v) PREMIUM PROVISION IN MULTIPLE AWARD CONTRACTS.—

(I) IN GENERAL.—If, under this subsection, the Secretary enters into contracts with more than one vendor to procure a security countermeasure, such Secretary may, notwithstanding any other provision of law, include in each of such contracts a provision that—

(aa) identifies an increment of the total quantity of security countermeasure required, whether by percentage or by numbers of units; and

(bb) promises to pay one or more specified premiums based on the priority of such vendors' production and delivery of the increment identified under item (aa), in accordance with the terms and conditions of the contract.

(II) DETERMINATION OF GOVERNMENT'S REQUIREMENT NOT REVIEWABLE.—If the Secretary includes in each of a set of contracts a provision as described in subclause (I), such Secretary's determination of the total quantity of security countermeasure required, and any amendment of such determination, is committed to agency discretion.

(vi) EXTENSION OF CLOSING DATE FOR RECEIPT OF PROPOSALS NOT REVIEWABLE.—A decision by the Secretary to extend the closing date for receipt of proposals for a procurement under this subsection is committed to agency discretion.

(vii) LIMITING COMPETITION TO SOURCES RESPONDING TO REQUEST FOR INFORMATION.—In conducting a procurement under this subsection, the Secretary may exclude a source that has not responded to a request for information under section 303A(a)(1)(B) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253a(a)(1)(B)) if such request has given notice that the Secretary may so exclude such a source.

(viii) FLEXIBILITY.—In carrying out this section, the Secretary may, consistent with the applicable provisions of this section, enter into contracts and other agreements that are in the best interest of the Government in meeting identified security countermeasure needs, including with respect to reimbursement of the cost of advanced research and development as a reasonable, allowable, and allocable direct cost of the contract involved.

(8) INTERAGENCY COOPERATION.—

(A) IN GENERAL.—In carrying out activities under this section, the Homeland Security Secretary and the Secretary are authorized, subject to subparagraph (B), to enter into interagency agreements and other collaborative undertakings with other agencies of the United States Government. Such agreements may allow other executive agencies to order qualified and security countermeasures under procurement contracts or other agreements established by the Secretary. Such ordering process (including transfers of appropriated funds between an agency and the Department of Health and Human Services as reimbursements for such orders for countermeasures) may be conducted under the authority of section 1535 of title 31, United States Code, except that all such orders shall be processed under the terms established under this subsection for the procurement of countermeasures.

(B) LIMITATION.—An agreement or undertaking under this paragraph shall not authorize another agency to exercise the authorities provided by this section to the Homeland Security Secretary or to the Secretary.

(d) DISCLOSURES.—No Federal agency shall disclose under section 552 of title 5, United States Code, any information identifying the location at which materials in the stockpile under subsection (a) are stored.

(e) DEFINITION.—For purposes of subsection (a), the term "stockpile" includes—

(1) a physical accumulation (at one or more locations) of the supplies described in subsection (a); or

(2) a contractual agreement between the Secretary and a vendor or vendors under which such vendor or vendors agree to provide to such Secretary supplies described in subsection (a).

(f) AUTHORIZATION OF APPROPRIATIONS.—

(1) STRATEGIC NATIONAL STOCKPILE.—For the purpose of carrying out subsection (a), there are authorized to be appropriated $533,800,000 for each of fiscal years 2014 through

2018. Such authorization is in addition to amounts in the special reserve fund referred to in subsection (h).

(2) SMALLPOX VACCINE DEVELOPMENT.—For the purpose of carrying out subsection (b), there are authorized to be appropriated $509,000,000 for fiscal year 2002, and such sums as may be necessary for each of fiscal years 2003 through 2006.

(g) SPECIAL RESERVE FUND.—

(1) AUTHORIZATION OF APPROPRIATIONS.—In addition to amounts appropriated to the special reserve fund prior to the date of the enactment of this subsection, there is authorized to be appropriated, for the procurement of security countermeasures under subsection (c) and for carrying out section 319L (relating to the Biomedical Advanced Research and Development Authority), $2,800,000,000 for the period of fiscal years 2014 through 2018. Amounts appropriated pursuant to the preceding sentence are authorized to remain available until September 30, 2019.

(2) USE OF SPECIAL RESERVE FUND FOR ADVANCED RESEARCH AND DEVELOPMENT.—The Secretary may utilize not more than 50 percent of the amounts authorized to be appropriated under paragraph (1) to carry out section 319L (related to the Biomedical Advanced Research and Development Authority). Amounts authorized to be appropriated under this subsection to carry out section 319L are in addition to amounts otherwise authorized to be appropriated to carry out such section.

(3) RESTRICTIONS ON USE OF FUNDS.—Amounts in the special reserve fund shall not be used to pay costs other than payments made by the Secretary to a vendor for advanced development (under section 319L) or for procurement of a security countermeasure under subsection (c)(7).

(4) REPORT.—Not later than 30 days after any date on which the Secretary determines that the amount of funds in the special reserve fund available for procurement is less than $1,500,000,000, the Secretary shall submit to the appropriate committees of Congress a report detailing the amount of such funds available for procurement and the impact such reduction in funding will have—

(A) in meeting the security countermeasure needs identified under this section; and

(B) on the annual Public Health Emergency Medical Countermeasures Enterprise and Strategy Implementation Plan (pursuant to section 2811(d)).

(h) DEFINITIONS.—In this section:

(1) The term "advanced research and development" has the meaning given such term in section 319L(a).

(2) The term "special reserve fund" means the "Biodefense Countermeasures" appropriations account, any appropriation made available pursuant to section 521(a) of the Homeland Security Act of 2002, and any appropriation made available pursuant to subsection (g)(1).

SEC. 319F–3.[247d–6d] TARGETED LIABILITY PROTECTIONS FOR PANDEMIC AND EPIDEMIC PRODUCTS AND SECURITY COUNTERMEASURES.

(a) LIABILITY PROTECTIONS.—

(1) IN GENERAL.—Subject to the other provisions of this section, a covered person shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure if a declaration under subsection (b) has been issued with respect to such countermeasure.

(2) SCOPE OF CLAIMS FOR LOSS.—

(A) LOSS.—For purposes of this section, the term "loss" means any type of loss, including—

(i) death;

(ii) physical, mental, or emotional injury, illness, disability, or condition;

(iii) fear of physical, mental, or emotional injury, illness, disability, or condition, including any need for medical monitoring; and

(iv) loss of or damage to property, including business interruption loss.

Each of clauses (i) through (iv) applies without regard to the date of the occurrence, presentation, or discovery of the loss described in the clause.

(B) SCOPE.—The immunity under paragraph (1) applies to any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure, including a causal relationship with the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use of such countermeasure.

(3) CERTAIN CONDITIONS.—Subject to the other provisions of this section, immunity under paragraph (1) with respect to a covered countermeasure applies only if—

(A) the countermeasure was administered or used during the effective period of the declaration that was issued under subsection (b) with respect to the countermeasure;

(B) the countermeasure was administered or used for the category or categories of diseases, health conditions, or threats to health specified in the declaration; and

(C) in addition, in the case of a covered person who is a program planner or qualified person with respect to the administration or use of the countermeasure, the countermeasure was administered to or used by an individual who—

(i) was in a population specified by the declaration; and

(ii) was at the time of administration physically present in a geographic area specified by the declaration or had a connection to such area specified in the declaration.

(4) APPLICABILITY OF CERTAIN CONDITIONS.—With respect to immunity under paragraph (1) and subject to the other provisions of this section:

(A) In the case of a covered person who is a manufacturer or distributor of the covered countermeasure involved, the immunity applies without regard to whether such countermeasure was administered to or used by an individual in accordance with the conditions described in paragraph (3)(C).

(B) In the case of a covered person who is a program planner or qualified person with respect to the administration or use of the covered countermeasure, the scope of immunity includes circumstances in which the countermeasure was administered to or used by an individual in circumstances in which the covered person reasonably could have believed that the countermeasure was administered or used in accordance with the conditions described in paragraph (3)(C).

(5) EFFECT OF DISTRIBUTION METHOD.—The provisions of this section apply to a covered countermeasure regardless of whether such countermeasure is obtained by donation, commercial sale, or any other means of distribution, except to the extent that, under paragraph (2)(E) of subsection (b), the declaration under such subsection provides that subsection (a) applies only to covered countermeasures obtained through a particular means of distribution.

(6) REBUTTABLE PRESUMPTION.—For purposes of paragraph (1), there shall be a rebuttable presumption that any administration or use, during the effective period of the emergency declaration by the Secretary under subsection (b), of a covered countermeasure shall have been for the category or categories of diseases, health conditions, or threats to health with respect to which such declaration was issued.

(b) DECLARATION BY SECRETARY.—

(1) AUTHORITY TO ISSUE DECLARATION.—Subject to paragraph (2), if the Secretary makes a determination that a disease or other health condition or other threat to health constitutes a public health emergency, or that there is a credible risk that the disease, condition, or threat may in the future constitute such an emergency, the Secretary may make a declaration, through publication in the Federal Register, recommending, under conditions as the Secretary may specify, the manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures, and stating that subsection (a) is in effect with respect to the activities so recommended.

(2) CONTENTS.—In issuing a declaration under paragraph (1), the Secretary shall identify, for each covered countermeasure specified in the declaration—

(A) the category or categories of diseases, health conditions, or threats to health for which the Secretary recommends the administration or use of the countermeasure;

(B) the period or periods during which, including as modified by paragraph (3), subsection (a) is in effect, which

period or periods may be designated by dates, or by milestones or other description of events, including factors specified in paragraph (6);

(C) the population or populations of individuals for which subsection (a) is in effect with respect to the administration or use of the countermeasure (which may be a specification that such subsection applies without geographic limitation to all individuals);

(D) the geographic area or areas for which subsection (a) is in effect with respect to the administration or use of the countermeasure (which may be a specification that such subsection applies without geographic limitation), including, with respect to individuals in the populations identified under subparagraph (C), a specification, as determined appropriate by the Secretary, of whether the declaration applies only to individuals physically present in such areas or whether in addition the declaration applies to individuals who have a connection to such areas, which connection is described in the declaration; and

(E) whether subsection (a) is effective only to a particular means of distribution as provided in subsection (a)(5) for obtaining the countermeasure, and if so, the particular means to which such subsection is effective.

(3) EFFECTIVE PERIOD OF DECLARATION.—

(A) FLEXIBILITY OF PERIOD.—The Secretary may, in describing periods under paragraph (2)(B), have different periods for different covered persons to address different logistical, practical or other differences in responsibilities.

(B) ADDITIONAL TIME TO BE SPECIFIED.—In each declaration under paragraph (1), the Secretary, after consulting, to the extent the Secretary deems appropriate, with the manufacturer of the covered countermeasure, shall also specify a date that is after the ending date specified under paragraph (2)(B) and that allows what the Secretary determines is—

(i) a reasonable period for the manufacturer to arrange for disposition of the covered countermeasure, including the return of such product to the manufacturer; and

(ii) a reasonable period for covered persons to take such other actions as may be appropriate to limit administration or use of the covered countermeasure.

(C) ADDITIONAL PERIOD FOR CERTAIN STRATEGIC NATIONAL STOCKPILE COUNTERMEASURES.—With respect to a covered countermeasure that is in the stockpile under section 319F-2, if such countermeasure was the subject of a declaration under paragraph (1) at the time that it was obtained for the stockpile, the effective period of such declaration shall include a period when the countermeasure is administered or used pursuant to a distribution or release from the stockpile.

(4) AMENDMENTS TO DECLARATION.—The Secretary may through publication in the Federal Register amend any portion of a declaration under paragraph (1). Such an amendment

shall not retroactively limit the applicability of subsection (a) with respect to the administration or use of the covered countermeasure involved.

(5) CERTAIN DISCLOSURES.—In publishing a declaration under paragraph (1) in the Federal Register, the Secretary is not required to disclose any matter described in section 552(b) of title 5, United States Code.

(6) FACTORS TO BE CONSIDERED.—In deciding whether and under what circumstances or conditions to issue a declaration under paragraph (1) with respect to a covered countermeasure, the Secretary shall consider the desirability of encouraging the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of such countermeasure.

(7) JUDICIAL REVIEW.—No court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary under this subsection.

(8) PREEMPTION OF STATE LAW.—During the effective period of a declaration under subsection (b), or at any time with respect to conduct undertaken in accordance with such declaration, no State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that—

(A) is different from, or is in conflict with, any requirement applicable under this section; and

(B) relates to the design, development, clinical testing or investigation, formulation, manufacture, distribution, sale, donation, purchase, marketing, promotion, packaging, labeling, licensing, use, any other aspect of safety or efficacy, or the prescribing, dispensing, or administration by qualified persons of the covered countermeasure, or to any matter included in a requirement applicable to the covered countermeasure under this section or any other provision of this Act, or under the Federal Food, Drug, and Cosmetic Act.

(9) REPORT TO CONGRESS.—Within 30 days after making a declaration under paragraph (1), the Secretary shall submit to the appropriate committees of the Congress a report that provides an explanation of the reasons for issuing the declaration and the reasons underlying the determinations of the Secretary with respect to paragraph (2). Within 30 days after making an amendment under paragraph (4), the Secretary shall submit to such committees a report that provides the reasons underlying the determination of the Secretary to make the amendment.

(c) DEFINITION OF WILLFUL MISCONDUCT.—

(1) DEFINITION.—

(A) IN GENERAL.—Except as the meaning of such term is further restricted pursuant to paragraph (2), the term "willful misconduct" shall, for purposes of subsection (d), denote an act or omission that is taken—

(i) intentionally to achieve a wrongful purpose;

(ii) knowingly without legal or factual justification; and

(iii) in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit.

(B) RULE OF CONSTRUCTION.—The criterion stated in subparagraph (A) shall be construed as establishing a standard for liability that is more stringent than a standard of negligence in any form or recklessness.

(2) AUTHORITY TO PROMULGATE REGULATORY DEFINITION.—

(A) IN GENERAL.—The Secretary, in consultation with the Attorney General, shall promulgate regulations, which may be promulgated through interim final rules, that further restrict the scope of actions or omissions by a covered person that may qualify as "willful misconduct" for purposes of subsection (d).

(B) FACTORS TO BE CONSIDERED.—In promulgating the regulations under this paragraph, the Secretary, in consultation with the Attorney General, shall consider the need to define the scope of permissible civil actions under subsection (d) in a way that will not adversely affect the public health.

(C) TEMPORAL SCOPE OF REGULATIONS.—The regulations under this paragraph may specify the temporal effect that they shall be given for purposes of subsection (d).

(D) INITIAL RULEMAKING.—Within 180 days after the enactment of the Public Readiness and Emergency Preparedness Act, the Secretary, in consultation with the Attorney General, shall commence and complete an initial rulemaking process under this paragraph.

(3) PROOF OF WILLFUL MISCONDUCT.—In an action under subsection (d), the plaintiff shall have the burden of proving by clear and convincing evidence willful misconduct by each covered person sued and that such willful misconduct caused death or serious physical injury.

(4) DEFENSE FOR ACTS OR OMISSIONS TAKEN PURSUANT TO SECRETARY'S DECLARATION.—Notwithstanding any other provision of law, a program planner or qualified person shall not have engaged in "willful misconduct" as a matter of law where such program planner or qualified person acted consistent with applicable directions, guidelines, or recommendations by the Secretary regarding the administration or use of a covered countermeasure that is specified in the declaration under subsection (b), provided either the Secretary, or a State or local health authority, was provided with notice of information regarding serious physical injury or death from the administration or use of a covered countermeasure that is material to the plaintiff's alleged loss within 7 days of the actual discovery of such information by such program planner or qualified person.

(5) EXCLUSION FOR REGULATED ACTIVITY OF MANUFACTURER OR DISTRIBUTOR.—

(A) IN GENERAL.—If an act or omission by a manufacturer or distributor with respect to a covered countermeasure, which act or omission is alleged under subsection

(e)(3)(A) to constitute willful misconduct, is subject to regulation by this Act or by the Federal Food, Drug, and Cosmetic Act, such act or omission shall not constitute "willful misconduct" for purposes of subsection (d) if—

(i) neither the Secretary nor the Attorney General has initiated an enforcement action with respect to such act or omission; or

(ii) such an enforcement action has been initiated and the action has been terminated or finally resolved without a covered remedy.

Any action or proceeding under subsection (d) shall be stayed during the pendency of such an enforcement action.

(B) DEFINITIONS.—For purposes of this paragraph, the following terms have the following meanings:

(i) ENFORCEMENT ACTION.—The term "enforcement action" means a criminal prosecution, an action seeking an injunction, a seizure action, a civil monetary proceeding based on willful misconduct, a mandatory recall of a product because voluntary recall was refused, a proceeding to compel repair or replacement of a product, a termination of an exemption under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act, a debarment proceeding, an investigator disqualification proceeding where an investigator is an employee or agent of the manufacturer, a revocation, based on willful misconduct, of an authorization under section 564 of such Act, or a suspension or withdrawal, based on willful misconduct, of an approval or clearance under chapter V of such Act or of a licensure under section 351 of this Act.

(ii) COVERED REMEDY.—The term "covered remedy" means an outcome—

(I) that is a criminal conviction, an injunction, or a condemnation, a civil monetary payment, a product recall, a repair or replacement of a product, a termination of an exemption under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act, a debarment, an investigator disqualification, a revocation of an authorization under section 564 of such Act, or a suspension or withdrawal of an approval or clearance under chapter 5 of such Act or of a licensure under section 351 of this Act; and

(II) that results from a final determination by a court or from a final agency action.

(iii) FINAL.—The terms "final" and "finally"—

(I) with respect to a court determination, or to a final resolution of an enforcement action that is a court determination, mean a judgment from which an appeal of right cannot be taken or a voluntary or stipulated dismissal; and

(II) with respect to an agency action, or to a final resolution of an enforcement action that is an agency action, mean an order that is not sub-

ject to further review within the agency and that has not been reversed, vacated, enjoined, or otherwise nullified by a final court determination or a voluntary or stipulated dismissal.

(C) RULES OF CONSTRUCTION.—

(i) IN GENERAL.—Nothing in this paragraph shall be construed—

(I) to affect the interpretation of any provision of the Federal Food, Drug, and Cosmetic Act, of this Act, or of any other applicable statute or regulation; or

(II) to impair, delay, alter, or affect the authority, including the enforcement discretion, of the United States, of the Secretary, of the Attorney General, or of any other official with respect to any administrative or court proceeding under this Act, under the Federal Food, Drug, and Cosmetic Act, under title 18 of the United States Code, or under any other applicable statute or regulation.

(ii) MANDATORY RECALLS.—A mandatory recall called for in the declaration is not a Food and Drug Administration enforcement action.

(d) EXCEPTION TO IMMUNITY OF COVERED PERSONS.—

(1) IN GENERAL.—Subject to subsection (f), the sole exception to the immunity from suit and liability of covered persons set forth in subsection (a) shall be for an exclusive Federal cause of action against a covered person for death or serious physical injury proximately caused by willful misconduct, as defined pursuant to subsection (c), by such covered person. For purposes of section 2679(b)(2)(B) of title 28, United States Code, such a cause of action is not an action brought for violation of a statute of the United States under which an action against an individual is otherwise authorized.

(2) PERSONS WHO CAN SUE.—An action under this subsection may be brought for wrongful death or serious physical injury by any person who suffers such injury or by any representative of such a person.

(e) PROCEDURES FOR SUIT.—

(1) EXCLUSIVE FEDERAL JURISDICTION.—Any action under subsection (d) shall be filed and maintained only in the United States District Court for the District of Columbia.

(2) GOVERNING LAW.—The substantive law for decision in an action under subsection (d) shall be derived from the law, including choice of law principles, of the State in which the alleged willful misconduct occurred, unless such law is inconsistent with or preempted by Federal law, including provisions of this section.

(3) PLEADING WITH PARTICULARITY.—In an action under subsection (d), the complaint shall plead with particularity each element of the plaintiff's claim, including—

(A) each act or omission, by each covered person sued, that is alleged to constitute willful misconduct relating to

the covered countermeasure administered to or used by the person on whose behalf the complaint was filed;

(B) facts supporting the allegation that such alleged willful misconduct proximately caused the injury claimed; and

(C) facts supporting the allegation that the person on whose behalf the complaint was filed suffered death or serious physical injury.

(4) VERIFICATION, CERTIFICATION, AND MEDICAL RECORDS.—

(A) IN GENERAL.—In an action under subsection (d), the plaintiff shall verify the complaint in the manner stated in subparagraph (B) and shall file with the complaint the materials described in subparagraph (C). A complaint that does not substantially comply with subparagraphs (B) and (C) shall not be accepted for filing and shall not stop the running of the statute of limitations.

(B) VERIFICATION REQUIREMENT.—

(i) IN GENERAL.—The complaint shall include a verification, made by affidavit of the plaintiff under oath, stating that the pleading is true to the knowledge of the deponent, except as to matters specifically identified as being alleged on information and belief, and that as to those matters the plaintiff believes it to be true.

(ii) IDENTIFICATION OF MATTERS ALLEGED UPON INFORMATION AND BELIEF.—Any matter that is not specifically identified as being alleged upon the information and belief of the plaintiff, shall be regarded for all purposes, including a criminal prosecution, as having been made upon the knowledge of the plaintiff.

(C) MATERIALS REQUIRED.—In an action under subsection (d), the plaintiff shall file with the complaint—

(i) an affidavit, by a physician who did not treat the person on whose behalf the complaint was filed, certifying, and explaining the basis for such physician's belief, that such person suffered the serious physical injury or death alleged in the complaint and that such injury or death was proximately caused by the administration or use of a covered countermeasure; and

(ii) certified medical records documenting such injury or death and such proximate causal connection.

(5) THREE-JUDGE COURT.—Any action under subsection (d) shall be assigned initially to a panel of three judges. Such panel shall have jurisdiction over such action for purposes of considering motions to dismiss, motions for summary judgment, and matters related thereto. If such panel has denied such motions, or if the time for filing such motions has expired, such panel shall refer the action to the chief judge for assignment for further proceedings, including any trial. Section 1253 of title 28, United States Code, and paragraph (3) of subsection (b) of section 2284 of title 28, United States Code, shall not apply to actions under subsection (d).

(6) CIVIL DISCOVERY.—

(A) TIMING.—In an action under subsection (d), no discovery shall be allowed—

(i) before each covered person sued has had a reasonable opportunity to file a motion to dismiss;

(ii) in the event such a motion is filed, before the court has ruled on such motion; and

(iii) in the event a covered person files an interlocutory appeal from the denial of such a motion, before the court of appeals has ruled on such appeal.

(B) STANDARD.—Notwithstanding any other provision of law, the court in an action under subsection (d) shall permit discovery only with respect to matters directly related to material issues contested in such action, and the court shall compel a response to a discovery request (including a request for admission, an interrogatory, a request for production of documents, or any other form of discovery request) under Rule 37, Federal Rules of Civil Procedure, only if the court finds that the requesting party needs the information sought to prove or defend as to a material issue contested in such action and that the likely benefits of a response to such request equal or exceed the burden or cost for the responding party of providing such response.

(7) REDUCTION IN AWARD OF DAMAGES FOR COLLATERAL SOURCE BENEFITS.—

(A) IN GENERAL.—In an action under subsection (d), the amount of an award of damages that would otherwise be made to a plaintiff shall be reduced by the amount of collateral source benefits to such plaintiff.

(B) PROVIDER OF COLLATERAL SOURCE BENEFITS NOT TO HAVE LIEN OR SUBROGATION.—No provider of collateral source benefits shall recover any amount against the plaintiff or receive any lien or credit against the plaintiff's recovery or be equitably or legally subrogated to the right of the plaintiff in an action under subsection (d).

(C) COLLATERAL SOURCE BENEFIT DEFINED.—For purposes of this paragraph, the term "collateral source benefit" means any amount paid or to be paid in the future to or on behalf of the plaintiff, or any service, product, or other benefit provided or to be provided in the future to or on behalf of the plaintiff, as a result of the injury or wrongful death, pursuant to—

(i) any State or Federal health, sickness, income-disability, accident, or workers' compensation law;

(ii) any health, sickness, income-disability, or accident insurance that provides health benefits or income-disability coverage;

(iii) any contract or agreement of any group, organization, partnership, or corporation to provide, pay for, or reimburse the cost of medical, hospital, dental, or income disability benefits; or

(iv) any other publicly or privately funded program.

(8) NONECONOMIC DAMAGES.—In an action under subsection (d), any noneconomic damages may be awarded only in an amount directly proportional to the percentage of responsibility of a defendant for the harm to the plaintiff. For purposes of this paragraph, the term "noneconomic damages" means damages for losses for physical and emotional pain, suffering, inconvenience, physical impairment, mental anguish, disfigurement, loss of enjoyment of life, loss of society and companionship, loss of consortium, hedonic damages, injury to reputation, and any other nonpecuniary losses.

(9) RULE 11 SANCTIONS.—Whenever a district court of the United States determines that there has been a violation of Rule 11 of the Federal Rules of Civil Procedure in an action under subsection (d), the court shall impose upon the attorney, law firm, or parties that have violated Rule 11 or are responsible for the violation, an appropriate sanction, which may include an order to pay the other party or parties for the reasonable expenses incurred as a direct result of the filing of the pleading, motion, or other paper that is the subject of the violation, including a reasonable attorney's fee. Such sanction shall be sufficient to deter repetition of such conduct or comparable conduct by others similarly situated, and to compensate the party or parties injured by such conduct.

(10) INTERLOCUTORY APPEAL.—The United States Court of Appeals for the District of Columbia Circuit shall have jurisdiction of an interlocutory appeal by a covered person taken within 30 days of an order denying a motion to dismiss or a motion for summary judgment based on an assertion of the immunity from suit conferred by subsection (a) or based on an assertion of the exclusion under subsection (c)(5).

(f) ACTIONS BY AND AGAINST THE UNITED STATES.—Nothing in this section shall be construed to abrogate or limit any right, remedy, or authority that the United States or any agency thereof may possess under any other provision of law or to waive sovereign immunity or to abrogate or limit any defense or protection available to the United States or its agencies, instrumentalities, officers, or employees under any other law, including any provision of chapter 171 of title 28, United States Code (relating to tort claims procedure).

(g) SEVERABILITY.—If any provision of this section, or the application of such provision to any person or circumstance, is held to be unconstitutional, the remainder of this section and the application of such remainder to any person or circumstance shall not be affected thereby.

(h) RULE OF CONSTRUCTION CONCERNING NATIONAL VACCINE INJURY COMPENSATION PROGRAM.—Nothing in this section, or any amendment made by the Public Readiness and Emergency Preparedness Act, shall be construed to affect the National Vaccine Injury Compensation Program under title XXI of this Act.

(i) DEFINITIONS.—In this section:

(1) COVERED COUNTERMEASURE.—The term "covered countermeasure" means—

(A) a qualified pandemic or epidemic product (as defined in paragraph (7));

(B) a security countermeasure (as defined in section 319F–2(c)(1)(B)); or

(C) a drug (as such term is defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)), biological product (as such term is defined by section 351(i) of this Act), or device (as such term is defined by section 201(h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321(h)) that is authorized for emergency use in accordance with section 564, 564A, or 564B of the Federal Food, Drug, and Cosmetic Act.

(2) COVERED PERSON.—The term "covered person", when used with respect to the administration or use of a covered countermeasure, means—

(A) the United States; or

(B) a person or entity that is—

(i) a manufacturer of such countermeasure;

(ii) a distributor of such countermeasure;

(iii) a program planner of such countermeasure;

(iv) a qualified person who prescribed, administered, or dispensed such countermeasure; or

(v) an official, agent, or employee of a person or entity described in clause (i), (ii), (iii), or (iv).

(3) DISTRIBUTOR.—The term "distributor" means a person or entity engaged in the distribution of drugs, biologics, or devices, including but not limited to manufacturers; repackers; common carriers; contract carriers; air carriers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies.

(4) MANUFACTURER.—The term "manufacturer" includes—

(A) a contractor or subcontractor of a manufacturer;

(B) a supplier or licenser of any product, intellectual property, service, research tool, or component or other article used in the design, development, clinical testing, investigation, or manufacturing of a covered countermeasure; and

(C) any or all of the parents, subsidiaries, affiliates, successors, and assigns of a manufacturer.

(5) PERSON.—The term "person" includes an individual, partnership, corporation, association, entity, or public or private corporation, including a Federal, State, or local government agency or department.

(6) PROGRAM PLANNER.—The term "program planner" means a State or local government, including an Indian tribe, a person employed by the State or local government, or other person who supervised or administered a program with respect to the administration, dispensing, distribution, provision, or use of a security countermeasure or a qualified pandemic or epidemic product, including a person who has established requirements, provided policy guidance, or supplied technical or scientific advice or assistance or provides a facility to administer or use a covered countermeasure in accordance with a declaration under subsection (b).

(7) QUALIFIED PANDEMIC OR EPIDEMIC PRODUCT.—The term "qualified pandemic or epidemic product" means a drug (as such term is defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)), biological product (as such term is defined by section 351(i) of this Act), or device (as such term is defined by section 201(h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321(h)) that is—

(A)(i) a product manufactured, used, designed, developed, modified, licensed, or procured—

(I) to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic; or

(II) to limit the harm such pandemic or epidemic might otherwise cause;

(ii) a product manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a serious or life-threatening disease or condition caused by a product described in clause (i); or

(iii)[24] a product or technology intended to enhance the use or effect of a drug, biological product, or device described in clause (i) or (ii); and

(B)(i) approved or cleared under chapter V of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of this Act;

(ii) the object of research for possible use as described by subparagraph (A) and is the subject of an exemption under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act; or

(iii) authorized for emergency use in accordance with section 564, 564A, or 564B of the Federal Food, Drug, and Cosmetic Act.

(8) QUALIFIED PERSON.—The term "qualified person", when used with respect to the administration or use of a covered countermeasure, means—

(A) a licensed health professional or other individual who is authorized to prescribe, administer, or dispense such countermeasures under the law of the State in which the countermeasure was prescribed, administered, or dispensed; or

(B) a person within a category of persons so identified in a declaration by the Secretary under subsection (b).

(9) SECURITY COUNTERMEASURE.—The term "security countermeasure" has the meaning given such term in section 319F–2(c)(1)(B).

(10) SERIOUS PHYSICAL INJURY.—The term "serious physical injury" means an injury that—

(A) is life threatening;

(B) results in permanent impairment of a body function or permanent damage to a body structure; or

(C) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

[24] Margin of clause (iii) so in law.

SEC. 319F–4.[247d–6e] COVERED COUNTERMEASURE PROCESS.

(a) ESTABLISHMENT OF FUND.—Upon the issuance by the Secretary of a declaration under section 319F–3(b), there is hereby established in the Treasury an emergency fund designated as the "Covered Countermeasure Process Fund" for purposes of providing timely, uniform, and adequate compensation to eligible individuals for covered injuries directly caused by the administration or use of a covered countermeasure pursuant to such declaration, which Fund shall consist of such amounts designated as emergency appropriations under section 402 of H. Con. Res. 95 of the 109th Congress, this emergency designation shall remain in effect through October 1, 2006.

(b) PAYMENT OF COMPENSATION.—

(1) IN GENERAL.—If the Secretary issues a declaration under 319F–3(b), the Secretary shall, after amounts have by law been provided for the Fund under subsection (a), provide compensation to an eligible individual for a covered injury directly caused by the administration or use of a covered countermeasure pursuant to such declaration.

(2) ELEMENTS OF COMPENSATION.—The compensation that shall be provided pursuant to paragraph (1) shall have the same elements, and be in the same amount, as is prescribed by sections 264, 265, and 266 in the case of certain individuals injured as a result of administration of certain countermeasures against smallpox, except that section 266(a)(2)(B) shall not apply.

(3) RULE OF CONSTRUCTION.—Neither reasonable and necessary medical benefits nor lifetime total benefits for lost employment income due to permanent and total disability shall be limited by section 266.

(4) DETERMINATION OF ELIGIBILITY AND COMPENSATION.—Except as provided in this section, the procedures for determining, and for reviewing a determination of, whether an individual is an eligible individual, whether such individual has sustained a covered injury, whether compensation may be available under this section, and the amount of such compensation shall be those stated in section 262 (other than in subsection (d)(2) of such section), in regulations issued pursuant to that section, and in such additional or alternate regulations as the Secretary may promulgate for purposes of this section. In making determinations under this section, other than those described in paragraph (5)(A) as to the direct causation of a covered injury, the Secretary may only make such determination based on compelling, reliable, valid, medical and scientific evidence.

(5) COVERED COUNTERMEASURE INJURY TABLE.—

(A) IN GENERAL.—The Secretary shall by regulation establish a table identifying covered injuries that shall be presumed to be directly caused by the administration or use of a covered countermeasure and the time period in which the first symptom or manifestation of onset of each such adverse effect must manifest in order for such presumption to apply. The Secretary may only identify such covered injuries, for purpose of inclusion on the table,

where the Secretary determines, based on compelling, reliable, valid, medical and scientific evidence that administration or use of the covered countermeasure directly caused such covered injury.

(B) AMENDMENTS.—The provisions of section 263 (other than a provision of subsection (a)(2) of such section that relates to accidental vaccinia inoculation) shall apply to the table established under this section.

(C) JUDICIAL REVIEW.—No court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary under this paragraph.

(6) MEANINGS OF TERMS.—In applying sections 262, 263, 264, 265, and 266 for purposes of this section—

(A) the terms "vaccine" and "smallpox vaccine" shall be deemed to mean a covered countermeasure;

(B) the terms "smallpox vaccine injury table" and "table established under section 263" shall be deemed to refer to the table established under paragraph (4); and

(C) other terms used in those sections shall have the meanings given to such terms by this section.

(c) VOLUNTARY PROGRAM.—The Secretary shall ensure that a State, local, or Department of Health and Human Services plan to administer or use a covered countermeasure is consistent with any declaration under 319F–3 and any applicable guidelines of the Centers for Disease Control and Prevention and that potential participants are educated with respect to contraindications, the voluntary nature of the program, and the availability of potential benefits and compensation under this part.

(d) EXHAUSTION; EXCLUSIVITY; ELECTION.—

(1) EXHAUSTION.—Subject to paragraph (5), a covered individual may not bring a civil action under section 319F–3(d) against a covered person (as such term is defined in section 319F–3(i)(2)) unless such individual has exhausted such remedies as are available under subsection (a), except that if amounts have not by law been provided for the Fund under subsection (a), or if the Secretary fails to make a final determination on a request for benefits or compensation filed in accordance with the requirements of this section within 240 days after such request was filed, the individual may seek any remedy that may be available under section 319F–3(d).

(2) TOLLING OF STATUTE OF LIMITATIONS.—The time limit for filing a civil action under section 319F–3(d) for an injury or death shall be tolled during the pendency of a claim for compensation under subsection (a).

(3) RULE OF CONSTRUCTION.—This section shall not be construed as superseding or otherwise affecting the application of a requirement, under chapter 171 of title 28, United States Code, to exhaust administrative remedies.

(4) EXCLUSIVITY.—The remedy provided by subsection (a) shall be exclusive of any other civil action or proceeding for any claim or suit this section encompasses, except for a proceeding under section 319F–3.

(5) ELECTION.—If under subsection (a) the Secretary determines that a covered individual qualifies for compensation, the individual has an election to accept the compensation or to bring an action under section 319F–3(d). If such individual elects to accept the compensation, the individual may not bring such an action.

(e) DEFINITIONS.—For purposes of this section, the following terms shall have the following meanings:

(1) COVERED COUNTERMEASURE.—The term "covered countermeasure" has the meaning given such term in section 319F–3.

(2) COVERED INDIVIDUAL.—The term "covered individual", with respect to administration or use of a covered countermeasure pursuant to a declaration, means an individual—

(A) who is in a population specified in such declaration, and with respect to whom the administration or use of the covered countermeasure satisfies the other specifications of such declaration; or

(B) who uses the covered countermeasure, or to whom the covered countermeasure is administered, in a good faith belief that the individual is in the category described by subparagraph (A).

(3) COVERED INJURY.—The term "covered injury" means serious physical injury or death.

(4) DECLARATION.—The term "declaration" means a declaration under section 319F–3(b).

(5) ELIGIBLE INDIVIDUAL.—The term "eligible individual" means an individual who is determined, in accordance with subsection (b), to be a covered individual who sustains a covered injury.

SEC. 319G.[247d–7] DEMONSTRATION PROGRAM TO ENHANCE BIOTERRORISM TRAINING, COORDINATION, AND READINESS.

(a) IN GENERAL.—The Secretary shall make grants to not more than three eligible entities to carry out demonstration programs to improve the detection of pathogens likely to be used in a bioterrorist attack, the development of plans and measures to respond to bioterrorist attacks, and the training of personnel involved with the various responsibilities and capabilities needed to respond to acts of bioterrorism upon the civilian population. Such awards shall be made on a competitive basis and pursuant to scientific and technical review.

(b) ELIGIBLE ENTITIES.—Eligible entities for grants under subsection (a) are States, political subdivisions of States, and public or private non-profit organizations.

(c) SPECIFIC CRITERIA.—In making grants under subsection (a), the Secretary shall take into account the following factors:

(1) Whether the eligible entity involved is proximate to, and collaborates with, a major research university with expertise in scientific training, identification of biological agents, medicine, and life sciences.

(2) Whether the entity is proximate to, and collaborates with, a laboratory that has expertise in the identification of biological agents.

(3) Whether the entity demonstrates, in the application for the program, support and participation of State and local governments and research institutions in the conduct of the program.

(4) Whether the entity is proximate to, and collaborates with, or is, an academic medical center that has the capacity to serve an uninsured or underserved population, and is equipped to educate medical personnel.

(5) Such other factors as the Secretary determines to be appropriate.

(d) DURATION OF AWARD.—The period during which payments are made under a grant under subsection (a) may not exceed 5 years. The provision of such payments shall be subject to annual approval by the Secretary of the payments and subject to the availability of appropriations for the fiscal year involved to make the payments.

(e) SUPPLEMENT NOT SUPPLANT.—Grants under subsection (a) shall be used to supplement, and not supplant, other Federal, State, or local public funds provided for the activities described in such subsection.

(f) GENERAL ACCOUNTING OFFICE REPORT[25].—Not later than 180 days after the conclusion of the demonstration programs carried out under subsection (a), the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate, and the Committee on Commerce and the Committee on Appropriations of the House of Representatives, a report that describes the ability of grantees under such subsection to detect pathogens likely to be used in a bioterrorist attack, develop plans and measures for dealing with such threats, and train personnel involved with the various responsibilities and capabilities needed to deal with bioterrorist threats.

(g) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $6,000,000 for fiscal year 2001, and such sums as may be necessary through fiscal year 2006.

SEC. 319H.[247d–7a] GRANTS REGARDING TRAINING AND EDUCATION OF CERTAIN HEALTH PROFESSIONALS.

(a) IN GENERAL.—The Secretary may make awards of grants and cooperative agreements to appropriate public and nonprofit private health or educational entities, including health professions schools and programs as defined in section 799B, for the purpose of providing low-interest loans, partial scholarships, partial fellowships, revolving loan funds, or other cost-sharing forms of assistance for the education and training of individuals in any category of health professions for which there is a shortage that the Secretary determines should be alleviated in order to prepare for or respond effectively to bioterrorism and other public health emergencies.

(b) AUTHORITY REGARDING NON-FEDERAL CONTRIBUTIONS.—The Secretary may require as a condition of an award under sub-

[25] Now the Government Accountability Office. See section 8 of Public Law 108–271 (118 Stat. 814).

section (a) that a grantee under such subsection provide non-Federal contributions toward the purpose described in such subsection.

(c) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2002 through 2006.

SEC. 319I.[247d–7b] EMERGENCY SYSTEM FOR ADVANCE REGISTRATION OF HEALTH PROFESSIONS VOLUNTEERS.

(a) IN GENERAL.—Not later than 12 months after the date of enactment of the Pandemic and All-Hazards Preparedness Act, the Secretary shall link existing State verification systems to maintain a single national interoperable network of systems, each system being maintained by a State or group of States, for the purpose of verifying the credentials and licenses of health care professionals who volunteer to provide health services during a public health emergency.

(b) REQUIREMENTS.—The interoperable network of systems established under subsection (a) (referred to in this section as the "verification network") shall include—

(1) with respect to each volunteer health professional included in the verification network—

(A) information necessary for the rapid identification of, and communication with, such professionals; and

(B) the credentials, certifications, licenses, and relevant training of such individuals; and

(2) the name of each member of the Medical Reserve Corps, the National Disaster Medical System, and any other relevant federally-sponsored or administered programs determined necessary by the Secretary.

(c) OTHER ASSISTANCE.—The Secretary may make grants and provide technical assistance to States and other public or nonprofit private entities for activities relating to the verification network developed under subsection (a).

(d) ACCESSIBILITY.—The Secretary shall ensure that the verification network is electronically accessible by State, local, and tribal health departments and can be linked with the identification cards under section 2813.

(e) CONFIDENTIALITY.—The Secretary shall establish and require the application of and compliance with measures to ensure the effective security of, integrity of, and access to the data included in the verification network.

(f) COORDINATION.—The Secretary shall coordinate with the Secretary of Veterans Affairs and the Secretary of Homeland Security to assess the feasibility of integrating the verification network under this section with the VetPro system of the Department of Veterans Affairs and the National Emergency Responder Credentialing System of the Department of Homeland Security. The Secretary shall, if feasible, integrate the verification network under this section with such VetPro system and the National Emergency Responder Credentialing System.

(g) UPDATING OF INFORMATION.—The States that are participants in the verification network shall, on at least a quarterly basis, work with the Director to provide for the updating of the information contained in the verification network.

(h) CLARIFICATION.—Inclusion of a health professional in the verification network shall not constitute appointment of such individual as a Federal employee for any purpose, either under section 2812(c) or otherwise. Such appointment may only be made under section 2812 or 2813.

(i) HEALTH CARE PROVIDER LICENSES.—The Secretary shall encourage States to establish and implement mechanisms to waive the application of licensing requirements applicable to health professionals, who are seeking to provide medical services (within their scope of practice), during a national, State, local, or tribal public health emergency upon verification that such health professionals are licensed and in good standing in another State and have not been disciplined by any State health licensing or disciplinary board.

(j) RULE OF CONSTRUCTION.—This section may not be construed as authorizing the Secretary to issue requirements regarding the provision by the States of credentials, licenses, accreditations, or hospital privileges.

(k) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $5,000,000 for each of fiscal years 2014 through 2018.

SEC. 319J.[247d–7c] SUPPLIES AND SERVICES IN LIEU OF AWARD FUNDS.

(a) IN GENERAL.—Upon the request of a recipient of an award under any of sections 319 through 319I or section 319K, the Secretary may, subject to subsection (b), provide supplies, equipment, and services for the purpose of aiding the recipient in carrying out the purposes for which the award is made and, for such purposes, may detail to the recipient any officer or employee of the Department of Health and Human Services.

(b) CORRESPONDING REDUCTION IN PAYMENTS.—With respect to a request described in subsection (a), the Secretary shall reduce the amount of payments under the award involved by an amount equal to the costs of detailing personnel and the fair market value of any supplies, equipment, or services provided by the Secretary. The Secretary shall, for the payment of expenses incurred in complying with such request, expend the amounts withheld.

SEC. 319K.[247d–7d] SECURITY FOR COUNTERMEASURE DEVELOPMENT AND PRODUCTION.

(a) IN GENERAL.—The Secretary, in consultation with the Attorney General and the Secretary of Defense, may provide technical or other assistance to provide security to persons or facilities that conduct development, production, distribution, or storage of priority countermeasures (as defined in section 319F(h)(4)).

(b) GUIDELINES.—The Secretary may develop guidelines to enable entities eligible to receive assistance under subsection (a) to secure their facilities against potential terrorist attack.

SEC. 319L.[247d–7e] BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY.

(a) DEFINITIONS.—In this section:

(1) BARDA.—The term "BARDA" means the Biomedical Advanced Research and Development Authority.

(2) FUND.—The term "Fund" means the Biodefense Medical Countermeasure Development Fund established under subsection (d).

(3) OTHER TRANSACTIONS.—The term "other transactions" means transactions, other than procurement contracts, grants, and cooperative agreements, such as the Secretary of Defense may enter into under section 2371 of title 10, United States Code.

(4) QUALIFIED COUNTERMEASURE.—The term "qualified countermeasure" has the meaning given such term in section 319F–1.

(5) QUALIFIED PANDEMIC OR EPIDEMIC PRODUCT.—The term "qualified pandemic or epidemic product" has the meaning given the term in section 319F–3.

(6) ADVANCED RESEARCH AND DEVELOPMENT.—

(A) IN GENERAL.—The term "advanced research and development" means, with respect to a product that is or may become a qualified countermeasure or a qualified pandemic or epidemic product, activities that predominantly—

(i) are conducted after basic research and preclinical development of the product; and

(ii) are related to manufacturing the product on a commercial scale and in a form that satisfies the regulatory requirements under the Federal Food, Drug, and Cosmetic Act or under section 351 of this Act.

(B) ACTIVITIES INCLUDED.—The term under subparagraph (A) includes—

(i) testing of the product to determine whether the product may be approved, cleared, or licensed under the Federal Food, Drug, and Cosmetic Act or under section 351 of this Act for a use that is or may be the basis for such product becoming a qualified countermeasure or qualified pandemic or epidemic product, or to help obtain such approval, clearance, or license;

(ii) design and development of tests or models, including animal models, for such testing;

(iii) activities to facilitate manufacture of the product on a commercial scale with consistently high quality, as well as to improve and make available new technologies to increase manufacturing surge capacity;

(iv) activities to improve the shelf-life of the product or technologies for administering the product; and

(v) such other activities as are part of the advanced stages of testing, refinement, improvement, or preparation of the product for such use and as are specified by the Secretary.

(7) SECURITY COUNTERMEASURE.—The term "security countermeasure" has the meaning given such term in section 319F–2.

(8) RESEARCH TOOL.—The term "research tool" means a device, technology, biological material (including a cell line or an antibody), reagent, animal model, computer system, computer software, or analytical technique that is developed to assist in

the discovery, development, or manufacture of qualified countermeasures or qualified pandemic or epidemic products.

(9) PROGRAM MANAGER.—The term "program manager" means an individual appointed to carry out functions under this section and authorized to provide project oversight and management of strategic initiatives.

(10) PERSON.—The term "person" includes an individual, partnership, corporation, association, entity, or public or private corporation, and a Federal, State, or local government agency or department.

(b) STRATEGIC PLAN FOR COUNTERMEASURE RESEARCH, DEVELOPMENT, AND PROCUREMENT.—

(1) IN GENERAL.—Not later than 6 months after the date of enactment of the Pandemic and All-Hazards Preparedness Act, the Secretary shall develop and make public a strategic plan to integrate biodefense and emerging infectious disease requirements with the advanced research and development, strategic initiatives for innovation, and the procurement of qualified countermeasures and qualified pandemic or epidemic products. The Secretary shall carry out such activities as may be practicable to disseminate the information contained in such plan to persons who may have the capacity to substantially contribute to the activities described in such strategic plan. The Secretary shall update and incorporate such plan as part of the National Health Security Strategy described in section 2802.

(2) CONTENT.—The strategic plan under paragraph (1) shall guide—

(A) research and development, conducted or supported by the Department of Health and Human Services, of qualified countermeasures and qualified pandemic or epidemic products against possible biological, chemical, radiological, and nuclear agents and to emerging infectious diseases;

(B) innovation in technologies that may assist advanced research and development of qualified countermeasures and qualified pandemic or epidemic products (such research and development referred to in this section as "countermeasure and product advanced research and development"); and

(C) procurement of such qualified countermeasures and qualified pandemic or epidemic products by such Department.

(c) BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY.—

(1) ESTABLISHMENT.—There is established within the Department of Health and Human Services the Biomedical Advanced Research and Development Authority.

(2) IN GENERAL.—Based upon the strategic plan described in subsection (b), the Secretary shall coordinate the acceleration of countermeasure and product advanced research and development by—

(A) facilitating collaboration between the Department of Health and Human Services and other Federal agencies,

relevant industries, academia, and other persons, with respect to such advanced research and development;

(B) promoting countermeasure and product advanced research and development;

(C) facilitating contacts between interested persons and the offices or employees authorized by the Secretary to advise such persons regarding requirements under the Federal Food, Drug, and Cosmetic Act and under section 351 of this Act; and

(D) promoting innovation to reduce the time and cost of countermeasure and product advanced research and development.

(3) DIRECTOR.—The BARDA shall be headed by a Director (referred to in this section as the "Director") who shall be appointed by the Secretary and to whom the Secretary shall delegate such functions and authorities as necessary to implement this section.

(4) DUTIES.—

(A) COLLABORATION.—To carry out the purpose described in paragraph (2)(A), the Secretary shall—

(i) facilitate and increase the expeditious and direct communication between the Department of Health and Human Services and relevant persons with respect to countermeasure and product advanced research and development, including by—

(I) facilitating such communication regarding the processes for procuring such advanced research and development with respect to qualified countermeasures and qualified pandemic or epidemic products of interest; and

(II) soliciting information about and data from research on potential qualified countermeasures and qualified pandemic or epidemic products and related technologies;

(ii) at least annually—

(I) convene meetings with representatives from relevant industries, academia, other Federal agencies, international agencies as appropriate, and other interested persons;

(II) sponsor opportunities to demonstrate the operation and effectiveness of relevant biodefense countermeasure technologies; and

(III) convene such working groups on countermeasure and product advanced research and development as the Secretary may determine are necessary to carry out this section; and

(iii) carry out the activities described in section 405 of the Pandemic and All-Hazards Preparedness Act.

(B) SUPPORT ADVANCED RESEARCH AND DEVELOPMENT.—To carry out the purpose described in paragraph (2)(B), the Secretary shall—

(i) conduct ongoing searches for, and support calls for, potential qualified countermeasures and qualified pandemic or epidemic products;

(ii) direct and coordinate the countermeasure and product advanced research and development activities of the Department of Health and Human Services;

(iii) establish strategic initiatives to accelerate countermeasure and product advanced research and development (which may include advanced research and development for purposes of fulfilling requirements under the Federal Food, Drug, and Cosmetic Act or section 351 of this Act) and innovation in such areas as the Secretary may identify as priority unmet need areas; and

(iv) award contracts, grants, cooperative agreements, and enter into other transactions, for countermeasure and product advanced research and development.

(C) FACILITATING ADVICE.—To carry out the purpose described in paragraph (2)(C) the Secretary shall—

(i) connect interested persons with the offices or employees authorized by the Secretary to advise such persons regarding the regulatory requirements under the Federal Food, Drug, and Cosmetic Act and under section 351 of this Act related to the approval, clearance, or licensure of qualified countermeasures or qualified pandemic or epidemic products; and

(ii) with respect to persons performing countermeasure and product advanced research and development funded under this section, enable such offices or employees to provide to the extent practicable such advice in a manner that is ongoing and that is otherwise designed to facilitate expeditious development of qualified countermeasures and qualified pandemic or epidemic products that may achieve such approval, clearance, or licensure.

(D) SUPPORTING INNOVATION.—To carry out the purpose described in paragraph (2)(D), the Secretary may award contracts, grants, and cooperative agreements, or enter into other transactions, such as prize payments, to promote—

(i) innovation in technologies that may assist countermeasure and product advanced research and development;

(ii) research on and development of research tools and other devices and technologies; and

(iii) research to promote strategic initiatives, such as rapid diagnostics, broad spectrum antimicrobials, vaccine-manufacturing technologies, dose-sparing technologies, efficacy-increasing technologies, and platform technologies.

(5) TRANSACTION AUTHORITIES.—

(A) OTHER TRANSACTIONS.—

(i) IN GENERAL.—The Secretary shall have the authority to enter into other transactions under this subsection in the same manner as the Secretary of Defense enters into such transactions under section 2371 of title 10, United States Code.

(ii) LIMITATIONS ON AUTHORITY.—

(I) IN GENERAL.—Subsections (b), (c), and (h) of section 845 of the National Defense Authorization Act for Fiscal Year 1994 (10 U.S.C. 2371 note) shall apply to other transactions under this subparagraph as if such transactions were for prototype projects described by subsection (a) of such section 845.

(II) WRITTEN DETERMINATIONS REQUIRED.—The authority of this subparagraph may be exercised for a project that is expected to cost the Department of Health and Human Services in excess of $20,000,000 only upon a written determination by the senior procurement executive for the Department (as designated for purpose of section 16(c) of the Office of Federal Procurement Policy Act (41 U.S.C. 414(c))), that the use of such authority is essential to promoting the success of the project. The authority of the senior procurement executive under this subclause may not be delegated.

(iii) GUIDELINES.—The Secretary shall establish guidelines regarding the use of the authority under clause (i). Such guidelines shall include auditing requirements.

(B) EXPEDITED AUTHORITIES.—

(i) IN GENERAL.—In awarding contracts, grants, and cooperative agreements, and in entering into other transactions under subparagraph (B) or (D) of paragraph (4), the Secretary shall have the expedited procurement authorities, the authority to expedite peer review, and the authority for personal services contracts, supplied by subsections (b), (c), and (d) of section 319F–1.

(ii) APPLICATION OF PROVISIONS.—Provisions in such section 319F–1 that apply to such authorities and that require institution of internal controls, limit review, provide for Federal Tort Claims Act coverage of personal services contractors, and commit decisions to the discretion of the Secretary shall apply to the authorities as exercised pursuant to this paragraph.

(iii) AUTHORITY TO LIMIT COMPETITION.—For purposes of applying section 319F–1(b)(1)(D) to this paragraph, the phrase "BioShield Program under the Project BioShield Act of 2004" shall be deemed to mean the countermeasure and product advanced research and development program under this section.

(iv) AVAILABILITY OF DATA.—The Secretary shall require that, as a condition of being awarded a con-

tract, grant, cooperative agreement, or other transaction under subparagraph (B) or (D) of paragraph (4), a person make available to the Secretary on an ongoing basis, and submit upon request to the Secretary, all data related to or resulting from countermeasure and product advanced research and development carried out pursuant to this section.

(C) ADVANCE PAYMENTS; ADVERTISING.—The Secretary may waive the requirements of section 3324(a) of title 31, United States Code, or section 3709 of the Revised Statutes of the United States (41 U.S.C. 5) upon the determination by the Secretary that such waiver is necessary to obtain countermeasures or products under this section.

(D) MILESTONE-BASED PAYMENTS ALLOWED.—In awarding contracts, grants, and cooperative agreements, and in entering into other transactions, under this section, the Secretary may use milestone-based awards and payments.

(E) FOREIGN NATIONALS ELIGIBLE.—The Secretary may under this section award contracts, grants, and cooperative agreements to, and may enter into other transactions with, highly qualified foreign national persons outside the United States, alone or in collaboration with American participants, when such transactions may inure to the benefit of the American people.

(F) ESTABLISHMENT OF RESEARCH CENTERS.—The Secretary may assess the feasibility and appropriateness of establishing, through contract, grant, cooperative agreement, or other transaction, an arrangement with an existing research center in order to achieve the goals of this section. If such an agreement is not feasible and appropriate, the Secretary may establish one or more federally-funded research and development centers, or university-affiliated research centers, in accordance with section 303(c)(3) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(c)(3)).

(G) GOVERNMENT PURPOSE.—In awarding contracts, grants, and cooperative agreements under this section, the Secretary shall provide a clear statement of defined Government purpose related to activities included in subsection (a)(6)(B) for a qualified countermeasure or qualified pandemic or epidemic product.

(6) AT-RISK INDIVIDUALS.—In carrying out the functions under this section, the Secretary may give priority to the advanced research and development of qualified countermeasures and qualified pandemic or epidemic products that are likely to be safe and effective with respect to children, pregnant women, elderly, and other at-risk individuals.

(7) PERSONNEL AUTHORITIES.—

(A) SPECIALLY QUALIFIED SCIENTIFIC AND PROFESSIONAL PERSONNEL.—

(i) IN GENERAL.—In addition to any other personnel authorities, the Secretary may—

(I) without regard to those provisions of title 5, United States Code, governing appointments in

the competitive service, appoint highly qualified individuals to scientific or professional positions in BARDA, such as program managers, to carry out this section; and

(II) compensate them in the same manner and subject to the same terms and conditions in which individuals appointed under section 9903 of such title are compensated, without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates.

(ii) MANNER OF EXERCISE OF AUTHORITY.—The authority provided for in this subparagraph shall be exercised subject to the same limitations described in section 319F–1(e)(2).

(iii) TERM OF APPOINTMENT.—The term limitations described in section 9903(c) of title 5, United States Code, shall apply to appointments under this subparagraph, except that the references to the "Secretary" and to the "Department of Defense's national security missions" shall be deemed to be to the Secretary of Health and Human Services and to the mission of the Department of Health and Human Services under this section.

(B) SPECIAL CONSULTANTS.—In carrying out this section, the Secretary may appoint special consultants pursuant to section 207(f).

(C) LIMITATION.—

(i) IN GENERAL.—The Secretary may hire up to 100 highly qualified individuals, or up to 50 percent of the total number of employees, whichever is less, under the authorities provided for in subparagraphs (A) and (B).

(ii) REPORT.—The Secretary shall report to Congress on a biennial basis on the implementation of this subparagraph.

(d) FUND.—

(1) ESTABLISHMENT.—There is established the Biodefense Medical Countermeasure Development Fund, which shall be available to carry out this section in addition to such amounts as are otherwise available for this purpose.

(2) FUNDING.—To carry out the purposes of this section, there is authorized to be appropriated to the Fund $415,000,000 for each of fiscal years 2014 through 2018, such amounts to remain available until expended.

(e) INAPPLICABILITY OF CERTAIN PROVISIONS.—

(1) DISCLOSURE.—

(A) IN GENERAL.—The Secretary shall withhold from disclosure under section 552 of title 5, United States Code, specific technical data or scientific information that is created or obtained during the countermeasure and product advanced research and development carried out under subsection (c) that reveals significant and not otherwise publicly known vulnerabilities of existing medical or public

health defenses against biological, chemical, nuclear, or radiological threats. Such information shall be deemed to be information described in section 552(b)(3) of title 5, United States Code.

(B) REVIEW.—Information subject to nondisclosure under subparagraph (A) shall be reviewed by the Secretary every 5 years, or more frequently as determined necessary by the Secretary, to determine the relevance or necessity of continued nondisclosure.

(C) SUNSET.—This paragraph shall cease to have force or effect on the date that is 12 years after the date of enactment of the Pandemic and All-Hazards Preparedness Act.

(2) REVIEW.—Notwithstanding section 14 of the Federal Advisory Committee Act, a working group of BARDA under this section and the National Biodefense Science Board under section 319M shall each terminate on the date that is 5 years after the date on which each such group or Board, as applicable, was established. Such 5-year period may be extended by the Secretary for one or more additional 5-year periods if the Secretary determines that any such extension is appropriate.

(f) INDEPENDENT EVALUATION.—

(1) IN GENERAL.—Not later than 180 days after the date of enactment of this subsection, the Comptroller General of the United States shall conduct an independent evaluation of the activities carried out to facilitate flexible manufacturing capacity pursuant to this section.

(2) REPORT.—Not later than 1 year after the date of enactment of this subsection, the Comptroller General of the United States shall submit to the appropriate committees of Congress a report concerning the results of the evaluation conducted under paragraph (1). Such report shall review and assess—

(A) the extent to which flexible manufacturing capacity under this section is dedicated to chemical, biological, radiological, and nuclear threats;

(B) the activities supported by flexible manufacturing initiatives; and

(C) the ability of flexible manufacturing activities carried out under this section to—

(i) secure and leverage leading technical expertise with respect to countermeasure advanced research, development, and manufacturing processes; and

(ii) meet the surge manufacturing capacity needs presented by novel and emerging threats, including chemical, biological, radiological, and nuclear agents.

SEC. 319M.[247d–f] NATIONAL BIODEFENSE SCIENCE BOARD AND WORKING GROUPS.

(a) IN GENERAL.—

(1) ESTABLISHMENT AND FUNCTION.—The Secretary shall establish the National Biodefense Science Board (referred to in this section as the "Board") to provide expert advice and guidance to the Secretary on scientific, technical and other matters of special interest to the Department of Health and Human Services regarding current and future chemical, biological, nu-

clear, and radiological agents, whether naturally occurring, accidental, or deliberate.

(2) MEMBERSHIP.—The membership of the Board shall be comprised of individuals who represent the Nation's preeminent scientific, public health, and medical experts, as follows—

(A) such Federal officials as the Secretary may determine are necessary to support the functions of the Board;

(B) four individuals representing the pharmaceutical, biotechnology, and device industries;

(C) four individuals representing academia; and

(D) five other members as determined appropriate by the Secretary, of whom—

(i) one such member shall be a practicing healthcare professional;

(ii) one such member shall be an individual from an organization representing healthcare consumers;

(iii) one such member shall be an individual with pediatric subject matter expertise; and

(iv) one such member shall be a State, tribal, territorial, or local public health official.

Nothing in this paragraph shall preclude a member of the Board from satisfying two or more of the requirements described in subparagraph (D).

(3) TERM OF APPOINTMENT.—A member of the Board described in subparagraph (B), (C), or (D) of paragraph (2) shall serve for a term of 3 years, except that the Secretary may adjust the terms of the initial Board appointees in order to provide for a staggered term of appointment for all members.

(4) CONSECUTIVE APPOINTMENTS; MAXIMUM TERMS.—A member may be appointed to serve not more than 3 terms on the Board and may serve not more than 2 consecutive terms.

(5) DUTIES.—The Board shall—

(A) advise the Secretary on current and future trends, challenges, and opportunities presented by advances in biological and life sciences, biotechnology, and genetic engineering with respect to threats posed by naturally occurring infectious diseases and chemical, biological, radiological, and nuclear agents;

(B) at the request of the Secretary, review and consider any information and findings received from the working groups established under subsection (b);

(C) at the request of the Secretary, provide recommendations and findings for expanded, intensified, and coordinated biodefense research and development activities; and

(D) provide any recommendation, finding, or report provided to the Secretary under this paragraph to the appropriate committees of Congress.

(6) MEETINGS.—

(A) INITIAL MEETING.—Not later than one year after the date of enactment of the Pandemic and All-Hazards Preparedness Act, the Secretary shall hold the first meeting of the Board.

(B) SUBSEQUENT MEETINGS.—The Board shall meet at the call of the Secretary, but in no case less than twice annually.

(7) VACANCIES.—Any vacancy in the Board shall not affect its powers, but shall be filled in the same manner as the original appointment.

(8) CHAIRPERSON.—The Secretary shall appoint a chairperson from among the members of the Board.

(9) POWERS.—

(A) HEARINGS.—The Board may hold such hearings, sit and act at such times and places, take such testimony, and receive such evidence as the Board considers advisable to carry out this subsection.

(B) POSTAL SERVICES.—The Board may use the United States mails in the same manner and under the same conditions as other departments and agencies of the Federal Government.

(10) PERSONNEL.—

(A) EMPLOYEES OF THE FEDERAL GOVERNMENT.—A member of the Board that is an employee of the Federal Government may not receive additional pay, allowances, or benefits by reason of the member's service on the Board.

(B) OTHER MEMBERS.—A member of the Board that is not an employee of the Federal Government may be compensated at a rate not to exceed the daily equivalent of the annual rate of basic pay prescribed for level IV of the Executive Schedule under section 5315 of title 5, United States Code, for each day (including travel time) during which the member is engaged in the actual performance of duties as a member of the Board.

(C) TRAVEL EXPENSES.—Each member of the Board shall receive travel expenses, including per diem in lieu of subsistence, in accordance with applicable provisions under subchapter I of chapter 57 of title 5, United States Code.

(D) DETAIL OF GOVERNMENT EMPLOYEES.—Any Federal Government employee may be detailed to the Board with the approval for the contributing agency without reimbursement, and such detail shall be without interruption or loss of civil service status or privilege.

(b) OTHER WORKING GROUPS.—The Secretary may establish a working group of experts, or may use an existing working group or advisory committee, to—

(1) identify innovative research with the potential to be developed as a qualified countermeasure or a qualified pandemic or epidemic product;

(2) identify accepted animal models for particular diseases and conditions associated with any biological, chemical, radiological, or nuclear agent, any toxin, or any potential pandemic infectious disease, and identify strategies to accelerate animal model and research tool development and validation; and

(3) obtain advice regarding supporting and facilitating advanced research and development related to qualified countermeasures and qualified pandemic or epidemic products that

are likely to be safe and effective with respect to children, pregnant women, and other vulnerable populations, and other issues regarding activities under this section that affect such populations.

(c) DEFINITIONS.—Any term that is defined in section 319L and that is used in this section shall have the same meaning in this section as such term is given in section 319L.

(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated $1,000,000 to carry out this section for fiscal year 2007 and each fiscal year thereafter.

HANSEN'S DISEASE PROGRAM.

SEC. 320.[247e] (a)(1) At or through the National Hansen's Disease Programs Center (located in the State of Louisiana), the Secretary shall without charge provide short-term care and treatment, including outpatient care, for Hansen's disease and related complications to any person determined by the Secretary to be in need of such care and treatment. The Secretary may not at or through such Center provide long-term care for any such disease or complication.

(2) The Center referred to in paragraph (1) shall conduct training in the diagnosis and management of Hansen's disease and related complications, and shall conduct and promote the coordination of research (including clinical research), investigations, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of Hansen's disease and other mycobacterial diseases and complications related to such diseases.

(3) Paragraph (1) is subject to section 211 of the Department of Health and Human Services Appropriations Act, 1998.[26]

(b) In addition to the Center referred to in subsection (a), the Secretary may establish sites regarding persons with Hansen's disease. Each such site shall provide for the outpatient care and treatment for Hansen's disease and related complications to any person determined by the Secretary to be in need of such care and treatment.

(c) The Secretary shall carry out subsections (a) and (b) acting through an agency of the Service. For purposes of the preceding sentence, the agency designated by the Secretary shall carry out both activities relating to the provision of health services and activities relating to the conduct of research.

(d) The Secretary shall make payments to the Board of Health of the State of Hawaii for the care and treatment (including outpatient care) in its facilities of persons suffering from Hansen's disease at a rate determined by the Secretary. The rate shall be approximately equal to the operating cost per patient of such facilities, except that the rate may not exceed the comparable costs per patient with Hansen's disease for care and treatment provided by the Center referred to in subsection (a). Payments under this subsection are subject to the availability of appropriations for such purpose.

[26] Title II of Public Law 105–78. See 111 Stat. 1477, 1489.

COORDINATED PROGRAM TO IMPROVE PEDIATRIC ORAL HEALTH.

SEC. 320A.[27] [247d–8] (a) IN GENERAL.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall establish a program to fund innovative oral health activities that improve the oral health of children under 6 years of age who are eligible for services provided under a Federal health program, to increase the utilization of dental services by such children, and to decrease the incidence of early childhood and baby bottle tooth decay.

(b) GRANTS.—The Secretary shall award grants to or enter into contracts with public or private nonprofit schools of dentistry or accredited dental training institutions or programs, community dental programs, and programs operated by the Indian Health Service (including federally recognized Indian tribes that receive medical services from the Indian Health Service, urban Indian health programs funded under title V of the Indian Health Care Improvement Act, and tribes that contract with the Indian Health Service pursuant to the Indian Self-Determination and Education Assistance Act) to enable such schools, institutions, and programs to develop programs of oral health promotion, to increase training of oral health services providers in accordance with State practice laws, or to increase the utilization of dental services by eligible children.

(c) DISTRIBUTION.—In awarding grants under this section, the Secretary shall, to the extent practicable, ensure an equitable national geographic distribution of the grants, including areas of the United States where the incidence of early childhood caries is highest.

(d) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $10,000,000 for each the fiscal years 2001 through 2005.

PART C—HOSPITALS, MEDICAL EXAMINATIONS, AND MEDICAL CARE

HOSPITALS.

SEC. 321. [248] The Surgeon General, pursuant to regulations, shall—

(a) Control, manage, and operate all institutions, hospitals, and stations of the Service, including minor repairs and maintenance, and provide for the care, treatment, and hospitalization of patients, including the furnishing of prosthetic and orthopedic devices; and from time to time with the approval of the President, select suitable sites for and establish such additional institutions, hospitals, and stations in the States and possessions of the United States as in his judgment are necessary to enable the Service to discharge its functions and duties;

(b) Provide for the transfer of Public Health Service patients, in the care of attendants where necessary, between hos-

[27] The placement of this section in title III was carried out to reflect the probable intent of Congress. Section 1603 of Public Law 106–310 (114 Stat. 1151) provided for an amendment to "Part B of the Public Health Service Act", without specifying which title of this Act was the subject of the amendment.

pitals and stations operated by the Service or between such hospitals and stations and other hospitals and stations in which Public Health Service patients may be received, and the payment of expenses of such transfer;

(c) Provide for the disposal of articles produced by patients in the course of their curative treatment, either by allowing the patient to retain such articles or by selling them and depositing the money received therefor to the credit of the appropriation from which the materials for making the articles were purchased;

(d) Provide for the disposal of money and effects, in the custody of the hospitals or stations, of deceased patients; and

(e) Provide, to the extent the Surgeon General determines that other public or private funds are not available therefor, for the payment of expenses of preparing and transporting the remains of, or the payment of reasonable burial expenses for, any patient dying in a hospital or station.

CARE AND TREATMENT OF PERSONS UNDER QUARANTINE AND CERTAIN OTHER PERSONS.

SEC. 322.[249] (a) Any person when detained in accordance with quarantine laws, or, at the request of the Immigration and Naturalization Service, any person detained by that Service, may be treated and cared for by the Public Health Service.

(b) Persons not entitled to treatment and care at institutions, hospitals, and stations of the Service may, in accordance with regulations of the Surgeon General, be admitted thereto for temporary treatment and care in case of emergency.

(c) Persons whose care and treatment is authorized by subsection (a) may, in accordance with regulations, receive such care and treatment at the expense of the Service from public or private medical or hospital facilities other than those of the Service, when authorized by the officer in charge of the station at which the application is made.

CARE AND TREATMENT OF FEDERAL PRISONERS [28].

SEC. 323.[250] The Service shall supervise and furnish medical treatment and other necessary medical, psychiatric, and related technical and scientific services, authorized by the Act of May 13, 1930, as amended (U.S.C., 1940 edition, title 18, secs. 751, 752), [29] in penal and correctional institutions of the United States.

EXAMINATION AND TREATMENT OF FEDERAL EMPLOYEES.

SEC. 324.[251] (a) The Surgeon General is authorized to provide at institutions, hospitals, and stations of the Service medical,

[28] Title I of the Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Act, 2005 (as contained in division B of Public Law 108–447) provided that of the amounts appropriated for salaries and expenses regarding the Federal Prison System "the Attorney General may transfer to the Health Resources and Services Administration such amounts as may be necessary for direct expenditures by that Administration for medical relief for inmates of Federal penal and correctional institutions". (See 118 Stat. 2860.) Similar provisions have appeared in the analogous appropriations Act of many prior years. See section 250a of title 42, United States Code, and the notes following such section.

[29] Now codified to section 4005 of title 18, United States Code.

surgical, and hospital services and supplies for persons entitled to treatment under the United States Employees' Compensation Act[30] and extensions thereof. The Surgeon General may also provide for making medical examinations of—

(1) employees of the Federal Government for retirement purposes;

(2) employees in Federal classified service, and applicants for appointment, as requested by the Civil Service Commission for the purpose of promoting health and efficiency;

(3) seamen for purposes of qualifying for certificates of service; and

(4) employees eligible for benefits under the Longshoremen's and Harbor Workers' Compensation Act, as amended (U.S.C. 1940 edition, title 33, chapter 18),[31] as requested by any deputy commissioner thereunder.

(b) The Secretary is authorized to provide medical, surgical, and dental treatment and hospitalization and optometric care for Federal employees (as defined in section 8901(1) of title 5 of the United States Code) and their dependents at remote medical facilities of the Public Health Service where such care and treatment are not otherwise available. Such employees and their dependents who are not entitled to this care and treatment under any other provision of law shall be charged for it at rates established by the Secretary to reflect the reasonable cost of providing the care and treatment. Any payments pursuant to the preceding sentence shall be credited to the applicable appropriation to the Public Health Service for the year in which such payments are received.

EXAMINATION OF ALIENS.

SEC. 325.[252] The Surgeon General shall provide for making, at places within the United States or in other countries, such physical and mental examinations of aliens as are required by the immigration laws, subject to administrative regulations prescribed by the Attorney General and medical regulations prescribed by the Surgeon General with the approval of the Secretary.

SERVICES TO COAST GUARD, COAST AND GEODETIC SURVEY, AND PUBLIC HEALTH SERVICE.

SEC. 326.[253] (a) Subject to regulations of the President—

(1) commissioned officers, chief warrant officers, warrant officers, cadets, and enlisted personnel of the Regular Coast Guard on active duty, including those on shore duty and those on detached duty; and Regular and temporary members of the United States Coast Guard Reserve when on active duty;

(2) commissioned officers, ships' officers, and members of the crews of vessels of the United States Coast and Geodetic Survey on active duty including those on shore duty and those on detached duty; and

(3) commissioned officers of the Regular or Reserve Corps of the Public Health Service on active duty;

[30] Codified to chapter 81 of title 5, United States Code.
[31] Codification remains chapter 18 of title 33, United States Code.

shall be entitled to medical, surgical, and dental treatment and hospitalization by the Service. The Surgeon General may detail commissioned officers for duty aboard vessels of the Coast Guard or the Coast and Geodetic Survey.

(b)(1) The Secretary may provide health care for an officer of the Regular or Reserve Corps involuntarily separated from the Service, and for any dependent of such officer, if—

(A) the officer or dependent was receiving health care at the expense of the Service at the time of the separation; and

(B) the Secretary finds that the officer or dependent is unable to obtain appropriate insurance for the conditions for which the officer or dependent was receiving health care.

(2) Health care may be provided under paragraph (1) for a period of not more than one year from the date of separation of the officer from the Service.

(c) The Service shall provide all services referred to in subsection (a) required by the Coast Guard or Coast and Geodetic Survey and shall perform all duties prescribed by statute in connection with the examinations to determine physical or mental condition for purposes of appointment, enlistment, and reenlistment, promotion and retirement, and officers of the Service assigned to duty on Coast Guard or Coast and Geodetic Survey vessels may extend aid to the crews of American vessels engaged in deep-sea fishing.

INTERDEPARTMENTAL WORK.

SEC. 327.[254] Nothing contained in this part shall affect the authority of the Service to furnish any materials, supplies, or equipment, or perform any work or services, requested in accordance with section 7 of the Act of May 21, 1920, as amended (U.S.C., 1940 edition, title 31, sec. 686), or the authority of any other executive department to furnish any materials, supplies, or equipment, or perform any work or services, requested by the Department of Health, Education, and Welfare for the Service in accordance with that section.

SHARING OF MEDICAL CARE FACILITIES AND RESOURCES.

SEC. 327A.[254a] (a) For purposes of this section—

(1) the term "specialized health resources" means health care resources (whether equipment, space, or personnel) which, because of cost, limited availability, or unusual nature, are either unique in the health care community or are subject to maximum utilization only through mutual use;

(2) the term "hospital", unless otherwise specified, includes (in addition to other hospitals) any Federal hospital.

(b) For the purpose of maintaining or improving the quality of care in Public Health Service facilities and to provide a professional environment therein which will help to attract and retain highly qualified and talented health personnel, to encourage mutually beneficial relationships between Public Health Service facilities and hospitals and other health facilities in the health care community, and to promote the full utilization of hospitals and other health facilities and resources, the Secretary may—

(1) enter into agreements or arrangements with schools of medicine, schools of osteopathic medicine, and with other health professions schools, agencies, or institutions, for such interchange or cooperative use of facilities and services on a reciprocal or reimbursable basis, as will be of benefit to the training or research programs of the participating agencies; and

(2) enter into agreement or arrangements with hospitals and other health care facilities for the mutual use or the exchange of use of specialized health resources, and providing for reciprocal reimbursement.

Any reimbursement pursuant to any such agreement or arrangement shall be based on charges covering the reasonable cost of such utilization, including normal depreciation and amortization costs of equipment. Any proceeds to the Government under this subsection shall be credited to the applicable appropriation of the Public Health Service for the year in which such proceeds are received.

PART D—PRIMARY HEALTH CARE

Subpart I—Health Centers

SEC. 330.[254b] HEALTH CENTERS.

(a) DEFINITION OF HEALTH CENTER.—

(1) IN GENERAL.—For purposes of this section, the term "health center" means an entity that serves a population that is medically underserved, or a special medically underserved population comprised of migratory and seasonal agricultural workers, the homeless, and residents of public housing, by providing, either through the staff and supporting resources of the center or through contracts or cooperative arrangements—

(A) required primary health services (as defined in subsection (b)(1)); and

(B) as may be appropriate for particular centers, additional health services (as defined in subsection (b)(2)) necessary for the adequate support of the primary health services required under subparagraph (A);

for all residents of the area served by the center (hereafter referred to in this section as the "catchment area").

(2) LIMITATION.—The requirement in paragraph (1) to provide services for all residents within a catchment area shall not apply in the case of a health center receiving a grant only under subsection (g), (h), or (i).

(b) DEFINITIONS.—For purposes of this section:

(1) REQUIRED PRIMARY HEALTH SERVICES.—

(A) IN GENERAL.—The term "required primary health services" means—

(i) basic health services which, for purposes of this section, shall consist of—

(I) health services related to family medicine, internal medicine, pediatrics, obstetrics, or gynecology that are furnished by physicians and where appropriate, physician assistants, nurse practitioners, and nurse midwives;

(II) diagnostic laboratory and radiologic services;

(III) preventive health services, including—

(aa) prenatal and perinatal services;

(bb) appropriate cancer screening;

(cc) well-child services;

(dd) immunizations against vaccine-preventable diseases;

(ee) screenings for elevated blood lead levels, communicable diseases, and cholesterol;

(ff) pediatric eye, ear, and dental screenings to determine the need for vision and hearing correction and dental care;

(gg) voluntary family planning services; and

(hh) preventive dental services;

(IV) emergency medical services; and

(V) pharmaceutical services as may be appropriate for particular centers;

(ii) referrals to providers of medical services (including specialty referral when medically indicated) and other health-related services (including substance abuse and mental health services);

(iii) patient case management services (including counseling, referral, and follow-up services) and other services designed to assist health center patients in establishing eligibility for and gaining access to Federal, State, and local programs that provide or financially support the provision of medical, social, housing, educational, or other related services;

(iv) services that enable individuals to use the services of the health center (including outreach and transportation services and, if a substantial number of the individuals in the population served by a center are of limited English-speaking ability, the services of appropriate personnel fluent in the language spoken by a predominant number of such individuals); and

(v) education of patients and the general population served by the health center regarding the availability and proper use of health services.

(B) EXCEPTION.—With respect to a health center that receives a grant only under subsection (g), the Secretary, upon a showing of good cause, shall—

(i) waive the requirement that the center provide all required primary health services under this paragraph; and

(ii) approve, as appropriate, the provision of certain required primary health services only during certain periods of the year.

(2) ADDITIONAL HEALTH SERVICES.—The term "additional health services" means services that are not included as required primary health services and that are appropriate to meet the health needs of the population served by the health center involved. Such term may include—

(A) behavioral and mental health and substance abuse services;

(B) recuperative care services;

(C) environmental health services, including—

(i) the detection and alleviation of unhealthful conditions associated with—

(I) water supply;

(II) chemical and pesticide exposures;

(III) air quality; or

(IV) exposure to lead;

(ii) sewage treatment;

(iii) solid waste disposal;

(iv) rodent and parasitic infestation;

(v) field sanitation;

(vi) housing; and

(vii) other environmental factors related to health; and

(D) in the case of health centers receiving grants under subsection (g), special occupation-related health services for migratory and seasonal agricultural workers, including—

(i) screening for and control of infectious diseases, including parasitic diseases; and

(ii) injury prevention programs, including prevention of exposure to unsafe levels of agricultural chemicals including pesticides.

(3) MEDICALLY UNDERSERVED POPULATIONS.—

(A) IN GENERAL.—The term "medically underserved population" means the population of an urban or rural area designated by the Secretary as an area with a shortage of personal health services or a population group designated by the Secretary as having a shortage of such services.

(B) CRITERIA.—In carrying out subparagraph (A), the Secretary shall prescribe criteria for determining the specific shortages of personal health services of an area or population group. Such criteria shall—

(i) take into account comments received by the Secretary from the chief executive officer of a State and local officials in a State; and

(ii) include factors indicative of the health status of a population group or residents of an area, the ability of the residents of an area or of a population group to pay for health services and their accessibility to them, and the availability of health professionals to residents of an area or to a population group.

(C) LIMITATION.—The Secretary may not designate a medically underserved population in a State or terminate the designation of such a population unless, prior to such designation or termination, the Secretary provides reasonable notice and opportunity for comment and consults with—

(i) the chief executive officer of such State;

(ii) local officials in such State; and

(iii) the organization, if any, which represents a majority of health centers in such State.

(D) PERMISSIBLE DESIGNATION.—The Secretary may designate a medically underserved population that does not meet the criteria established under subparagraph (B) if the chief executive officer of the State in which such population is located and local officials of such State recommend the designation of such population based on unusual local conditions which are a barrier to access to or the availability of personal health services.

(c) PLANNING GRANTS.—

(1) IN GENERAL.—

(A) CENTERS.—The Secretary may make grants to public and nonprofit private entities for projects to plan and develop health centers which will serve medically underserved populations. A project for which a grant may be made under this subsection may include the cost of the acquisition and lease of buildings and equipment (including the costs of amortizing the principal of, and paying the interest on, loans) and shall include—

(i) an assessment of the need that the population proposed to be served by the health center for which the project is undertaken has for required primary health services and additional health services;

(ii) the design of a health center program for such population based on such assessment;

(iii) efforts to secure, within the proposed catchment area of such center, financial and professional assistance and support for the project;

(iv) initiation and encouragement of continuing community involvement in the development and operation of the project; and

(v) proposed linkages between the center and other appropriate provider entities, such as health departments, local hospitals, and rural health clinics, to provide better coordinated, higher quality, and more cost-effective health care services.

(B) MANAGED CARE NETWORKS AND PLANS.—The Secretary may make grants to health centers that receive assistance under this section to enable the centers to plan and develop a managed care network or plan. Such a grant may only be made for such a center if—

(i) the center has received grants under subsection (e)(1)(A) for at least 2 consecutive years preceding the year of the grant under this subparagraph or has otherwise demonstrated, as required by the Secretary, that such center has been providing primary care services for at least the 2 consecutive years immediately preceding such year; and

(ii) the center provides assurances satisfactory to the Secretary that the provision of such services on a prepaid basis, or under another managed care arrangement, will not result in the diminution of the level or quality of health services provided to the

medically underserved population served prior to the grant under this subparagraph.

(C) PRACTICE MANAGEMENT NETWORKS.—The Secretary may make grants to health centers that receive assistance under this section to enable the centers to plan and develop practice management networks that will enable the centers to—

(i) reduce costs associated with the provision of health care services;

(ii) improve access to, and availability of, health care services provided to individuals served by the centers;

(iii) enhance the quality and coordination of health care services; or

(iv) improve the health status of communities.

(D) USE OF FUNDS.—The activities for which a grant may be made under subparagraph (B) or (C) may include the purchase or lease of equipment, which may include data and information systems (including paying for the costs of amortizing the principal of, and paying the interest on, loans for equipment), the provision of training and technical assistance related to the provision of health care services on a prepaid basis or under another managed care arrangement, and other activities that promote the development of practice management or managed care networks and plans.

(2) LIMITATION.—Not more than two grants may be made under this subsection for the same project, except that upon a showing of good cause, the Secretary may make additional grant awards.

(3) RECOGNITION OF HIGH POVERTY.—

(A) IN GENERAL.—In making grants under this subsection, the Secretary may recognize the unique needs of high poverty areas.

(B) HIGH POVERTY AREA DEFINED.—For purposes of subparagraph (A), the term "high poverty area" means a catchment area which is established in a manner that is consistent with the factors in subsection (k)(3)(J), and the poverty rate of which is greater than the national average poverty rate as determined by the Bureau of the Census.

(d) LOAN GUARANTEE PROGRAM.—

(1) ESTABLISHMENT.—

(A) IN GENERAL.—The Secretary shall establish a program under which the Secretary may, in accordance with this subsection and to the extent that appropriations are provided in advance for such program, guarantee up to 90 percent of the principal and interest on loans made by non-Federal lenders to health centers, funded under this section, for the costs of developing and operating managed care networks or plans described in subsection (c)(1)(B), or practice management networks described in subsection (c)(1)(C).

(B) USE OF FUNDS.—Loan funds guaranteed under this subsection may be used—

(i) to establish reserves for the furnishing of services on a pre-paid basis;

(ii) for costs incurred by the center or centers, otherwise permitted under this section, as the Secretary determines are necessary to enable a center or centers to develop, operate, and own the network or plan; or

(iii) to refinance an existing loan (as of the date of refinancing) to the center or centers, if the Secretary determines—

(I) that such refinancing will be beneficial to the health center and the Federal Government; or

(II) that the center (or centers) can demonstrate an ability to repay the refinanced loan equal to or greater than the ability of the center (or centers) to repay the original loan on the date the original loan was made.

(C) PUBLICATION OF GUIDANCE.—Prior to considering an application submitted under this subsection, the Secretary shall publish guidelines to provide guidance on the implementation of this section. The Secretary shall make such guidelines available to the universe of parties affected under this subsection, distribute such guidelines to such parties upon the request of such parties, and provide a copy of such guidelines to the appropriate committees of Congress.

(D) PROVISION DIRECTLY TO NETWORKS OR PLANS.—At the request of health centers receiving assistance under this section, loan guarantees provided under this paragraph may be made directly to networks or plans that are at least majority controlled and, as applicable, at least majority owned by those health centers.

(E) FEDERAL CREDIT REFORM.—The requirements of the Federal Credit Reform Act of 1990 (2 U.S.C. 661 et seq.) shall apply with respect to loans refinanced under subparagraph (B)(iii).

(2) PROTECTION OF FINANCIAL INTERESTS.—

(A) IN GENERAL.—The Secretary may not approve a loan guarantee for a project under this subsection unless the Secretary determines that—

(i) the terms, conditions, security (if any), and schedule and amount of repayments with respect to the loan are sufficient to protect the financial interests of the United States and are otherwise reasonable, including a determination that the rate of interest does not exceed such percent per annum on the principal obligation outstanding as the Secretary determines to be reasonable, taking into account the range of interest rates prevailing in the private market for similar loans and the risks assumed by the United States, except that the Secretary may not require as security any center asset that is, or may be, needed by the center or centers involved to provide health services;

(ii) the loan would not be available on reasonable terms and conditions without the guarantee under this subsection; and

(iii) amounts appropriated for the program under this subsection are sufficient to provide loan guarantees under this subsection.

(B) RECOVERY OF PAYMENTS.—

(i) IN GENERAL.—The United States shall be entitled to recover from the applicant for a loan guarantee under this subsection the amount of any payment made pursuant to such guarantee, unless the Secretary for good cause waives such right of recovery (subject to appropriations remaining available to permit such a waiver) and, upon making any such payment, the United States shall be subrogated to all of the rights of the recipient of the payments with respect to which the guarantee was made. Amounts recovered under this clause shall be credited as reimbursements to the financing account of the program.

(ii) MODIFICATION OF TERMS AND CONDITIONS.—To the extent permitted by clause (iii) and subject to the requirements of section 504(e) of the Credit Reform Act of 1990 (2 U.S.C. 661c(e)), any terms and conditions applicable to a loan guarantee under this subsection (including terms and conditions imposed under clause (iv)) may be modified or waived by the Secretary to the extent the Secretary determines it to be consistent with the financial interest of the United States.

(iii) INCONTESTABILITY.—Any loan guarantee made by the Secretary under this subsection shall be incontestable—

(I) in the hands of an applicant on whose behalf such guarantee is made unless the applicant engaged in fraud or misrepresentation in securing such guarantee; and

(II) as to any person (or successor in interest) who makes or contracts to make a loan to such applicant in reliance thereon unless such person (or successor in interest) engaged in fraud or misrepresentation in making or contracting to make such loan.

(iv) FURTHER TERMS AND CONDITIONS.—Guarantees of loans under this subsection shall be subject to such further terms and conditions as the Secretary determines to be necessary to assure that the purposes of this section will be achieved.

(3) LOAN ORIGINATION FEES.—

(A) IN GENERAL.—The Secretary shall collect a loan origination fee with respect to loans to be guaranteed under this subsection, except as provided in subparagraph (C).

(B) AMOUNT.—The amount of a loan origination fee collected by the Secretary under subparagraph (A) shall be

equal to the estimated long term cost of the loan guarantees involved to the Federal Government (excluding administrative costs), calculated on a net present value basis, after taking into account any appropriations that may be made for the purpose of offsetting such costs, and in accordance with the criteria used to award loan guarantees under this subsection.

(C) WAIVER.—The Secretary may waive the loan origination fee for a health center applicant who demonstrates to the Secretary that the applicant will be unable to meet the conditions of the loan if the applicant incurs the additional cost of the fee.

(4) DEFAULTS.—

(A) IN GENERAL.—Subject to the requirements of the Credit Reform Act of 1990 (2 U.S.C. 661 et seq.), the Secretary may take such action as may be necessary to prevent a default on a loan guaranteed under this subsection, including the waiver of regulatory conditions, deferral of loan payments, renegotiation of loans, and the expenditure of funds for technical and consultative assistance, for the temporary payment of the interest and principal on such a loan, and for other purposes. Any such expenditure made under the preceding sentence on behalf of a health center or centers shall be made under such terms and conditions as the Secretary shall prescribe, including the implementation of such organizational, operational, and financial reforms as the Secretary determines are appropriate and the disclosure of such financial or other information as the Secretary may require to determine the extent of the implementation of such reforms.

(B) FORECLOSURE.—The Secretary may take such action, consistent with State law respecting foreclosure procedures and, with respect to reserves required for furnishing services on a prepaid basis, subject to the consent of the affected States, as the Secretary determines appropriate to protect the interest of the United States in the event of a default on a loan guaranteed under this subsection, except that the Secretary may only foreclose on assets offered as security (if any) in accordance with paragraph (2)(A)(i).

(5) LIMITATION.—Not more than one loan guarantee may be made under this subsection for the same network or plan, except that upon a showing of good cause the Secretary may make additional loan guarantees.

(6) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this subsection such sums as may be necessary.

(e) OPERATING GRANTS.—

(1) AUTHORITY.—

(A) IN GENERAL.—The Secretary may make grants for the costs of the operation of public and nonprofit private health centers that provide health services to medically underserved populations.

(B) ENTITIES THAT FAIL TO MEET CERTAIN REQUIREMENTS.—The Secretary may make grants, for a period of not to exceed 2 years, for the costs of the operation of public and nonprofit private entities which provide health services to medically underserved populations but with respect to which the Secretary is unable to make each of the determinations required by subsection (k)(3).

(C) OPERATION OF NETWORKS AND PLANS.—The Secretary may make grants to health centers that receive assistance under this section, or at the request of the health centers, directly to a network or plan (as described in subparagraphs (B) and (C) of subsection (c)(1)) that is at least majority controlled and, as applicable, at least majority owned by such health centers receiving assistance under this section, for the costs associated with the operation of such network or plan, including the purchase or lease of equipment (including the costs of amortizing the principal of, and paying the interest on, loans for equipment).

(2) USE OF FUNDS.—The costs for which a grant may be made under subparagraph (A) or (B) of paragraph (1) may include the costs of acquiring and leasing buildings and equipment (including the costs of amortizing the principal of, and paying interest on, loans), and the costs of providing training related to the provision of required primary health services and additional health services and to the management of health center programs.

(3) CONSTRUCTION.—The Secretary may award grants which may be used to pay the costs associated with expanding and modernizing existing buildings or constructing new buildings (including the costs of amortizing the principal of, and paying the interest on, loans) for projects approved prior to October 1, 1996.

(4) LIMITATION.—Not more than two grants may be made under subparagraph (B) of paragraph (1) for the same entity.

(5) AMOUNT.—

(A) IN GENERAL.—The amount of any grant made in any fiscal year under subparagraphs (A) and (B) of paragraph (1) to a health center shall be determined by the Secretary, but may not exceed the amount by which the costs of operation of the center in such fiscal year exceed the total of—

(i) State, local, and other operational funding provided to the center; and

(ii) the fees, premiums, and third-party reimbursements, which the center may reasonably be expected to receive for its operations in such fiscal year.

(B) NETWORKS AND PLANS.—The total amount of grant funds made available for any fiscal year under paragraph (1)(C) and subparagraphs (B) and (C) of subsection (c)(1) to a health center or to a network or plan shall be determined by the Secretary, but may not exceed 2 percent of the total amount appropriated under this section for such fiscal year.

(C) PAYMENTS.—Payments under grants under subparagraph (A) or (B) of paragraph (1) shall be made in advance or by way of reimbursement and in such installments as the Secretary finds necessary and adjustments may be made for overpayments or underpayments.

(D) USE OF NONGRANT FUNDS.—Nongrant funds described in clauses (i) and (ii) of subparagraph (A), including any such funds in excess of those originally expected, shall be used as permitted under this section, and may be used for such other purposes as are not specifically prohibited under this section if such use furthers the objectives of the project.

(f) INFANT MORTALITY GRANTS.—

(1) IN GENERAL.—The Secretary may make grants to health centers for the purpose of assisting such centers in—

(A) providing comprehensive health care and support services for the reduction of—

(i) the incidence of infant mortality; and

(ii) morbidity among children who are less than 3 years of age; and

(B) developing and coordinating service and referral arrangements between health centers and other entities for the health management of pregnant women and children described in subparagraph (A).

(2) PRIORITY.—In making grants under this subsection the Secretary shall give priority to health centers providing services to any medically underserved population among which there is a substantial incidence of infant mortality or among which there is a significant increase in the incidence of infant mortality.

(3) REQUIREMENTS.—The Secretary may make a grant under this subsection only if the health center involved agrees that—

(A) the center will coordinate the provision of services under the grant to each of the recipients of the services;

(B) such services will be continuous for each such recipient;

(C) the center will provide follow-up services for individuals who are referred by the center for services described in paragraph (1);

(D) the grant will be expended to supplement, and not supplant, the expenditures of the center for primary health services (including prenatal care) with respect to the purpose described in this subsection; and

(E) the center will coordinate the provision of services with other maternal and child health providers operating in the catchment area.

(g) MIGRATORY AND SEASONAL AGRICULTURAL WORKERS.—

(1) IN GENERAL.—The Secretary may award grants for the purposes described in subsections (c), (e), and (f) for the planning and delivery of services to a special medically underserved population comprised of—

(A) migratory agricultural workers, seasonal agricultural workers, and members of the families of such migra-

tory and seasonal agricultural workers who are within a designated catchment area; and

(B) individuals who have previously been migratory agricultural workers but who no longer meet the requirements of subparagraph (A) of paragraph (3) because of age or disability and members of the families of such individuals who are within such catchment area.

(2) ENVIRONMENTAL CONCERNS.—The Secretary may enter into grants or contracts under this subsection with public and private entities to—

(A) assist the States in the implementation and enforcement of acceptable environmental health standards, including enforcement of standards for sanitation in migratory agricultural worker and seasonal agricultural worker labor camps, and applicable Federal and State pesticide control standards; and

(B) conduct projects and studies to assist the several States and entities which have received grants or contracts under this section in the assessment of problems related to camp and field sanitation, exposure to unsafe levels of agricultural chemicals including pesticides, and other environmental health hazards to which migratory agricultural workers and seasonal agricultural workers, and members of their families, are exposed.

(3) DEFINITIONS.—For purposes of this subsection:

(A) MIGRATORY AGRICULTURAL WORKER.—The term "migratory agricultural worker" means an individual whose principal employment is in agriculture, who has been so employed within the last 24 months, and who establishes for the purposes of such employment a temporary abode.

(B) SEASONAL AGRICULTURAL WORKER.—The term "seasonal agricultural worker" means an individual whose principal employment is in agriculture on a seasonal basis and who is not a migratory agricultural worker.

(C) AGRICULTURE.—The term "agriculture" means farming in all its branches, including—

(i) cultivation and tillage of the soil;

(ii) the production, cultivation, growing, and harvesting of any commodity grown on, in, or as an adjunct to or part of a commodity grown in or on, the land; and

(iii) any practice (including preparation and processing for market and delivery to storage or to market or to carriers for transportation to market) performed by a farmer or on a farm incident to or in conjunction with an activity described in clause (ii).

(h) HOMELESS POPULATION.—

(1) IN GENERAL.—The Secretary may award grants for the purposes described in subsections (c), (e), and (f) for the planning and delivery of services to a special medically underserved population comprised of homeless individuals, including grants for innovative programs that provide outreach and com-

prehensive primary health services to homeless children and youth and children and youth at risk of homelessness.

(2) REQUIRED SERVICES.—In addition to required primary health services (as defined in subsection (b)(1)), an entity that receives a grant under this subsection shall be required to provide substance abuse services as a condition of such grant.

(3) SUPPLEMENT NOT SUPPLANT REQUIREMENT.—A grant awarded under this subsection shall be expended to supplement, and not supplant, the expenditures of the health center and the value of in kind contributions for the delivery of services to the population described in paragraph (1).

(4) TEMPORARY CONTINUED PROVISION OF SERVICES TO CERTAIN FORMER HOMELESS INDIVIDUALS.—If any grantee under this subsection has provided services described in this section under the grant to a homeless individual, such grantee may, notwithstanding that the individual is no longer homeless as a result of becoming a resident in permanent housing, expend the grant to continue to provide such services to the individual for not more than 12 months.

(5) DEFINITIONS.—For purposes of this section:

(A) HOMELESS INDIVIDUAL.—The term "homeless individual" means an individual who lacks housing (without regard to whether the individual is a member of a family), including an individual whose primary residence during the night is a supervised public or private facility that provides temporary living accommodations and an individual who is a resident in transitional housing.

(B) SUBSTANCE ABUSE.—The term "substance abuse" has the same meaning given such term in section 534(4).

(C) SUBSTANCE ABUSE SERVICES.—The term "substance abuse services" includes detoxification, risk reduction, outpatient treatment, residential treatment, and rehabilitation for substance abuse provided in settings other than hospitals.

(i) RESIDENTS OF PUBLIC HOUSING.—

(1) IN GENERAL.—The Secretary may award grants for the purposes described in subsections (c), (e), and (f) for the planning and delivery of services to a special medically underserved population comprised of residents of public housing (such term, for purposes of this subsection, shall have the same meaning given such term in section 3(b)(1) of the United States Housing Act of 1937) and individuals living in areas immediately accessible to such public housing.

(2) SUPPLEMENT NOT SUPPLANT.—A grant awarded under this subsection shall be expended to supplement, and not supplant, the expenditures of the health center and the value of in kind contributions for the delivery of services to the population described in paragraph (1).

(3) CONSULTATION WITH RESIDENTS.—The Secretary may not make a grant under paragraph (1) unless, with respect to the residents of the public housing involved, the applicant for the grant—

(A) has consulted with the residents in the preparation of the application for the grant; and

(B) agrees to provide for ongoing consultation with the residents regarding the planning and administration of the program carried out with the grant.

(j) ACCESS GRANTS.—

(1) IN GENERAL.—The Secretary may award grants to eligible health centers with a substantial number of clients with limited English speaking proficiency to provide translation, interpretation, and other such services for such clients with limited English speaking proficiency.

(2) ELIGIBLE HEALTH CENTER.—In this subsection, the term "eligible health center" means an entity that—

(A) is a health center as defined under subsection (a);

(B) provides health care services for clients for whom English is a second language; and

(C) has exceptional needs with respect to linguistic access or faces exceptional challenges with respect to linguistic access.

(3) GRANT AMOUNT.—The amount of a grant awarded to a center under this subsection shall be determined by the Administrator. Such determination of such amount shall be based on the number of clients for whom English is a second language that is served by such center, and larger grant amounts shall be awarded to centers serving larger numbers of such clients.

(4) USE OF FUNDS.—An eligible health center that receives a grant under this subsection may use funds received through such grant to—

(A) provide translation, interpretation, and other such services for clients for whom English is a second language, including hiring professional translation and interpretation services; and

(B) compensate bilingual or multilingual staff for language assistance services provided by the staff for such clients.

(5) APPLICATION.—An eligible health center desiring a grant under this subsection shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may reasonably require, including—

(A) an estimate of the number of clients that the center serves for whom English is a second language;

(B) the ratio of the number of clients for whom English is a second language to the total number of clients served by the center;

(C) a description of any language assistance services that the center proposes to provide to aid clients for whom English is a second language; and

(D) a description of the exceptional needs of such center with respect to linguistic access or a description of the exceptional challenges faced by such center with respect to linguistic access.

(6) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this subsection, in addition to any funds authorized to be appropriated or appropriated for

health centers under any other subsection of this section, such sums as may be necessary for each of fiscal years 2002 through 2006.

(k) APPLICATIONS.—

(1) SUBMISSION.—No grant may be made under this section unless an application therefore is submitted to, and approved by, the Secretary. Such an application shall be submitted in such form and manner and shall contain such information as the Secretary shall prescribe.

(2) DESCRIPTION OF NEED.—An application for a grant under subparagraph (A) or (B) of subsection (e)(1) for a health center shall include—

(A) a description of the need for health services in the catchment area of the center;

(B) a demonstration by the applicant that the area or the population group to be served by the applicant has a shortage of personal health services; and

(C) a demonstration that the center will be located so that it will provide services to the greatest number of individuals residing in the catchment area or included in such population group.

Such a demonstration shall be made on the basis of the criteria prescribed by the Secretary under subsection (b)(3) or on any other criteria which the Secretary may prescribe to determine if the area or population group to be served by the applicant has a shortage of personal health services. In considering an application for a grant under subparagraph (A) or (B) of subsection (e)(1), the Secretary may require as a condition to the approval of such application an assurance that the applicant will provide any health service defined under paragraphs (1) and (2) of subsection (b) that the Secretary finds is needed to meet specific health needs of the area to be served by the applicant. Such a finding shall be made in writing and a copy shall be provided to the applicant.

(3) REQUIREMENTS.—Except as provided in subsection (e)(1)(B), the Secretary may not approve an application for a grant under subparagraph (A) or (B) of subsection (e)(1) unless the Secretary determines that the entity for which the application is submitted is a health center (within the meaning of subsection (a)) and that—

(A) the required primary health services of the center will be available and accessible in the catchment area of the center promptly, as appropriate, and in a manner which assures continuity;

(B) the center has made and will continue to make every reasonable effort to establish and maintain collaborative relationships with other health care providers in the catchment area of the center;

(C) the center will have an ongoing quality improvement system that includes clinical services and management, and that maintains the confidentiality of patient records;

(D) the center will demonstrate its financial responsibility by the use of such accounting procedures and other requirements as may be prescribed by the Secretary;

(E) the center—

(i)(I) has or will have a contractual or other arrangement with the agency of the State, in which it provides services, which administers or supervises the administration of a State plan approved under title XIX of the Social Security Act for the payment of all or a part of the center's costs in providing health services to persons who are eligible for medical assistance under such a State plan; and

(II)[32] has or will have a contractual or other arrangement with the State agency administering the program under title XXI of such Act (42 U.S.C. 1397aa et seq.) with respect to individuals who are State children's health insurance program beneficiaries; or

(ii) has made or will make every reasonable effort to enter into arrangements described in subclauses (I) and (II) of clause (i);

(F) the center has made or will make and will continue to make every reasonable effort to collect appropriate reimbursement for its costs in providing health services to persons who are entitled to insurance benefits under title XVIII of the Social Security Act, to medical assistance under a State plan approved under title XIX of such Act, or to assistance for medical expenses under any other public assistance program or private health insurance program;

(G) the center—

(i) has prepared a schedule of fees or payments for the provision of its services consistent with locally prevailing rates or charges and designed to cover its reasonable costs of operation and has prepared a corresponding schedule of discounts to be applied to the payment of such fees or payments, which discounts are adjusted on the basis of the patient's ability to pay;

(ii) has made and will continue to make every reasonable effort—

(I) to secure from patients payment for services in accordance with such schedules; and

(II) to collect reimbursement for health services to persons described in subparagraph (F) on the basis of the full amount of fees and payments for such services without application of any discount;

(iii)(I) will assure that no patient will be denied health care services due to an individual's inability to pay for such services; and

[32] Indentation is so in law. See section 101(7)(A)(i)(III) of Public Law 107–251 (116 Stat. 225).

(II) will assure that any fees or payments required by the center for such services will be reduced or waived to enable the center to fulfill the assurance described in subclause (I); and

(iv) has submitted to the Secretary such reports as the Secretary may require to determine compliance with this subparagraph;

(H) the center has established a governing board which except in the case of an entity operated by an Indian tribe or tribal or Indian organization under the Indian Self-Determination Act or an urban Indian organization under the Indian Health Care Improvement Act (25 U.S.C. 1651 et seq.)—

(i) is composed of individuals, a majority of whom are being served by the center and who, as a group, represent the individuals being served by the center;

(ii) meets at least once a month, selects the services to be provided by the center, schedules the hours during which such services will be provided, approves the center's annual budget, approves the selection of a director for the center, and, except in the case of a governing board of a public center (as defined in the second sentence of this paragraph), establishes general policies for the center; and

(iii) in the case of an application for a second or subsequent grant for a public center, has approved the application or if the governing body has not approved the application, the failure of the governing body to approve the application was unreasonable;

except that, upon a showing of good cause the Secretary shall waive, for the length of the project period, all or part of the requirements of this subparagraph in the case of a health center that receives a grant pursuant to subsection (g), (h), (i), or (p);

(I) the center has developed—

(i) an overall plan and budget that meets the requirements of the Secretary; and

(ii) an effective procedure for compiling and reporting to the Secretary such statistics and other information as the Secretary may require relating to—

(I) the costs of its operations;

(II) the patterns of use of its services;

(III) the availability, accessibility, and acceptability of its services; and

(IV) such other matters relating to operations of the applicant as the Secretary may require;

(J) the center will review periodically its catchment area to—

(i) ensure that the size of such area is such that the services to be provided through the center (including any satellite) are available and accessible to the residents of the area promptly and as appropriate;

(ii) ensure that the boundaries of such area conform, to the extent practicable, to relevant boundaries

of political subdivisions, school districts, and Federal and State health and social service programs; and

(iii) ensure that the boundaries of such area eliminate, to the extent possible, barriers to access to the services of the center, including barriers resulting from the area's physical characteristics, its residential patterns, its economic and social grouping, and available transportation;

(K) in the case of a center which serves a population including a substantial proportion of individuals of limited English-speaking ability, the center has—

(i) developed a plan and made arrangements responsive to the needs of such population for providing services to the extent practicable in the language and cultural context most appropriate to such individuals; and

(ii) identified an individual on its staff who is fluent in both that language and in English and whose responsibilities shall include providing guidance to such individuals and to appropriate staff members with respect to cultural sensitivities and bridging linguistic and cultural differences;

(L) the center, has developed an ongoing referral relationship with one or more hospitals; and

(M) the center encourages persons receiving or seeking health services from the center to participate in any public or private (including employer-offered) health programs or plans for which the persons are eligible, so long as the center, in complying with this subparagraph, does not violate the requirements of subparagraph (G)(iii)(I).

For purposes of subparagraph (H), the term "public center" means a health center funded (or to be funded) through a grant under this section to a public agency.

(4) APPROVAL OF NEW OR EXPANDED SERVICE APPLICATIONS.—The Secretary shall approve applications for grants under subparagraph (A) or (B) of subsection (e)(1) for health centers which—

(A) have not received a previous grant under such subsection; or

(B) have applied for such a grant to expand their services;

in such a manner that the ratio of the medically underserved populations in rural areas which may be expected to use the services provided by such centers to the medically underserved populations in urban areas which may be expected to use the services provided by such centers is not less than two to three or greater than three to two.

(l) TECHNICAL ASSISTANCE.—The Secretary shall establish a program through which the Secretary shall provide (either through the Department of Health and Human Services or by grant or contract) technical and other assistance to eligible entities to assist such entities to meet the requirements of subsection (k)(3). Services provided through the program may include necessary technical and nonfinancial assistance, including fiscal and program management

assistance, training in fiscal and program management, operational and administrative support, and the provision of information to the entities of the variety of resources available under this title and how those resources can be best used to meet the health needs of the communities served by the entities.

(m) MEMORANDUM OF AGREEMENT.—In carrying out this section, the Secretary may enter into a memorandum of agreement with a State. Such memorandum may include, where appropriate, provisions permitting such State to—

(1) analyze the need for primary health services for medically underserved populations within such State;

(2) assist in the planning and development of new health centers;

(3) review and comment upon annual program plans and budgets of health centers, including comments upon allocations of health care resources in the State;

(4) assist health centers in the development of clinical practices and fiscal and administrative systems through a technical assistance plan which is responsive to the requests of health centers; and

(5) share information and data relevant to the operation of new and existing health centers.

(n) RECORDS.—

(1) IN GENERAL.—Each entity which receives a grant under subsection (e) shall establish and maintain such records as the Secretary shall require.

(2) AVAILABILITY.—Each entity which is required to establish and maintain records under this subsection shall make such books, documents, papers, and records available to the Secretary or the Comptroller General of the United States, or any of their duly authorized representatives, for examination, copying or mechanical reproduction on or off the premises of such entity upon a reasonable request therefore. The Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have the authority to conduct such examination, copying, and reproduction.

(o) DELEGATION OF AUTHORITY.—The Secretary may delegate the authority to administer the programs authorized by this section to any office, except that the authority to enter into, modify, or issue approvals with respect to grants or contracts may be delegated only within the central office of the Health Resources and Services Administration.

(p) SPECIAL CONSIDERATION.—In making grants under this section, the Secretary shall give special consideration to the unique needs of sparsely populated rural areas, including giving priority in the awarding of grants for new health centers under subsections (c) and (e), and the granting of waivers as appropriate and permitted under subsections (b)(1)(B)(i) and (k)(3)(G).

(q) AUDITS.—

(1) IN GENERAL.—Each entity which receives a grant under this section shall provide for an independent annual financial audit of any books, accounts, financial records, files, and other papers and property which relate to the disposition or use of the funds received under such grant and such other funds re-

ceived by or allocated to the project for which such grant was made. For purposes of assuring accurate, current, and complete disclosure of the disposition or use of the funds received, each such audit shall be conducted in accordance with generally accepted accounting principles. Each audit shall evaluate—

(A) the entity's implementation of the guidelines established by the Secretary respecting cost accounting,

(B) the processes used by the entity to meet the financial and program reporting requirements of the Secretary, and

(C) the billing and collection procedures of the entity and the relation of the procedures to its fee schedule and schedule of discounts and to the availability of health insurance and public programs to pay for the health services it provides.

A report of each such audit shall be filed with the Secretary at such time and in such manner as the Secretary may require.

(2) RECORDS.—Each entity which receives a grant under this section shall establish and maintain such records as the Secretary shall by regulation require to facilitate the audit required by paragraph (1). The Secretary may specify by regulation the form and manner in which such records shall be established and maintained.

(3) AVAILABILITY OF RECORDS.—Each entity which is required to establish and maintain records or to provide for and audit under this subsection shall make such books, documents, papers, and records available to the Secretary or the Comptroller General of the United States, or any of their duly authorized representatives, for examination, copying or mechanical reproduction on or off the premises of such entity upon a reasonable request therefore. The Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have the authority to conduct such examination, copying, and reproduction.

(4) WAIVER.—The Secretary may, under appropriate circumstances, waive the application of all or part of the requirements of this subsection with respect to an entity.

(r) AUTHORIZATION OF APPROPRIATIONS.—

(1) GENERAL AMOUNTS FOR GRANTS.—For the purpose of carrying out this section, in addition to the amounts authorized to be appropriated under subsection (d), there is authorized to be appropriated the following:

(A) For fiscal year 2010, $2,988,821,592.

(B) For fiscal year 2011, $3,862,107,440.

(C) For fiscal year 2012, $4,990,553,440.

(D) For fiscal year 2013, $6,448,713,307.

(E) For fiscal year 2014, $7,332,924,155.

(F) For fiscal year 2015, $8,332,924,155.

(G) For fiscal year 2016, and each subsequent fiscal year, the amount appropriated for the preceding fiscal year adjusted by the product of—

(i) one plus the average percentage increase in costs incurred per patient served; and

(ii) one plus the average percentage increase in the total number of patients served.

(2) SPECIAL PROVISIONS.—

(A) PUBLIC CENTERS.—The Secretary may not expend in any fiscal year, for grants under this section to public centers (as defined in the second sentence of subsection (k)(3)) the governing boards of which (as described in subsection (k)(3)(H)) do not establish general policies for such centers, an amount which exceeds 5 percent of the amounts appropriated under this section for that fiscal year. For purposes of applying the preceding sentence, the term "public centers" shall not include health centers that receive grants pursuant to subsection (h) or (i).

(B) DISTRIBUTION OF GRANTS.—For fiscal year 2002 and each of the following fiscal years, the Secretary, in awarding grants under this section, shall ensure that the proportion of the amount made available under each of subsections (g), (h), and (i), relative to the total amount appropriated to carry out this section for that fiscal year, is equal to the proportion of the amount made available under that subsection for fiscal year 2001, relative to the total amount appropriated to carry out this section for fiscal year 2001.

(3) FUNDING REPORT.—The Secretary shall annually prepare and submit to the appropriate committees of Congress a report concerning the distribution of funds under this section that are provided to meet the health care needs of medically underserved populations, including the homeless, residents of public housing, and migratory and seasonal agricultural workers, and the appropriateness of the delivery systems involved in responding to the needs of the particular populations. Such report shall include an assessment of the relative health care access needs of the targeted populations and the rationale for any substantial changes in the distribution of funds.

(4) RULE OF CONSTRUCTION WITH RESPECT TO RURAL HEALTH CLINICS.—

(A) IN GENERAL.—Nothing in this section shall be construed to prevent a community health center from contracting with a Federally certified rural health clinic (as defined in section 1861(aa)(2) of the Social Security Act), a low-volume hospital (as defined for purposes of section 1886 of such Act), a critical access hospital, a sole community hospital (as defined for purposes of section 1886(d)(5)(D)(iii) of such Act), or a medicare-dependent share hospital (as defined for purposes of section 1886(d)(5)(G)(iv) of such Act) for the delivery of primary health care services that are available at the clinic or hospital to individuals who would otherwise be eligible for free or reduced cost care if that individual were able to obtain that care at the community health center. Such services may be limited in scope to those primary health care services available in that clinic or hospitals.

(B) ASSURANCES.—In order for a clinic or hospital to receive funds under this section through a contract with a

community health center under subparagraph (A), such clinic or hospital shall establish policies to ensure—

(i) nondiscrimination based on the ability of a patient to pay; and

(ii) the establishment of a sliding fee scale for low-income patients.

(s) DEMONSTRATION PROGRAM FOR INDIVIDUALIZED WELLNESS PLANS.—

(1) IN GENERAL.—The Secretary shall establish a pilot program to test the impact of providing at-risk populations who utilize community health centers funded under this section an individualized wellness plan that is designed to reduce risk factors for preventable conditions as identified by a comprehensive risk-factor assessment.

(2) AGREEMENTS.—The Secretary shall enter into agreements with not more than 10 community health centers funded under this section to conduct activities under the pilot program under paragraph (1).

(3) WELLNESS PLANS.—

(A) IN GENERAL.—An individualized wellness plan prepared under the pilot program under this subsection may include one or more of the following as appropriate to the individual's identified risk factors:

(i) Nutritional counseling.

(ii) A physical activity plan.

(iii) Alcohol and smoking cessation counseling and services.

(iv) Stress management.

(v) Dietary supplements that have health claims approved by the Secretary.

(vi) Compliance assistance provided by a community health center employee.

(B) RISK FACTORS.—Wellness plan risk factors shall include—

(i) weight;

(ii) tobacco and alcohol use;

(iii) exercise rates;

(iv) nutritional status; and

(v) blood pressure.

(C) COMPARISONS.—Individualized wellness plans shall make comparisons between the individual involved and a control group of individuals with respect to the risk factors described in subparagraph (B).

(4) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this subsection, such sums as may be necessary.

SEC. 330A.[254c] RURAL HEALTH CARE SERVICES OUTREACH, RURAL HEALTH NETWORK DEVELOPMENT, AND SMALL HEALTH CARE PROVIDER QUALITY IMPROVEMENT GRANT PROGRAMS.

(a) PURPOSE.—The purpose of this section is to provide grants for expanded delivery of health care services in rural areas, for the planning and implementation of integrated health care networks in

rural areas, and for the planning and implementation of small health care provider quality improvement activities.

(b) DEFINITIONS.—

(1) DIRECTOR.—The term "Director" means the Director specified in subsection (d).

(2) FEDERALLY QUALIFIED HEALTH CENTER; RURAL HEALTH CLINIC.—The terms "Federally qualified health center" and "rural health clinic" have the meanings given the terms in section 1861(aa) of the Social Security Act (42 U.S.C. 1395x(aa)).

(3) HEALTH PROFESSIONAL SHORTAGE AREA.—The term "health professional shortage area" means a health professional shortage area designated under section 332.

(4) MEDICALLY UNDERSERVED COMMUNITY.—The term "medically underserved community" has the meaning given the term in section 799B(6).

(5) MEDICALLY UNDERSERVED POPULATION.—The term "medically underserved population" has the meaning given the term in section 330(b)(3).

(c) PROGRAM.—The Secretary shall establish, under section 301, a small health care provider quality improvement grant program.

(d) ADMINISTRATION.—

(1) PROGRAMS.—The rural health care services outreach, rural health network development, and small health care provider quality improvement grant programs established under section 301 shall be administered by the Director of the Office of Rural Health Policy of the Health Resources and Services Administration, in consultation with State offices of rural health or other appropriate State government entities.

(2) GRANTS.—

(A) IN GENERAL.—In carrying out the programs described in paragraph (1), the Director may award grants under subsections (e), (f), and (g) to expand access to, coordinate, and improve the quality of essential health care services, and enhance the delivery of health care, in rural areas.

(B) TYPES OF GRANTS.—The Director may award the grants—

(i) to promote expanded delivery of health care services in rural areas under subsection (e);

(ii) to provide for the planning and implementation of integrated health care networks in rural areas under subsection (f); and

(iii) to provide for the planning and implementation of small health care provider quality improvement activities under subsection (g).

(e) RURAL HEALTH CARE SERVICES OUTREACH GRANTS.—

(1) GRANTS.—The Director may award grants to eligible entities to promote rural health care services outreach by expanding the delivery of health care services to include new and enhanced services in rural areas. The Director may award the grants for periods of not more than 3 years.

(2) ELIGIBILITY.—To be eligible to receive a grant under this subsection for a project, an entity—

(A) shall be a rural public or rural nonprofit private entity;

(B) shall represent a consortium composed of members—

(i) that include 3 or more health care providers; and

(ii) that may be nonprofit or for-profit entities; and

(C) shall not previously have received a grant under this subsection for the same or a similar project, unless the entity is proposing to expand the scope of the project or the area that will be served through the project.

(3) APPLICATIONS.—To be eligible to receive a grant under this subsection, an eligible entity, in consultation with the appropriate State office of rural health or another appropriate State entity, shall prepare and submit to the Secretary an application, at such time, in such manner, and containing such information as the Secretary may require, including—

(A) a description of the project that the eligible entity will carry out using the funds provided under the grant;

(B) a description of the manner in which the project funded under the grant will meet the health care needs of rural underserved populations in the local community or region to be served;

(C) a description of how the local community or region to be served will be involved in the development and ongoing operations of the project;

(D) a plan for sustaining the project after Federal support for the project has ended;

(E) a description of how the project will be evaluated; and

(F) other such information as the Secretary determines to be appropriate.

(f) RURAL HEALTH NETWORK DEVELOPMENT GRANTS.—

(1) GRANTS.—

(A) IN GENERAL.—The Director may award rural health network development grants to eligible entities to promote, through planning and implementation, the development of integrated health care networks that have combined the functions of the entities participating in the networks in order to—

(i) achieve efficiencies;

(ii) expand access to, coordinate, and improve the quality of essential health care services; and

(iii) strengthen the rural health care system as a whole.

(B) GRANT PERIODS.—The Director may award such a rural health network development grant for implementation activities for a period of 3 years. The Director may also award such a rural health network development grant for planning activities for a period of 1 year, to assist in the development of an integrated health care network, if the proposed participants in the network do not have a

history of collaborative efforts and a 3-year grant would be inappropriate.

(2) ELIGIBILITY.—To be eligible to receive a grant under this subsection, an entity—

(A) shall be a rural public or rural nonprofit private entity;

(B) shall represent a network composed of participants—

(i) that include 3 or more health care providers; and

(ii) that may be nonprofit or for-profit entities; and

(C) shall not previously have received a grant under this subsection (other than a grant for planning activities) for the same or a similar project.

(3) APPLICATIONS.—To be eligible to receive a grant under this subsection, an eligible entity, in consultation with the appropriate State office of rural health or another appropriate State entity, shall prepare and submit to the Secretary an application, at such time, in such manner, and containing such information as the Secretary may require, including—

(A) a description of the project that the eligible entity will carry out using the funds provided under the grant;

(B) an explanation of the reasons why Federal assistance is required to carry out the project;

(C) a description of—

(i) the history of collaborative activities carried out by the participants in the network;

(ii) the degree to which the participants are ready to integrate their functions; and

(iii) how the local community or region to be served will benefit from and be involved in the activities carried out by the network;

(D) a description of how the local community or region to be served will experience increased access to quality health care services across the continuum of care as a result of the integration activities carried out by the network;

(E) a plan for sustaining the project after Federal support for the project has ended;

(F) a description of how the project will be evaluated; and

(G) other such information as the Secretary determines to be appropriate.

(g) SMALL HEALTH CARE PROVIDER QUALITY IMPROVEMENT GRANTS.—

(1) GRANTS.—The Director may award grants to provide for the planning and implementation of small health care provider quality improvement activities. The Director may award the grants for periods of 1 to 3 years.

(2) ELIGIBILITY.—To be eligible for a grant under this subsection, an entity—

(A)(i) shall be a rural public or rural nonprofit private health care provider or provider of health care services,

such as a critical access hospital or a rural health clinic; or

(ii) shall be another rural provider or network of small rural providers identified by the Secretary as a key source of local care; and

(B) shall not previously have received a grant under this subsection for the same or a similar project.

(3) APPLICATIONS.—To be eligible to receive a grant under this subsection, an eligible entity, in consultation with the appropriate State office of rural health or another appropriate State entity shall prepare and submit to the Secretary an application, at such time, in such manner, and containing such information as the Secretary may require, including—

(A) a description of the project that the eligible entity will carry out using the funds provided under the grant;

(B) an explanation of the reasons why Federal assistance is required to carry out the project;

(C) a description of the manner in which the project funded under the grant will assure continuous quality improvement in the provision of services by the entity;

(D) a description of how the local community or region to be served will experience increased access to quality health care services across the continuum of care as a result of the activities carried out by the entity;

(E) a plan for sustaining the project after Federal support for the project has ended;

(F) a description of how the project will be evaluated; and

(G) other such information as the Secretary determines to be appropriate.

(4) EXPENDITURES FOR SMALL HEALTH CARE PROVIDER QUALITY IMPROVEMENT GRANTS.—In awarding a grant under this subsection, the Director shall ensure that the funds made available through the grant will be used to provide services to residents of rural areas. The Director shall award not less than 50 percent of the funds made available under this subsection to providers located in and serving rural areas.

(h) GENERAL REQUIREMENTS.—

(1) PROHIBITED USES OF FUNDS.—An entity that receives a grant under this section may not use funds provided through the grant—

(A) to build or acquire real property; or

(B) for construction.

(2) COORDINATION WITH OTHER AGENCIES.—The Secretary shall coordinate activities carried out under grant programs described in this section, to the extent practicable, with Federal and State agencies and nonprofit organizations that are operating similar grant programs, to maximize the effect of public dollars in funding meritorious proposals.

(3) PREFERENCE.—In awarding grants under this section, the Secretary shall give preference to entities that—

(A) are located in health professional shortage areas or medically underserved communities, or serve medically underserved populations; or

(B) propose to develop projects with a focus on primary care, and wellness and prevention strategies.

(i) REPORT.—Not later than September 30, 2005, the Secretary shall prepare and submit to the appropriate committees of Congress a report on the progress and accomplishments of the grant programs described in subsections (e), (f), and (g).

(j) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $45,000,000 for each of fiscal years 2008 through 2012.

SEC. 330A–1.[254c–1a] GRANTS TO NURSE–MANAGED HEALTH CLINICS.

(a) DEFINITIONS.—

(1) COMPREHENSIVE PRIMARY HEALTH CARE SERVICES.—In this section, the term "comprehensive primary health care services" means the primary health services described in section 330(b)(1).

(2) NURSE-MANAGED HEALTH CLINIC.—The term "nurse-managed health clinic" means a nurse-practice arrangement, managed by advanced practice nurses, that provides primary care or wellness services to underserved or vulnerable populations and that is associated with a school, college, university or department of nursing, federally qualified health center, or independent nonprofit health or social services agency.

(b) AUTHORITY TO AWARD GRANTS.—The Secretary shall award grants for the cost of the operation of nurse-managed health clinics that meet the requirements of this section.

(c) APPLICATIONS.—To be eligible to receive a grant under this section, an entity shall—

(1) be an NMHC; and

(2) submit to the Secretary an application at such time, in such manner, and containing—

(A) assurances that nurses are the major providers of services at the NMHC and that at least 1 advanced practice nurse holds an executive management position within the organizational structure of the NMHC;

(B) an assurance that the NMHC will continue providing comprehensive primary health care services or wellness services without regard to income or insurance status of the patient for the duration of the grant period; and

(C) an assurance that, not later than 90 days of receiving a grant under this section, the NMHC will establish a community advisory committee, for which a majority of the members shall be individuals who are served by the NMHC.

(d) GRANT AMOUNT.—The amount of any grant made under this section for any fiscal year shall be determined by the Secretary, taking into account—

(1) the financial need of the NMHC, considering State, local, and other operational funding provided to the NMHC; and

(2) other factors, as the Secretary determines appropriate.

(e) AUTHORIZATION OF APPROPRIATIONS.—For the purposes of carrying out this section, there are authorized to be appropriated

$50,000,000 for the fiscal year 2010 and such sums as may be necessary for each of the fiscal years 2011 through 2014.

SEC. 330B.[254c–2] SPECIAL DIABETES PROGRAMS FOR TYPE I DIABETES.[33].

(a) IN GENERAL.—The Secretary, directly or through grants, shall provide for research into the prevention and cure of Type I diabetes.

(b) FUNDING.—

(1) TRANSFERRED FUNDS.—Notwithstanding section 2104(a) of the Social Security Act, from the amounts appropriated in such section for each of fiscal years 1998 through 2002, $30,000,000 is hereby transferred and made available in such fiscal year for grants under this section.

(2) APPROPRIATIONS.—For the purpose of making grants under this section, there is appropriated, out of any funds in the Treasury not otherwise appropriated—

(A) $70,000,000 for each of fiscal years 2001 and 2002 (which shall be combined with amounts transferred under paragraph (1) for each such fiscal years);

(B) $100,000,000 for fiscal year 2003; and

(C) $150,000,000 for each of fiscal years 2004 through 2014.

SEC. 330C.[254c–3] SPECIAL DIABETES PROGRAMS FOR INDIANS.[34].

(a) IN GENERAL.—The Secretary shall make grants for providing services for the prevention and treatment of diabetes in accordance with subsection (b).

(b) SERVICES THROUGH INDIAN HEALTH FACILITIES.—For purposes of subsection (a), services under such subsection are provided in accordance with this subsection if the services are provided through any of the following entities:

(1) The Indian Health Service.

(2) An Indian health program operated by an Indian tribe or tribal organization pursuant to a contract, grant, cooperative agreement, or compact with the Indian Health Service pursuant to the Indian Self-Determination Act.

(3) An urban Indian health program operated by an urban Indian organization pursuant to a grant or contract with the Indian Health Service pursuant to title V of the Indian Health Care Improvement Act.

(c) FUNDING.—

(1) TRANSFERRED FUNDS.—Notwithstanding section 2104(a) of the Social Security Act, from the amounts appropriated in such section for each of fiscal years 1998 through 2002, $30,000,000, to remain available until expended, is hereby transferred and made available in such fiscal year for grants under this section.

[33] Section 4923 of Public Law 105–33 (111 Stat. 574, as amended by section 1(c) of Public Law 107–360 (116 Stat. 3019),) requires the Secretary of Health and Human Services to conduct evaluations regarding programs under sections 330B and 330C. An interim report is required to be submitted to the appropriate committees of Congress not later than January 1, 2000, and a final report is required to be submitted not later than January 1, 2007.

[34] See footnote to section 330B.

(2) APPROPRIATIONS.—For the purpose of making grants under this section, there is appropriated, out of any money in the Treasury not otherwise appropriated—

(A) $70,000,000 for each of fiscal years 2001 and 2002 (which shall be combined with amounts transferred under paragraph (1) for each such fiscal years);

(B) $100,000,000 for fiscal year 2003; and

(C) $150,000,000 for each of fiscal years 2004 through 2014.

SEC. 330D.[254c–4] CENTERS FOR STRATEGIES ON FACILITATING UTILIZATION OF PREVENTIVE HEALTH SERVICES AMONG VARIOUS POPULATIONS.

(a) IN GENERAL.—The Secretary, acting through the appropriate agencies of the Public Health Service, shall make grants to public or nonprofit private entities for the establishment and operation of regional centers whose purpose is to develop, evaluate, and disseminate effective strategies, which utilize quality management measures, to assist public and private health care programs and providers in the appropriate utilization of preventive health care services by specific populations.

(b) RESEARCH AND TRAINING.—The activities carried out by a center under subsection (a) may include establishing programs of research and training with respect to the purpose described in such subsection, including the development of curricula for training individuals in implementing the strategies developed under such subsection.

(c) PRIORITY REGARDING INFANTS AND CHILDREN.—In carrying out the purpose described in subsection (a), the Secretary shall give priority to various populations of infants, young children, and their mothers.

(d) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2000 through 2004.

SEC. 330E.[254c–5] EPILEPSY; SEIZURE DISORDER.

(a) NATIONAL PUBLIC HEALTH CAMPAIGN.—

(1) IN GENERAL.—The Secretary shall develop and implement public health surveillance, education, research, and intervention strategies to improve the lives of persons with epilepsy, with a particular emphasis on children. Such projects may be carried out by the Secretary directly and through awards of grants or contracts to public or nonprofit private entities. The Secretary may directly or through such awards provide technical assistance with respect to the planning, development, and operation of such projects.

(2) CERTAIN ACTIVITIES.—Activities under paragraph (1) shall include—

(A) expanding current surveillance activities through existing monitoring systems and improving registries that maintain data on individuals with epilepsy, including children;

(B) enhancing research activities on the diagnosis, treatment, and management of epilepsy;

(C) implementing public and professional information and education programs regarding epilepsy, including initiatives which promote effective management of the disease through children's programs which are targeted to parents, schools, daycare providers, patients;

(D) undertaking educational efforts with the media, providers of health care, schools and others regarding stigmas and secondary disabilities related to epilepsy and seizures, and its effects on youth;

(E) utilizing and expanding partnerships with organizations with experience addressing the health and related needs of people with disabilities; and

(F) other activities the Secretary deems appropriate.

(3) COORDINATION OF ACTIVITIES.—The Secretary shall ensure that activities under this subsection are coordinated as appropriate with other agencies of the Public Health Service that carry out activities regarding epilepsy and seizure.

(b) SEIZURE DISORDER; DEMONSTRATION PROJECTS IN MEDICALLY UNDERSERVED AREAS.—

(1) IN GENERAL.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, may make grants for the purpose of carrying out demonstration projects to improve access to health and other services regarding seizures to encourage early detection and treatment in children and others residing in medically underserved areas.

(2) APPLICATION FOR GRANT.—A grant may not be awarded under paragraph (1) unless an application therefore is submitted to the Secretary and the Secretary approves such application. Such application shall be submitted in such form and manner and shall contain such information as the Secretary may prescribe.

(c) DEFINITIONS.—For purposes of this section:

(1) The term "epilepsy" refers to a chronic and serious neurological condition characterized by excessive electrical discharges in the brain causing recurring seizures affecting all life activities. The Secretary may revise the definition of such term to the extent the Secretary determines necessary.

(2) The term "medically underserved" has the meaning applicable under section 799B(6).

(d) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005.

SEC. 330F.[254c–6] CERTAIN SERVICES FOR PREGNANT WOMEN.

(a) INFANT ADOPTION AWARENESS.—

(1) IN GENERAL.—The Secretary shall make grants to national, regional, or local adoption organizations for the purpose of developing and implementing programs to train the designated staff of eligible health centers in providing adoption information and referrals to pregnant women on an equal basis with all other courses of action included in nondirective counseling to pregnant women.

(2) BEST-PRACTICES GUIDELINES.—

(A) IN GENERAL.—A condition for the receipt of a grant under paragraph (1) is that the adoption organization involved agree that, in providing training under such paragraph, the organization will follow the guidelines developed under subparagraph (B).

(B) PROCESS FOR DEVELOPMENT OF GUIDELINES.—

(i) IN GENERAL.—The Secretary shall establish and supervise a process described in clause (ii) in which the participants are—

(I) an appropriate number and variety of adoption organizations that, as a group, have expertise in all models of adoption practice and that represent all members of the adoption triad (birth mother, infant, and adoptive parent); and

(II) affected public health entities.

(ii) DESCRIPTION OF PROCESS.—The process referred to in clause (i) is a process in which the participants described in such clause collaborate to develop best-practices guidelines on the provision of adoption information and referrals to pregnant women on an equal basis with all other courses of action included in nondirective counseling to pregnant women.

(iii) DATE CERTAIN FOR DEVELOPMENT.—The Secretary shall ensure that the guidelines described in clause (ii) are developed not later than 180 days after the date of the enactment of the Children's Health Act of 2000[35].

(C) RELATION TO AUTHORITY FOR GRANTS.—The Secretary may not make any grant under paragraph (1) before the date on which the guidelines under subparagraph (B) are developed.

(3) USE OF GRANT.—

(A) IN GENERAL.—With respect to a grant under paragraph (1)—

(i) an adoption organization may expend the grant to carry out the programs directly or through grants to or contracts with other adoption organizations;

(ii) the purposes for which the adoption organization expends the grant may include the development of a training curriculum, consistent with the guidelines developed under paragraph (2)(B); and

(iii) a condition for the receipt of the grant is that the adoption organization agree that, in providing training for the designated staff of eligible health centers, such organization will make reasonable efforts to ensure that the individuals who provide the training are individuals who are knowledgeable in all elements of the adoption process and are experienced in providing adoption information and referrals in the geographic areas in which the eligible health centers are

[35] Public Law 106–310, enacted October 17, 2000.

located, and that the designated staff receive the training in such areas.

(B) RULE OF CONSTRUCTION REGARDING TRAINING OF TRAINERS.—With respect to individuals who under a grant under paragraph (1) provide training for the designated staff of eligible health centers (referred to in this subparagraph as "trainers"), subparagraph (A)(iii) may not be construed as establishing any limitation regarding the geographic area in which the trainers receive instruction in being such trainers. A trainer may receive such instruction in a different geographic area than the area in which the trainer trains (or will train) the designated staff of eligible health centers.

(4) ADOPTION ORGANIZATIONS; ELIGIBLE HEALTH CENTERS; OTHER DEFINITIONS.—For purposes of this section:

(A) The term "adoption organization" means a national, regional, or local organization—

(i) among whose primary purposes are adoption;

(ii) that is knowledgeable in all elements of the adoption process and on providing adoption information and referrals to pregnant women; and

(iii) that is a nonprofit private entity.

(B) The term "designated staff", with respect to an eligible health center, means staff of the center who provide pregnancy or adoption information and referrals (or will provide such information and referrals after receiving training under a grant under paragraph (1)).

(C) The term "eligible health centers" means public and nonprofit private entities that provide health services to pregnant women.

(5) TRAINING FOR CERTAIN ELIGIBLE HEALTH CENTERS.—A condition for the receipt of a grant under paragraph (1) is that the adoption organization involved agree to make reasonable efforts to ensure that the eligible health centers with respect to which training under the grant is provided include—

(A) eligible health centers that receive grants under section 1001 (relating to voluntary family planning projects);

(B) eligible health centers that receive grants under section 330 (relating to community health centers, migrant health centers, and centers regarding homeless individuals and residents of public housing); and

(C) eligible health centers that receive grants under this Act for the provision of services in schools.

(6) PARTICIPATION OF CERTAIN ELIGIBLE HEALTH CLINICS.—In the case of eligible health centers that receive grants under section 330 or 1001:

(A) Within a reasonable period after the Secretary begins making grants under paragraph (1), the Secretary shall provide eligible health centers with complete information about the training available from organizations receiving grants under such paragraph. The Secretary shall make reasonable efforts to encourage eligible health centers to arrange for designated staff to participate in such

training. Such efforts shall affirm Federal requirements, if any, that the eligible health center provide nondirective counseling to pregnant women.

(B) All costs of such centers in obtaining the training shall be reimbursed by the organization that provides the training, using grants under paragraph (1).

(C) Not later than 1 year after the date of the enactment of the Children's Health Act of 2000[36], the Secretary shall submit to the appropriate committees of the Congress a report evaluating the extent to which adoption information and referral, upon request, are provided by eligible health centers. Within a reasonable time after training under this section is initiated, the Secretary shall submit to the appropriate committees of the Congress a report evaluating the extent to which adoption information and referral, upon request, are provided by eligible health centers in order to determine the effectiveness of such training and the extent to which such training complies with subsection (a)(1). In preparing the reports required by this subparagraph, the Secretary shall in no respect interpret the provisions of this section to allow any interference in the provider-patient relationship, any breach of patient confidentiality, or any monitoring or auditing of the counseling process or patient records which breaches patient confidentiality or reveals patient identity. The reports required by this subparagraph shall be conducted by the Secretary acting through the Administrator of the Health Resources and Services Administration and in collaboration with the Director of the Agency for Healthcare Research and Quality.

(b) APPLICATION FOR GRANT.—The Secretary may make a grant under subsection (a) only if an application for the grant is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(c) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005.

SEC. 330G.[254c–7] SPECIAL NEEDS ADOPTION PROGRAMS; PUBLIC AWARENESS CAMPAIGN AND OTHER ACTIVITIES.

(a) SPECIAL NEEDS ADOPTION AWARENESS CAMPAIGN.—

(1) IN GENERAL.—The Secretary shall, through making grants to nonprofit private entities, provide for the planning, development, and carrying out of a national campaign to provide information to the public regarding the adoption of children with special needs.

(2) INPUT ON PLANNING AND DEVELOPMENT.—In providing for the planning and development of the national campaign under paragraph (1), the Secretary shall provide for input from a number and variety of adoption organizations throughout the

[36] Public Law 106–310, enacted October 17, 2000.

States in order that the full national diversity of interests among adoption organizations is represented in the planning and development of the campaign.

(3) CERTAIN FEATURES.—With respect to the national campaign under paragraph (1):

(A) The campaign shall be directed at various populations, taking into account as appropriate differences among geographic regions, and shall be carried out in the language and cultural context that is most appropriate to the population involved.

(B) The means through which the campaign may be carried out include—

(i) placing public service announcements on television, radio, and billboards; and

(ii) providing information through means that the Secretary determines will reach individuals who are most likely to adopt children with special needs.

(C) The campaign shall provide information on the subsidies and supports that are available to individuals regarding the adoption of children with special needs.

(D) The Secretary may provide that the placement of public service announcements, and the dissemination of brochures and other materials, is subject to review by the Secretary.

(4) MATCHING REQUIREMENT.—

(A) IN GENERAL.—With respect to the costs of the activities to be carried out by an entity pursuant to paragraph (1), a condition for the receipt of a grant under such paragraph is that the entity agree to make available (directly or through donations from public or private entities) non-Federal contributions toward such costs in an amount that is not less than 25 percent of such costs.

(B) DETERMINATION OF AMOUNT CONTRIBUTED.—Non-Federal contributions under subparagraph (A) may be in cash or in kind, fairly evaluated, including plant, equipment, or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such contributions.

(b) NATIONAL RESOURCES PROGRAM.—The Secretary shall (directly or through grant or contract) carry out a program that, through toll-free telecommunications, makes available to the public information regarding the adoption of children with special needs. Such information shall include the following:

(1) A list of national, State, and regional organizations that provide services regarding such adoptions, including exchanges and other information on communicating with the organizations. The list shall represent the full national diversity of adoption organizations.

(2) Information beneficial to individuals who adopt such children, including lists of support groups for adoptive parents and other postadoptive services.

(c) OTHER PROGRAMS.—With respect to the adoption of children with special needs, the Secretary shall make grants—

(1) to provide assistance to support groups for adoptive parents, adopted children, and siblings of adopted children; and

(2) to carry out studies to identify—

(A) the barriers to completion of the adoption process; and

(B) those components that lead to favorable long-term outcomes for families that adopt children with special needs.

(d) APPLICATION FOR GRANT.—The Secretary may make an award of a grant or contract under this section only if an application for the award is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(e) FUNDING.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005.

SEC. 330H.[254c–8] HEALTHY START FOR INFANTS.

(a) IN GENERAL.—

(1) CONTINUATION AND EXPANSION OF PROGRAM.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, Maternal and Child Health Bureau, shall under authority of this section continue in effect the Healthy Start Initiative and may, during fiscal year 2001 and subsequent years, carry out such program on a national basis.

(2) DEFINITION.—For purposes of paragraph (1), the term "Healthy Start Initiative" is a reference to the program that, as an initiative to reduce the rate of infant mortality and improve perinatal outcomes, makes grants for project areas with high annual rates of infant mortality and that, prior to the effective date of this section, was a demonstration program carried out under section 301.

(b) CONSIDERATIONS IN MAKING GRANTS.—

(1) REQUIREMENTS.—In making grants under subsection (a), the Secretary shall require that applicants (in addition to meeting all eligibility criteria established by the Secretary) establish, for project areas under such subsection, community-based consortia of individuals and organizations (including agencies responsible for administering block grant programs under title V of the Social Security Act, consumers of project services, public health departments, hospitals, health centers under section 330, and other significant sources of health care services) that are appropriate for participation in projects under subsection (a).

(2) OTHER CONSIDERATIONS.—In making grants under subsection (a), the Secretary shall take into consideration the following:

(A) Factors that contribute to infant mortality, such as low birthweight.

(B) The extent to which applicants for such grants facilitate—

(i) a community-based approach to the delivery of services; and

(ii) a comprehensive approach to women's health care to improve perinatal outcomes.

(3) SPECIAL PROJECTS.—Nothing in paragraph (2) shall be construed to prevent the Secretary from awarding grants under subsection (a) for special projects that are intended to address significant disparities in perinatal health indicators in communities along the United States-Mexico border or in Alaska or Hawaii.

(c) COORDINATION.—Recipients of grants under subsection (a) shall coordinate their services and activities with the State agency or agencies that administer block grant programs under title V of the Social Security Act in order to promote cooperation, integration, and dissemination of information with Statewide systems and with other community services funded under the Maternal and Child Health Block Grant.

(d) RULE OF CONSTRUCTION.—Except to the extent inconsistent with this section, this section may not be construed as affecting the authority of the Secretary to make modifications in the program carried out under subsection (a).

(e) FUNDING.—

(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated—

(A) $120,000,000 for fiscal year 2008; and

(B) for each of fiscal years 2009 through 2013, the amount authorized for the preceding fiscal year increased by the percentage increase in the Consumer Price Index for all urban consumers for such year.

(2) ALLOCATION.—

(A) PROGRAM ADMINISTRATION.—Of the amounts appropriated under paragraph (1) for a fiscal year, the Secretary may reserve up to 5 percent for coordination, dissemination, technical assistance, and data activities that are determined by the Secretary to be appropriate for carrying out the program under this section.

(B) EVALUATION.—Of the amounts appropriated under paragraph (1) for a fiscal year, the Secretary may reserve up to 1 percent for evaluations of projects carried out under subsection (a). Each such evaluation shall include a determination of whether such projects have been effective in reducing the disparity in health status between the general population and individuals who are members of racial or ethnic minority groups.

SEC. 330I.[254c–14] TELEHEALTH NETWORK AND TELEHEALTH RESOURCE CENTERS GRANT PROGRAMS.

(a) DEFINITIONS.—In this section:

(1) DIRECTOR; OFFICE.—The terms "Director" and "Office" mean the Director and Office specified in subsection (c).

(2) FEDERALLY QUALIFIED HEALTH CENTER AND RURAL HEALTH CLINIC.—The term "Federally qualified health center" and "rural health clinic" have the meanings given the terms in

section 1861(aa) of the Social Security Act (42 U.S.C. 1395x(aa)).

(3) FRONTIER COMMUNITY.—The term "frontier community" shall have the meaning given the term in regulations issued under subsection (r).

(4) MEDICALLY UNDERSERVED AREA.—The term "medically underserved area" has the meaning given the term "medically underserved community" in section 799B(6).

(5) MEDICALLY UNDERSERVED POPULATION.—The term "medically underserved population" has the meaning given the term in section 330(b)(3).

(6) TELEHEALTH SERVICES.—The term "telehealth services" means services provided through telehealth technologies.

(7) TELEHEALTH TECHNOLOGIES.—The term "telehealth technologies" means technologies relating to the use of electronic information, and telecommunications technologies, to support and promote, at a distance, health care, patient and professional health-related education, health administration, and public health.

(b) PROGRAMS.—The Secretary shall establish, under section 301, telehealth network and telehealth resource centers grant programs.

(c) ADMINISTRATION.—

(1) ESTABLISHMENT.—There is established in the Health Resources and Services Administration an Office for the Advancement of Telehealth. The Office shall be headed by a Director.

(2) DUTIES.—The telehealth network and telehealth resource centers grant programs established under section 301 shall be administered by the Director, in consultation with the State offices of rural health, State offices concerning primary care, or other appropriate State government entities.

(d) GRANTS.—

(1) TELEHEALTH NETWORK GRANTS.—The Director may, in carrying out the telehealth network grant program referred to in subsection (b), award grants to eligible entities for projects to demonstrate how telehealth technologies can be used through telehealth networks in rural areas, frontier communities, and medically underserved areas, and for medically underserved populations, to—

(A) expand access to, coordinate, and improve the quality of health care services;

(B) improve and expand the training of health care providers; and

(C) expand and improve the quality of health information available to health care providers, and patients and their families, for decisionmaking.

(2) TELEHEALTH RESOURCE CENTERS GRANTS.—The Director may, in carrying out the telehealth resource centers grant program referred to in subsection (b), award grants to eligible entities for projects to demonstrate how telehealth technologies can be used in the areas and communities, and for the populations, described in paragraph (1), to establish telehealth resource centers.

(e) GRANT PERIODS.—The Director may award grants under this section for periods of not more than 4 years.

(f) ELIGIBLE ENTITIES.—

(1) TELEHEALTH NETWORK GRANTS.—

(A) GRANT RECIPIENT.—To be eligible to receive a grant under subsection (d)(1), an entity shall be a nonprofit entity.

(B) TELEHEALTH NETWORKS.—

(i) IN GENERAL.—To be eligible to receive a grant under subsection (d)(1), an entity shall demonstrate that the entity will provide services through a telehealth network.

(ii) NATURE OF ENTITIES.—Each entity participating in the telehealth network may be a nonprofit or for-profit entity.

(iii) COMPOSITION OF NETWORK.—The telehealth network shall include at least 2 of the following entities (at least 1 of which shall be a community-based health care provider):

(I) Community or migrant health centers or other Federally qualified health centers.

(II) Health care providers, including pharmacists, in private practice.

(III) Entities operating clinics, including rural health clinics.

(IV) Local health departments.

(V) Nonprofit hospitals, including community access hospitals.

(VI) Other publicly funded health or social service agencies.

(VII) Long-term care providers.

(VIII) Providers of health care services in the home.

(IX) Providers of outpatient mental health services and entities operating outpatient mental health facilities.

(X) Local or regional emergency health care providers.

(XI) Institutions of higher education.

(XII) Entities operating dental clinics.

(2) TELEHEALTH RESOURCE CENTERS GRANTS.—To be eligible to receive a grant under subsection (d)(2), an entity shall be a nonprofit entity.

(g) APPLICATIONS.—To be eligible to receive a grant under subsection (d), an eligible entity, in consultation with the appropriate State office of rural health or another appropriate State entity, shall prepare and submit to the Secretary an application, at such time, in such manner, and containing such information as the Secretary may require, including—

(1) a description of the project that the eligible entity will carry out using the funds provided under the grant;

(2) a description of the manner in which the project funded under the grant will meet the health care needs of rural or other populations to be served through the project, or improve

the access to services of, and the quality of the services received by, those populations;

(3) evidence of local support for the project, and a description of how the areas, communities, or populations to be served will be involved in the development and ongoing operations of the project;

(4) a plan for sustaining the project after Federal support for the project has ended;

(5) information on the source and amount of non-Federal funds that the entity will provide for the project;

(6) information demonstrating the long-term viability of the project, and other evidence of institutional commitment of the entity to the project;

(7) in the case of an application for a project involving a telehealth network, information demonstrating how the project will promote the integration of telehealth technologies into the operations of health care providers, to avoid redundancy, and improve access to and the quality of care; and

(8) other such information as the Secretary determines to be appropriate.

(h) TERMS; CONDITIONS; MAXIMUM AMOUNT OF ASSISTANCE.—The Secretary shall establish the terms and conditions of each grant program described in subsection (b) and the maximum amount of a grant to be awarded to an individual recipient for each fiscal year under this section. The Secretary shall publish, in a publication of the Health Resources and Services Administration, notice of the application requirements for each grant program described in subsection (b) for each fiscal year.

(i) PREFERENCES.—

(1) TELEHEALTH NETWORKS.—In awarding grants under subsection (d)(1) for projects involving telehealth networks, the Secretary shall give preference to an eligible entity that meets at least 1 of the following requirements:

(A) ORGANIZATION.—The eligible entity is a rural community-based organization or another community-based organization.

(B) SERVICES.—The eligible entity proposes to use Federal funds made available through such a grant to develop plans for, or to establish, telehealth networks that provide mental health, public health, long-term care, home care, preventive, or case management services.

(C) COORDINATION.—The eligible entity demonstrates how the project to be carried out under the grant will be coordinated with other relevant federally funded projects in the areas, communities, and populations to be served through the grant.

(D) NETWORK.—The eligible entity demonstrates that the project involves a telehealth network that includes an entity that—

(i) provides clinical health care services, or educational services for health care providers and for patients or their families; and

(ii) is—

(I) a public library;

(II) an institution of higher education; or

(III) a local government entity.

(E) CONNECTIVITY.—The eligible entity proposes a project that promotes local connectivity within areas, communities, or populations to be served through the project.

(F) INTEGRATION.—The eligible entity demonstrates that health care information has been integrated into the project.

(2) TELEHEALTH RESOURCE CENTERS.—In awarding grants under subsection (d)(2) for projects involving telehealth resource centers, the Secretary shall give preference to an eligible entity that meets at least 1 of the following requirements:

(A) PROVISION OF SERVICES.—The eligible entity has a record of success in the provision of telehealth services to medically underserved areas or medically underserved populations.

(B) COLLABORATION AND SHARING OF EXPERTISE.—The eligible entity has a demonstrated record of collaborating and sharing expertise with providers of telehealth services at the national, regional, State, and local levels.

(C) BROAD RANGE OF TELEHEALTH SERVICES.—The eligible entity has a record of providing a broad range of telehealth services, which may include—

(i) a variety of clinical specialty services;

(ii) patient or family education;

(iii) health care professional education; and

(iv) rural residency support programs.

(j) DISTRIBUTION OF FUNDS.—

(1) IN GENERAL.—In awarding grants under this section, the Director shall ensure, to the greatest extent possible, that such grants are equitably distributed among the geographical regions of the United States.

(2) TELEHEALTH NETWORKS.—In awarding grants under subsection (d)(1) for a fiscal year, the Director shall ensure that—

(A) not less than 50 percent of the funds awarded shall be awarded for projects in rural areas; and

(B) the total amount of funds awarded for such projects for that fiscal year shall be not less than the total amount of funds awarded for such projects for fiscal year 2001 under section 330A (as in effect on the day before the date of enactment of the Health Care Safety Net Amendments of 2002).

(k) USE OF FUNDS.—

(1) TELEHEALTH NETWORK PROGRAM.—The recipient of a grant under subsection (d)(1) may use funds received through such grant for salaries, equipment, and operating or other costs, including the cost of—

(A) developing and delivering clinical telehealth services that enhance access to community-based health care services in rural areas, frontier communities, or medically underserved areas, or for medically underserved populations;

(B) developing and acquiring, through lease or purchase, computer hardware and software, audio and video equipment, computer network equipment, interactive equipment, data terminal equipment, and other equipment that furthers the objectives of the telehealth network grant program;

(C)(i) developing and providing distance education, in a manner that enhances access to care in rural areas, frontier communities, or medically underserved areas, or for medically underserved populations; or

(ii) mentoring, precepting, or supervising health care providers and students seeking to become health care providers, in a manner that enhances access to care in the areas and communities, or for the populations, described in clause (i);

(D) developing and acquiring instructional programming;

(E)(i) providing for transmission of medical data, and maintenance of equipment; and

(ii) providing for compensation (including travel expenses) of specialists, and referring health care providers, who are providing telehealth services through the telehealth network, if no third party payment is available for the telehealth services delivered through the telehealth network;

(F) developing projects to use telehealth technology to facilitate collaboration between health care providers;

(G) collecting and analyzing usage statistics and data to document the cost-effectiveness of the telehealth services; and

(H) carrying out such other activities as are consistent with achieving the objectives of this section, as determined by the Secretary.

(2) TELEHEALTH RESOURCE CENTERS.—The recipient of a grant under subsection (d)(2) may use funds received through such grant for salaries, equipment, and operating or other costs for—

(A) providing technical assistance, training, and support, and providing for travel expenses, for health care providers and a range of health care entities that provide or will provide telehealth services;

(B) disseminating information and research findings related to telehealth services;

(C) promoting effective collaboration among telehealth resource centers and the Office;

(D) conducting evaluations to determine the best utilization of telehealth technologies to meet health care needs;

(E) promoting the integration of the technologies used in clinical information systems with other telehealth technologies;

(F) fostering the use of telehealth technologies to provide health care information and education for health care providers and consumers in a more effective manner; and

(G) implementing special projects or studies under the direction of the Office.

(l) PROHIBITED USES OF FUNDS.—An entity that receives a grant under this section may not use funds made available through the grant—

(1) to acquire real property;

(2) for expenditures to purchase or lease equipment, to the extent that the expenditures would exceed 40 percent of the total grant funds;

(3) in the case of a project involving a telehealth network, to purchase or install transmission equipment (such as laying cable or telephone lines, or purchasing or installing microwave towers, satellite dishes, amplifiers, or digital switching equipment);

(4) to pay for any equipment or transmission costs not directly related to the purposes for which the grant is awarded;

(5) to purchase or install general purpose voice telephone systems;

(6) for construction; or

(7) for expenditures for indirect costs (as determined by the Secretary), to the extent that the expenditures would exceed 15 percent of the total grant funds.

(m) COLLABORATION.—In providing services under this section, an eligible entity shall collaborate, if feasible, with entities that—

(1)(A) are private or public organizations, that receive Federal or State assistance; or

(B) are public or private entities that operate centers, or carry out programs, that receive Federal or State assistance; and

(2) provide telehealth services or related activities.

(n) COORDINATION WITH OTHER AGENCIES.—The Secretary shall coordinate activities carried out under grant programs described in subsection (b), to the extent practicable, with Federal and State agencies and nonprofit organizations that are operating similar programs, to maximize the effect of public dollars in funding meritorious proposals.

(o) OUTREACH ACTIVITIES.—The Secretary shall establish and implement procedures to carry out outreach activities to advise potential end users of telehealth services in rural areas, frontier communities, medically underserved areas, and medically underserved populations in each State about the grant programs described in subsection (b).

(p) TELEHEALTH.—It is the sense of Congress that, for purposes of this section, States should develop reciprocity agreements so that a provider of services under this section who is a licensed or otherwise authorized health care provider under the law of 1 or more States, and who, through telehealth technology, consults with a licensed or otherwise authorized health care provider in another State, is exempt, with respect to such consultation, from any State law of the other State that prohibits such consultation on the basis that the first health care provider is not a licensed or authorized health care provider under the law of that State.

(q) REPORT.—Not later than September 30, 2005, the Secretary shall prepare and submit to the appropriate committees of Con-

gress a report on the progress and accomplishments of the grant programs described in subsection (b).

(r) REGULATIONS.—The Secretary shall issue regulations specifying, for purposes of this section, a definition of the term "frontier area". The definition shall be based on factors that include population density, travel distance in miles to the nearest medical facility, travel time in minutes to the nearest medical facility, and such other factors as the Secretary determines to be appropriate. The Secretary shall develop the definition in consultation with the Director of the Bureau of the Census and the Administrator of the Economic Research Service of the Department of Agriculture.

(s) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section—

(1) for grants under subsection (d)(1), $40,000,000 for fiscal year 2002, and such sums as may be necessary for each of fiscal years 2003 through 2006; and

(2) for grants under subsection (d)(2), $20,000,000 for fiscal year 2002, and such sums as may be necessary for each of fiscal years 2003 through 2006.

SEC. 330J.[254c–15] RURAL EMERGENCY MEDICAL SERVICE TRAINING AND EQUIPMENT ASSISTANCE PROGRAM.

(a) GRANTS.—The Secretary, acting through the Administrator of the Health Resources and Services Administration (referred to in this section as the "Secretary") shall award grants to eligible entities to enable such entities to provide for improved emergency medical services in rural areas.

(b) ELIGIBILITY.—To be eligible to receive a grant under this section, an entity shall—

(1) be—

(A) a State emergency medical services office;

(B) a State emergency medical services association;

(C) a State office of rural health;

(D) a local government entity;

(E) a State or local ambulance provider; or

(F) any other entity determined appropriate by the Secretary; and

(2) prepare and submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require, that includes—

(A) a description of the activities to be carried out under the grant; and

(B) an assurance that the eligible entity will comply with the matching requirement of subsection (e).

(c) USE OF FUNDS.—An entity shall use amounts received under a grant made under subsection (a), either directly or through grants to emergency medical service squads that are located in, or that serve residents of, a nonmetropolitan statistical area, an area designated as a rural area by any law or regulation of a State, or a rural census tract of a metropolitan statistical area (as determined under the most recent Goldsmith Modification, originally published in a notice of availability of funds in the Federal Register on February 27, 1992, 57 Fed. Reg. 6725), to—

(1) recruit emergency medical service personnel;

(2) recruit volunteer emergency medical service personnel;

(3) train emergency medical service personnel in emergency response, injury prevention, safety awareness, and other topics relevant to the delivery of emergency medical services;

(4) fund specific training to meet Federal or State certification requirements;

(5) develop new ways to educate emergency health care providers through the use of technology-enhanced educational methods (such as distance learning);

(6) acquire emergency medical services equipment, including cardiac defibrillators;

(7) acquire personal protective equipment for emergency medical services personnel as required by the Occupational Safety and Health Administration; and

(8) educate the public concerning cardiopulmonary resuscitation, first aid, injury prevention, safety awareness, illness prevention, and other related emergency preparedness topics.

(d) PREFERENCE.—In awarding grants under this section the Secretary shall give preference to—

(1) applications that reflect a collaborative effort by 2 or more of the entities described in subparagraphs (A) through (F) of subsection (b)(1); and

(2) applications submitted by entities that intend to use amounts provided under the grant to fund activities described in any of paragraphs (1) through (5) of subsection (c).

(e) MATCHING REQUIREMENT.—The Secretary may not award a grant under this section to an entity unless the entity agrees that the entity will make available (directly or through contributions from other public or private entities) non-Federal contributions toward the activities to be carried out under the grant in an amount equal to 25 percent of the amount received under the grant.

(f) EMERGENCY MEDICAL SERVICES.—In this section, the term "emergency medical services"—

(1) means resources used by a qualified public or private nonprofit entity, or by any other entity recognized as qualified by the State involved, to deliver medical care outside of a medical facility under emergency conditions that occur—

(A) as a result of the condition of the patient; or

(B) as a result of a natural disaster or similar situation; and

(2) includes services delivered by an emergency medical services provider (either compensated or volunteer) or other provider recognized by the State involved that is licensed or certified by the State as an emergency medical technician or its equivalent (as determined by the State), a registered nurse, a physician assistant, or a physician that provides services similar to services provided by such an emergency medical services provider.

(g) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—There are authorized to be appropriated to carry out this section such sums as may be necessary for each of fiscal years 2002 through 2006.

(2) ADMINISTRATIVE COSTS.—The Secretary may use not more than 10 percent of the amount appropriated under para-

graph (1) for a fiscal year for the administrative expenses of carrying out this section.

SEC. 330K.[254c–16] MENTAL HEALTH SERVICES DELIVERED VIA TELEHEALTH.

(a) DEFINITIONS.—In this section:

(1) ELIGIBLE ENTITY.—The term "eligible entity" means a public or nonprofit private telehealth provider network that offers services that include mental health services provided by qualified mental health providers.

(2) QUALIFIED MENTAL HEALTH PROFESSIONALS.—The term "qualified mental health professionals" refers to providers of mental health services reimbursed under the medicare program carried out under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) who have additional training in the treatment of mental illness in children and adolescents or who have additional training in the treatment of mental illness in the elderly.

(3) SPECIAL POPULATIONS.—The term "special populations" refers to the following 2 distinct groups:

(A) Children and adolescents in mental health underserved rural areas or in mental health underserved urban areas.

(B) Elderly individuals located in long-term care facilities in mental health underserved rural or urban areas.

(4) TELEHEALTH.—The term "telehealth" means the use of electronic information and telecommunications technologies to support long distance clinical health care, patient and professional health-related education, public health, and health administration.

(b) PROGRAM AUTHORIZED.—

(1) IN GENERAL.—The Secretary, acting through the Director of the Office for the Advancement of Telehealth of the Health Resources and Services Administration, shall award grants to eligible entities to establish demonstration projects for the provision of mental health services to special populations as delivered remotely by qualified mental health professionals using telehealth and for the provision of education regarding mental illness as delivered remotely by qualified mental health professionals using telehealth.

(2) POPULATIONS SERVED.—The Secretary shall award the grants under paragraph (1) in a manner that distributes the grants so as to serve equitably the populations described in subparagraphs (A) and (B) of subsection (a)(3).

(c) USE OF FUNDS.—

(1) IN GENERAL.—An eligible entity that receives a grant under this section shall use the grant funds—

(A) for the populations described in subsection (a)(3)(A)—

(i) to provide mental health services, including diagnosis and treatment of mental illness, as delivered remotely by qualified mental health professionals using telehealth; and

(ii) to collaborate with local public health entities to provide the mental health services; and

(B) for the populations described in subsection (a)(3)(B)—

(i) to provide mental health services, including diagnosis and treatment of mental illness, in long-term care facilities as delivered remotely by qualified mental health professionals using telehealth; and

(ii) to collaborate with local public health entities to provide the mental health services.

(2) OTHER USES.—An eligible entity that receives a grant under this section may also use the grant funds to—

(A) pay telecommunications costs; and

(B) pay qualified mental health professionals on a reasonable cost basis as determined by the Secretary for services rendered.

(3) PROHIBITED USES.—An eligible entity that receives a grant under this section shall not use the grant funds to—

(A) purchase or install transmission equipment (other than such equipment used by qualified mental health professionals to deliver mental health services using telehealth under the project involved); or

(B) build upon or acquire real property.

(d) EQUITABLE DISTRIBUTION.—In awarding grants under this section, the Secretary shall ensure, to the greatest extent possible, that such grants are equitably distributed among geographical regions of the United States.

(e) APPLICATION.—An entity that desires a grant under this section shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary determines to be reasonable.

(f) REPORT.—Not later than 4 years after the date of enactment of the Health Care Safety Net Amendments of 2002, the Secretary shall prepare and submit to the appropriate committees of Congress a report that shall evaluate activities funded with grants under this section.

(g) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, $20,000,000 for fiscal year 2002 and such sums as may be necessary for fiscal years 2003 through 2006.

SEC. 330L.[254c–18] TELEMEDICINE; INCENTIVE GRANTS REGARDING COORDINATION AMONG STATES.

(a) IN GENERAL.—The Secretary may make grants to State professional licensing boards to carry out programs under which such licensing boards of various States cooperate to develop and implement State policies that will reduce statutory and regulatory barriers to telemedicine.

(b) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out subsection (a), there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2002 through 2006.

Subpart II—National Health Service Corps Program

NATIONAL HEALTH SERVICE CORPS.

SEC. 331.[254d] (a)(1) For the purpose of eliminating health manpower[37] shortages in health professional shortage areas, there is established, within the Service, the National Health Service Corps, which shall consist of—

(A) such officers of the Regular and Reserve Corps of the Service as the Secretary may designate,

(B) such civilian employees of the United States as the Secretary may appoint, and

(C) such other individuals who are not employees of the United States.

(2) The Corps shall be utilized by the Secretary to provide primary health services in health professional shortage areas.

(3) For purposes of this subpart and subpart III:

(A) The term "Corps" means the National Health Service Corps.

(B) The term "Corps member" means each of the officers, employees, and individuals of which the Corps consists pursuant to paragraph (1).

(C) The term "health professional shortage area" has the meaning given such term in section 332(a).

(D) The term "primary health services" means health services regarding family medicine, internal medicine, pediatrics, obstetrics and gynecology, dentistry, or mental health, that are provided by physicians or other health professionals.

(E)(i) The term "behavioral and mental health professionals" means health service psychologists, licensed clinical social workers, licensed professional counselors, marriage and family therapists, psychiatric nurse specialists, and psychiatrists.

(ii) The term "graduate program of behavioral and mental health" means a program that trains behavioral and mental health professionals.

(b)(1) The Secretary may conduct at schools of medicine, osteopathic medicine, dentistry, and, as appropriate, nursing and other schools of the health professions, including schools at which graduate programs of behavioral and mental health are offered, and at entities which train allied health personnel, recruiting programs for the Corps, the Scholarship Program, and the Loan Repayment Program. Such recruiting programs shall include efforts to recruit individuals who will serve in the Corps other than pursuant to obligated service under the Scholarship or Loan Repayment Program.

(2) In the case of physicians, dentists, behavioral and mental health professionals, certified nurse midwives, certified nurse practitioners, and physician assistants who have an interest and a commitment to providing primary health care, the Secretary may establish fellowship programs to enable such health professionals to gain exposure to and expertise in the delivery of primary health services in health professional shortage areas. To the maximum ex-

[37] So in law. Probably should be "health professional shortages". See section 401 of Public Law 101–597 (104 Stat. 3035).

tent practicable, the Secretary shall ensure that any such programs are established in conjunction with accredited residency programs, and other training programs, regarding such health professions.

(c)(1) The Secretary may reimburse an applicant for a position in the Corps (including an individual considering entering into a written agreement pursuant to section 338D) for the actual and reasonable expenses incurred in traveling to and from the applicant's place of residence to an eligible site to which the applicant may be assigned under section 333 for the purpose of evaluating such site with regard to being assigned at such site. The Secretary may establish a maximum total amount that may be paid to an individual as reimbursement for such expenses.

(2) The Secretary may also reimburse the applicant for the actual and reasonable expenses incurred for the travel of 1 family member to accompany the applicant to such site. The Secretary may establish a maximum total amount that may be paid to an individual as reimbursement for such expenses.

(3) In the case of an individual who has entered into a contract for obligated service under the Scholarship Program or under the Loan Repayment Program, the Secretary may reimburse such individual for all or part of the actual and reasonable expenses incurred in transporting the individual, the individual's family, and the family's possessions to the site of the individual's assignment under section 333. The Secretary may establish a maximum total amount that may be paid to an individual as reimbursement for such expenses.

(d)(1) The Secretary may, under regulations promulgated by the Secretary, adjust the monthly pay of each member of the Corps (other than a member described in subsection (a)(1)(C)) who is directly engaged in the delivery of health services in a health professional shortage area as follows:

(A) During the first 36 months in which such a member is so engaged in the delivery of health services, his monthly pay may be increased by an amount which when added to the member's monthly pay and allowances will provide a monthly income competitive with the average monthly income from a practice of an individual who is a member of the profession of the Corps member, who has equivalent training, and who has been in practice for a period equivalent to the period during which the Corps member has been in practice.

(B) During the period beginning upon the expiration of the 36 months referred to in subparagraph (A) and ending with the month in which the member's monthly pay and allowances are equal to or exceed the monthly income he received for the last of such 36 months, the member may receive in addition to his monthly pay and allowances an amount which when added to such monthly pay and allowances equals the monthly income he received for such last month.

(C) For each month in which a member is directly engaged in the delivery of health services in a health professional shortage area in accordance with an agreement with the Secretary entered into under section 741(f)(1)(C), under which the Secretary is obligated to make payments in accordance with section 741(f)(2), the amount of any monthly increase under sub-

paragraph (A) or (B) with respect to such member shall be decreased by an amount equal to one-twelfth of the amount which the Secretary is obligated to pay upon the completion of the year of practice in which such month occurs.

For purposes of subparagraphs (A) and (B), the term "monthly pay" includes special pay received under chapter 5 of title 37 of the United States Code.

(2) In the case of a member of the Corps who is directly engaged in the delivery of health services in a health professional shortage area in accordance with a service obligation incurred under the Scholarship Program or the Loan Repayment Program, the adjustment in pay authorized by paragraph (1) may be made for such a member only upon satisfactory completion of such service obligation, and the first 36 months of such member's being so engaged in the delivery of health services shall, for purposes of paragraph (1)(A), be deemed to begin upon such satisfactory completion.

(3) A member of the Corps described in subparagraph (C) of subsection (a)(1) shall when assigned to an entity under section 333 be subject to the personnel system of such entity, except that such member shall receive during the period of assignment the income that the member would receive if the member was a member of the Corps described in subparagraph (B) of such subsection.

(e) Corps members assigned under section 333 to provide health services in health professional shortage areas shall not be counted against any employment ceiling affecting the Department.

(f) Sections 214 and 216 shall not apply to members of the National Health Service Corps during their period of obligated service under the Scholarship Program or the Loan Repayment Program, except when such members are Commissioned Corps officers who entered into a contract with Secretary under section 338A or 338B after December 31, 2006 and when the Secretary determines that exercising the authority provided under section 214 or 216 with respect to any such officer to would not cause unreasonable disruption to health care services provided in the community in which such officer is providing health care services.

(g)(1) The Secretary shall, by rule, prescribe conversion provisions applicable to any individual who, within a year after completion of service as a member of the Corps described in subsection (a)(1)(C), becomes a commissioned officer in the Regular or Reserve Corps of the Service.

(2) The rules prescribed under paragraph (1) shall provide that in applying the appropriate provisions of this Act which relate to retirement, any individual who becomes such an officer shall be entitled to have credit for any period of service as a member of the Corps described in subsection (a)(1)(C).

(h) The Secretary shall ensure that adequate staff is provided to the Service with respect to effectively administering the program for the Corps.

(i)(1) In carrying out subpart III, the Secretary may, in accordance with this subsection, issue waivers to individuals who have entered into a contract for obligated service under the Scholarship Program or the Loan Repayment Program under which the individ-

uals are authorized to satisfy the requirement of obligated service through providing clinical practice that is half time.

(2) A waiver described in paragraph (1) may be provided by the Secretary only if—

(A) the entity for which the service is to be performed—

(i) has been approved under section 333A for assignment of a Corps member; and

(ii) has requested in writing assignment of a health professional who would serve half time;

(B) the Secretary has determined that assignment of a health professional who would serve half time would be appropriate for the area where the entity is located;

(C) a Corps member who is required to perform obligated service has agreed in writing to be assigned for half-time service to an entity described in subparagraph (A);

(D) the entity and the Corps member agree in writing that the Corps member will perform half-time clinical practice;

(E) the Corps member agrees in writing to fulfill all of the service obligations under section 338C through half-time clinical practice and either—

(i) double the period of obligated service that would otherwise be required; or

(ii) in the case of contracts entered into under section 338B, accept a minimum service obligation of 2 years with an award amount equal to 50 percent of the amount that would otherwise be payable for full-time service; and

(F) the Corps member agrees in writing that if the Corps member begins providing half-time service but fails to begin or complete the period of obligated service, the method stated in 338E(c) for determining the damages for breach of the individual's written contract will be used after converting periods of obligated service or of service performed into their full-time equivalents.

(3) In evaluating waivers issued under paragraph (1), the Secretary shall examine the effect of multidisciplinary teams.

(j) For the purposes of this subpart and subpart III:

(1) The term "Department" means the Department of Health and Human Services.

(2) The term "Loan Repayment Program" means the National Health Service Corps Loan Repayment Program established under section 338B.

(3) The term "Scholarship Program" means the National Health Service Corps Scholarship Program established under section 338A.

(4) The term "State" includes, in addition to the several States, only the District of Columbia, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, the Virgin Islands, Guam, American Samoa, and the Trust Territory of the Pacific Islands.

(5) The terms "full time" and "full-time" mean a minimum of 40 hours per week in a clinical practice, for a minimum of 45 weeks per year.

(6) The terms "half time" and "half-time" mean a minimum of 20 hours per week (not to exceed 39 hours per week) in a clinical practice, for a minimum of 45 weeks per year.

DESIGNATION OF HEALTH PROFESSIONAL SHORTAGE AREAS.

SEC. 332.[254e] (a)(1) For purposes of this subpart the term "health professional shortage area" means (A) an area in an urban or rural area (which need not conform to the geographic boundaries of a political subdivision and which is a rational area for the delivery of health services) which the Secretary determines has a health manpower shortage, (B) a population group which the Secretary determines has such a shortage, or (C) a public or nonprofit private medical facility or other public facility which the Secretary determines has such a shortage. All Federally qualified health centers and rural health clinics, as defined in section 1861(aa) of the Social Security Act (42 U.S.C. 1395x(aa)), that meet the requirements of section 334 shall be automatically designated as having such a shortage. The Secretary shall not remove an area from the areas determined to be health professional shortage areas under subparagraph (A) of the preceding sentence until the Secretary has afforded interested persons and groups in such area an opportunity to provide data and information in support of the designation as a health professional shortage area or a population group described in subparagraph (B) of such sentence or a facility described in subparagraph (C) of such sentence, and has made a determination on the basis of the data and information submitted by such persons and groups and other data and information available to the Secretary.

(2) For purposes of this subsection, the term "medical facility" means a facility for the delivery of health services and includes—

(A) a hospital, State mental hospital, public health center, outpatient medical facility, rehabilitation facility, facility for long-term care, community mental health center, migrant health center, facility operated by a city or county health department, and community health center and which is not reasonably accessible to an adequately served area;

(B) such a facility of a State correctional institution or of the Indian Health Service, and a health program or facility operated by a tribe or tribal organization under the Indian Self-Determination Act;

(C) such a facility used in connection with the delivery of health services under section 321 (relating to hospitals), 322 (relating to care and treatment of persons under quarantine and others), 323 (relating to care and treatment of Federal prisoners), 324 (relating to examination and treatment of certain Federal employees), 325 (relating to examination of aliens), 326 (relating to services to certain Federal employees), 320 (relating to services for persons with Hansen's disease), or 330(h) (relating to the provision of health services to homeless individuals); and

(D) a Federal medical facility.

(3) Homeless individuals (as defined in section 330(h)(5)), seasonal agricultural workers (as defined in section 330(g)(3)) and mi-

gratory agricultural workers (as so defined)), and residents of public housing (as defined in section 3(b)(1) of the United States Housing Act of 1937 (42 U.S.C. 1437a(b)(1))) may be population groups under paragraph (1).

(b) The Secretary shall establish by regulation criteria for the designation of areas, population groups, medical facilities, and other public facilities, in the States, as health professional shortage areas. In establishing such criteria, the Secretary shall take into consideration the following:

(1) The ratio of available health manpower to the number of individuals in an area or population group, or served by a medical facility or other public facility under consideration for designation.

(2) Indicators of a need, notwithstanding the supply of health manpower, for health services for the individuals in an area or population group or served by a medical facility or other public facility under consideration for designation.

(3) The percentage of physicians serving an area, population group, medical facility, or other public facility under consideration for designation who are employed by hospitals and who are graduates of foreign medical schools.

(c) In determining whether to make a designation, the Secretary shall take into consideration the following:

(1) The recommendations of the Governor of each State in which the area, population group, medical facility, or other public facility under consideration for designation is in whole or part located.

(2) The extent to which individuals who are (A) residents of the area, members of the population group, or patients in the medical facility or other public facility under consideration for designation, and (B) entitled to have payment made for medical services under title XVIII, XIX, or XXI of the Social Security Act, cannot obtain such services because of suspension of physicians from the programs under such titles.

(d)(1) In accordance with the criteria established under subsection (b) and the considerations listed in subsection (c), the Secretary shall designate health professional shortage areas in the States, publish a descriptive list of the areas, population groups, medical facilities, and other public facilities so designated, and at least annually review and, as necessary, revise such designations.

(2) For purposes of paragraph (1), a complete descriptive list shall be published in the Federal Register not later than July 1 of 1991 and each subsequent year.

(e)(1) Prior to the designation of a public facility, including a Federal medical facility, as a health professional shortage area, the Secretary shall give written notice of such proposed designation to the chief administrative officer of such facility and request comments within 30 days with respect to such designation.

(2) Prior to the designation of a health professional shortage area under this section, the Secretary shall, to the extent practicable, give written notice of the proposed designation of such area to appropriate public or private nonprofit entities which are located or have a demonstrated interest in such area and request com-

ments from such entities with respect to the proposed designation of such area.

(f) The Secretary shall give written notice of the designation of a health professional shortage area, not later than 60 days from the date of such designation, to—

(1) the Governor of each State in which the area, population group, medical facility, or other public facility so designated is in whole or part located; and

(2) appropriate public or nonprofit private entities which are located or which have a demonstrated interest in the area so designated.

(g) Any person may recommend to the Secretary the designation of an area, population group, medical facility, or other public facility as a health professional shortage area.

(h) The Secretary may conduct such information programs in areas, among population groups, and in medical facilities and other public facilities designated under this section as health professional shortage areas as may be necessary to inform public and nonprofit private entities which are located or have a demonstrated interest in such areas of the assistance available under this title by virtue of the designation of such areas.

(i) DISSEMINATION.—The Administrator of the Health Resources and Services Administration shall disseminate information concerning the designation criteria described in subsection (b) to—

(1) the Governor of each State;

(2) the representative of any area, population group, or facility selected by any such Governor to receive such information;

(3) the representative of any area, population group, or facility that requests such information; and

(4) the representative of any area, population group, or facility determined by the Administrator to be likely to meet the criteria described in subsection (b).

(j)(1) The Secretary shall submit the report described in paragraph (2) if the Secretary, acting through the Administrator of the Health Resources and Services Administration, issues—

(A) a regulation that revises the definition of a health professional shortage area for purposes of this section; or

(B) a regulation that revises the standards concerning priority of such an area under section 333A.

(2) On issuing a regulation described in paragraph (1), the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report that describes the regulation.

(3) Each regulation described in paragraph (1) shall take effect 180 days after the committees described in paragraph (2) receive a report referred to in such paragraph describing the regulation.

ASSIGNMENT OF CORPS PERSONNEL.

SEC. 333.[254f] (a)(1) The Secretary may assign members of the Corps to provide, under regulations promulgated by the Sec-

retary, health services in or to a health professional shortage area during the assignment period only if—

(A) a public or private entity, which is located or has a demonstrated interest in such area, makes application to the Secretary for such assignment;

(B) such application has been approved by the Secretary;

(C) the entity agrees to comply with the requirements of section 334; and

(D) the Secretary has (i) conducted an evaluation of the need and demand for health professional shortage area, the intended use of Corps members to be assigned to the area, community support for the assignment of Corps members to the area, the area's efforts to secure health professional shortage area, and the fiscal management capability of the entity to which Corps members would be assigned and (ii) on the basis of such evaluation has determined that—

(I) there is a need and demand for health manpower for the area;

(II) there has been appropriate and efficient use of any Corps members previously assigned to the entity for the area;

(III) there is general community support for the assignment of Corps members to the entity;

(IV) the area has made unsuccessful efforts to secure health manpower for the area;

(V) there is a reasonable prospect of sound fiscal management, including efficient collection of fee-for-service, third-party, and other appropriate funds, by the entity with respect to Corps members assigned to such entity; and

(VI)[38] the entity demonstrates willingness to support or facilitate mentorship, professional development, and training opportunities for Corps members.

An application for assignment of a Corps member to a health professional shortage area shall include a demonstration by the applicant that the area or population group to be served by the applicant has a shortage of personal health services and that the Corps member will be located so that the member will provide services to the greatest number of persons residing in such area or included in such population group. Such a demonstration shall be made on the basis of the criteria prescribed by the Secretary under section 332(b) and on additional criteria which the Secretary shall prescribe to determine if the area or population group to be served by the applicant has a shortage of personal health services.

(2) Corps members may be assigned to a Federal health care facility, but only upon the request of the head of the department or agency of which such facility is a part.

(3) In approving applications for assignment of members of the Corps the Secretary shall not discriminate against applications from entities which are not receiving Federal financial assistance under this Act. In approving such applications, the Secretary shall

[38] Margin so in law.

give preference to applications in which a nonprofit entity or public entity shall provide a site to which Corps members may be assigned.

(b)(1) The Secretary may not approve an application for the assignment of a member of the Corps described in subparagraph (C) of section 331(a)(1) to an entity unless the application of the entity contains assurances satisfactory to the Secretary that the entity (A) has sufficient financial resources to provide the member of the Corps with an income of not less than the income to which the member would be entitled if the member was a member described in subparagraph (B) of section 331(a)(1), or (B) would have such financial resources if a grant was made to the entity under paragraph (2).

(2)(A) If in approving an application of an entity for the assignment of a member of the Corps described in subparagraph (C) of section 331(a)(1) the Secretary determines that the entity does not have sufficient financial resources to provide the member of the Corps with an income of not less than the income to which the member would be entitled if the member was a member described in subparagraph (B) of section 331(a)(1), the Secretary may make a grant to the entity to assure that the member of the Corps assigned to it will receive during the period of assignment to the entity such an income.

(B) The amount of any grant under subparagraph (A) shall be determined by the Secretary. Payments under such a grant may be made in advance or by way of reimbursement, and at such intervals and on such conditions, as the Secretary finds necessary. No grant may be made unless an application therefor is submitted to and approved by the Secretary. Such an application shall be in such form, submitted in such manner, and contain such information, as the Secretary shall by regulation prescribe.

(c) The Secretary shall assign Corps members to entities in health professional shortage areas without regard to the ability of the individuals in such areas, population groups, medical facilities, or other public facilities to pay for such services.

(d)(1) The Secretary may provide technical assistance to a public or private entity which is located in a health professional shortage area and which desires to make an application under this section for assignment of a Corps member to such area. Assistance provided under this paragraph may include assistance to an entity in (A) analyzing the potential use of health professions personnel in defined health services delivery areas by the residents of such areas, (B) determining the need for such personnel in such areas, (C) determining the extent to which such areas will have a financial base to support the practice of such personnel and the extent to which additional financial resources are needed to adequately support the practice, (D) determining the types of inpatient and other health services that should be provided by such personnel in such areas, and (E) developing long-term plans for addressing health professional shortages and improving access to health care. The Secretary shall encourage entities that receive technical assistance under this paragraph to communicate with other communities, State Offices of Rural Health, State Primary Care Associa-

tions and Offices, and other entities concerned with site development and community needs assessment.

(2) The Secretary may provide, to public and private entities which are located in a health professional shortage area to which area a Corps member has been assigned, technical assistance to assist in the retention of such member in such area after the completion of such member's assignment to the area.

(3) The Secretary may provide, to health professional shortage areas to which no Corps member has been assigned, (A) technical assistance to assist in the recruitment of health manpower for such areas, and (B) current information on public and private programs which provide assistance in the securing of health manpower.

(4)(A) The Secretary shall undertake to demonstrate the improvements that can be made in the assignment of members of the Corps to health professional shortage areas and in the delivery of health care by Corps members in such areas through coordination with States, political subdivisions of States, agencies of States and political subdivisions, and other public and private entities which have expertise in the planning, development, and operation of centers for the delivery of primary health care. In carrying out this subparagraph, the Secretary shall enter into agreements with qualified entities which provide that if—

(i) the entity places in effect a program for the planning, development, and operation of centers for the delivery of primary health care in health professional shortage areas which reasonably addresses the need for such care in such areas, and

(ii) under the program the entity will perform the functions described in subparagraph (B),

the Secretary will assign under this section members of the Corps in accordance with the program.

(B) For purposes of subparagraph (A), the term "qualified entity" means a State, political subdivision of a State, an agency of a State or political subdivision, or other public or private entity operating solely within one State, which the Secretary determines is able—

(i) to analyze the potential use of health professions personnel in defined health services delivery areas by the residents of such areas;

(ii) to determine the need for such personnel in such areas and to recruit, select, and retain health professions personnel (including members of the National Health Service Corps) to meet such need;

(iii) to determine the extent to which such areas will have a financial base to support the practice of such personnel and the extent to which additional financial resources are needed to adequately support the practice;

(iv) to determine the types of inpatient and other health services that should be provided by such personnel in such areas;

(v) to assist such personnel in the development of their clinical practice and fee schedules and in the management of their practice;

(vi) to assist in the planning and development of facilities for the delivery of primary health care; and

(vii) to assist in establishing the governing bodies of centers for the delivery of such care and to assist such bodies in defining and carrying out their responsibilities.

(e) Notwithstanding any other law, any member of the Corps licensed to practice medicine, osteopathic medicine, dentistry, or any other health profession in any State shall, while serving in the Corps, be allowed to practice such profession in any State.

SEC. 333A.[254f–1] PRIORITIES IN ASSIGNMENT OF CORPS PERSONNEL.

(a) IN GENERAL.—In approving applications made under section 333 for the assignment of Corps members, the Secretary shall—

(1) give priority to any such application that—

(A) is made regarding the provision of primary health services to a health professional shortage area with the greatest such shortage; and

(B) is made by an entity that—

(i) serves a health professional shortage area described in subparagraph (A);

(ii) coordinates the delivery of primary health services with related health and social services;

(iii) has a documented record of sound fiscal management; and

(iv) will experience a negative impact on its capacity to provide primary health services if a Corps member is not assigned to the entity;

(2) with respect to the geographic area in which the health professional shortage area is located, take into consideration the willingness of individuals in the geographic area, and of the appropriate governmental agencies or health entities in the area, to assist and cooperate with the Corps in providing effective primary health services; and

(3) take into consideration comments of medical, osteopathic, dental, or other health professional societies whose members deliver services to the health professional shortage area, or if no such societies exist, comments of physicians, dentists, or other health professionals delivering services to the area.

(b) ESTABLISHMENT OF CRITERIA FOR DETERMINING PRIORITIES.—

(1) IN GENERAL.—The Secretary shall establish criteria specifying the manner in which the Secretary makes a determination under subsection (a)(1)(A) of the health professional shortage areas with the greatest such shortages.

(2) PUBLICATION OF CRITERIA.—The criteria required in paragraph (1) shall be published in the Federal Register not later than July 1, 1991. Any revisions made in the criteria by the Secretary shall be effective upon publication in the Federal Register.

(c) NOTIFICATIONS REGARDING PRIORITIES.—

(1) PROPOSED LIST.—The Secretary shall prepare and publish a proposed list of health professional shortage areas and entities that would receive priority under subsection (a)(1) in the assignment of Corps members. The list shall contain the

information described in paragraph (2), and the relative scores and relative priorities of the entities submitting applications under section 333, in a proposed format. All such entities shall have 30 days after the date of publication of the list to provide additional data and information in support of inclusion on the list or in support of a higher priority determination and the Secretary shall reasonably consider such data and information in preparing the final list under paragraph (2).

(2) PREPARATION OF LIST FOR APPLICABLE PERIOD.—For the purpose of carrying out paragraph (3), the Secretary shall prepare and, as appropriate, update a list of health professional shortage areas and entities that are receiving priority under subsection (a)(1) in the assignment of Corps members. Such list—

(A) shall include a specification, for each such health professional shortage area, of the entities for which the Secretary has provided an authorization to receive assignments of Corps members in the event that Corps members are available for the assignments; and

(B) shall, of the entities for which an authorization described in subparagraph (A) has been provided, specify—

(i) the entities provided such an authorization for the assignment of Corps members who are participating in the Scholarship Program;

(ii) the entities provided such an authorization for the assignment of Corps members who are participating in the Loan Repayment Program; and

(iii) the entities provided such an authorization for the assignment of Corps members who have become Corps members other than pursuant to contractual obligations under the Scholarship or Loan Repayment Programs.

The Secretary may set forth such specifications by medical specialty.

(3) NOTIFICATION OF AFFECTED PARTIES.—

(A) ENTITIES.—Not later than 30 days after the Secretary has added to a list under paragraph (2) an entity specified as described in subparagraph (A) of such paragraph, the Secretary shall notify such entity that the entity has been provided an authorization to receive assignments of Corps members in the event that Corps members are available for the assignments.

(B) INDIVIDUALS.—In the case of an individual obligated to provide service under the Scholarship Program, not later than 3 months before the date described in section 338C(b)(5), the Secretary shall provide to such individual the names of each of the entities specified as described in paragraph (2)(B)(i) that is appropriate for the individual's medical specialty and discipline.

(4) REVISIONS.—If the Secretary proposes to make a revision in the list under paragraph (2), and the revision would adversely alter the status of an entity with respect to the list, the Secretary shall notify the entity of the revision. Any entity adversely affected by such a revision shall be notified in writing

by the Secretary of the reasons for the revision and shall have 30 days from such notification to file a written appeal of the determination involved which shall be reasonably considered by the Secretary before the revision to the list becomes final. The revision to the list shall be effective with respect to assignment of Corps members beginning on the date that the revision becomes final.

(d) LIMITATION ON NUMBER OF ENTITIES OFFERED AS ASSIGNMENT CHOICES IN SCHOLARSHIP PROGRAM.—

(1) DETERMINATION OF AVAILABLE CORPS MEMBERS.—By April 1 of each calendar year, the Secretary shall determine the number of participants in the Scholarship Program who will be available for assignments under section 333 during the program year beginning on July 1 of that calendar year.

(2) DETERMINATION OF NUMBER OF ENTITIES.—At all times during a program year, the number of entities specified under subsection (c)(2)(B)(i) shall be—

(A) not less than the number of participants determined with respect to that program year under paragraph (1); and

(B) not greater than twice the number of participants determined with respect to that program year under paragraph (1).

SEC. 334.[254g] CHARGES FOR SERVICES BY ENTITIES USING CORPS MEMBERS.

(a) AVAILABILITY OF SERVICES REGARDLESS OF ABILITY TO PAY OR PAYMENT SOURCE.—An entity to which a Corps member is assigned shall not deny requested health care services, and shall not discriminate in the provision of services to an individual—

(1) because the individual is unable to pay for the services; or

(2) because payment for the services would be made under—

(A) the medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.);

(B) the medicaid program under title XIX of such Act (42 U.S.C. 1396 et seq.); or

(C) the State children's health insurance program under title XXI of such Act (42 U.S.C. 1397aa et seq.).

(b) CHARGES FOR SERVICES.—The following rules shall apply to charges for health care services provided by an entity to which a Corps member is assigned:

(1) IN GENERAL.—

(A) SCHEDULE OF FEES OR PAYMENTS.—Except as provided in paragraph (2), the entity shall prepare a schedule of fees or payments for the entity's services, consistent with locally prevailing rates or charges and designed to cover the entity's reasonable cost of operation.

(B) SCHEDULE OF DISCOUNTS.—Except as provided in paragraph (2), the entity shall prepare a corresponding schedule of discounts (including, in appropriate cases, waivers) to be applied to the payment of such fees or payments. In preparing the schedule, the entity shall adjust the discounts on the basis of a patient's ability to pay.

(C) USE OF SCHEDULES.—The entity shall make every reasonable effort to secure from patients fees and payments for services in accordance with such schedules, and fees or payments shall be sufficiently discounted in accordance with the schedule described in subparagraph (B).

(2) SERVICES TO BENEFICIARIES OF FEDERAL AND FEDERALLY ASSISTED PROGRAMS.—In the case of health care services furnished to an individual who is a beneficiary of a program listed in subsection (a)(2), the entity—

(A) shall accept an assignment pursuant to section 1842(b)(3)(B)(ii) of the Social Security Act (42 U.S.C. 1395u(b)(3)(B)(ii)) with respect to an individual who is a beneficiary under the medicare program; and

(B) shall enter into an appropriate agreement with—

(i) the State agency administering the program under title XIX of such Act with respect to an individual who is a beneficiary under the medicaid program; and

(ii) the State agency administering the program under title XXI of such Act with respect to an individual who is a beneficiary under the State children's health insurance program.

(3) COLLECTION OF PAYMENTS.—The entity shall take reasonable and appropriate steps to collect all payments due for health care services provided by the entity, including payments from any third party (including a Federal, State, or local government agency and any other third party) that is responsible for part or all of the charge for such services.

PROVISION OF HEALTH SERVICES BY CORPS MEMBERS.

SEC. 335.[254h] (a) In providing health services in a health professional shortage area, Corps members shall utilize the techniques, facilities, and organizational forms most appropriate for the area, population group, medical facility, or other public facility, and shall, to the maximum extent feasible, provide such services (1) to all individuals in, or served by, such health professional shortage area regardless of their ability to pay for the services, and (2) in a manner which is cooperative with other health care providers serving such health professional shortage area.

(b)(1) Notwithstanding any other provision of law, the Secretary may (A) to the maximum extent feasible make such arrangements as he determines necessary to enable Corps members to utilize the health facilities in or serving the health professional shortage area in providing health services; (B) make such arrangements as he determines are necessary for the use of equipment and supplies of the Service and for the lease or acquisition of other equipment and supplies; and (C) secure the permanent or temporary services of physicians, dentists, nurses, administrators, and other health personnel. If there are no health facilities in or serving such area, the Secretary may arrange to have Corps members provide health services in the nearest health facilities of the Service or may lease or otherwise provide facilities in or serving such area for the provision of health services.

(2) If the individuals in or served by a health professional shortage area are being served (as determined under regulations of the Secretary) by a hospital or other health care delivery facility of the Service, the Secretary may, in addition to such other arrangements as he may make under paragraph (1), arrange for the utilization of such hospital or facility by Corps members in providing health services, but only to the extent that such utilization will not impair the delivery of health services and treatment through such hospital or facility to individuals who are entitled to health services and treatment through such hospital or facility.

(c) The Secretary may make one loan to any entity with an approved application under section 333 to assist such entity in meeting the costs of (1) establishing medical, dental, or other health profession practices, including the development of medical practice management systems; (2) acquiring equipment for use in providing health services; and (3) renovating buildings to establish health facilities. No loan may be made under this subsection unless an application therefor is submitted to, and approved by, the Secretary. The amount of any such loan shall be determined by the Secretary, except that no such loan may exceed $50,000.

(d) Upon the expiration of the assignment of all Corps members to a health professional shortage area, the Secretary may (notwithstanding any other provision of law) sell, to any appropriate local entity, equipment and other property of the United States utilized by such members in providing health services. Sales made under this subsection shall be made at the fair market value (as determined by the Secretary) of the equipment or such other property; except that the Secretary may make such sales for a lesser value to an appropriate local entity, if he determines that the entity is financially unable to pay the full market value.

(e)(1)(A) It shall be unlawful for any hospital to deny an authorized Corps member admitting privileges when such Corps member otherwise meets the professional qualifications established by the hospital for granting such privileges and agrees to abide by the published bylaws of the hospital and the published bylaws, rules, and regulations of its medical staff.

(B) Any hospital which is found by the Secretary, after notice and an opportunity for a hearing on the record, to have violated this subsection shall upon such finding cease, for a period to be determined by the Secretary, to receive and to be eligible to receive any Federal funds under this Act or under titles XVIII, XIX, or XXI of the Social Security Act.

(2) For purposes of this subsection, the term "hospital" includes a State or local public hospital, a private profit hospital, a private nonprofit hospital, a general or special hospital, and any other type of hospital (excluding a hospital owned or operated by an agency of the Federal Government), and any related facilities.

SEC. 336.[254h–1] FACILITATION OF EFFECTIVE PROVISION OF CORPS SERVICES.

(a) CONSIDERATION OF INDIVIDUAL CHARACTERISTICS OF MEMBERS IN MAKING ASSIGNMENTS.—In making an assignment of a Corps member to an entity that has had an application approved under section 333, the Secretary shall, subject to making the assignment in accordance with section 333A, seek to assign to the en-

tity a Corps member who has (and whose spouse, if any, has) characteristics that increase the probability that the member will remain in the health professional shortage area involved after the completion of the period of service in the Corps.

(b) COUNSELING ON SERVICE IN CORPS.—

(1) IN GENERAL.—The Secretary shall, subject to paragraph (3), offer appropriate counseling on service in the Corps to individuals during the period of membership in the Corps, particularly during the initial period of each assignment.

(2) CAREER ADVISOR REGARDING OBLIGATED SERVICE.—

(A) In the case of individuals who have entered into contracts for obligated service under the Scholarship or Loan Repayment Program, counseling under paragraph (1) shall include appropriate counseling on matters particular to such obligated service. The Secretary shall ensure that career advisors for providing such counseling are available to such individuals throughout the period of participation in the Scholarship or Loan Repayment Program.

(B) With respect to the Scholarship Program, counseling under paragraph (1) shall include counseling individuals during the period in which the individuals are pursuing an educational degree in the health profession involved, including counseling to prepare the individual for service in the Corps.

(3) EXTENT OF COUNSELING SERVICES.—With respect to individuals who have entered into contracts for obligated service under the Scholarship or Loan Repayment Program, this subsection shall be carried out regarding such individuals throughout the period of obligated service (and, additionally, throughout the period specified in paragraph (2)(B), in the case of the Scholarship Program). With respect to Corps members generally, this subsection shall be carried out to the extent practicable.

(c) GRANTS REGARDING PREPARATION OF STUDENTS FOR PRACTICE.—With respect to individuals who have entered into contracts for obligated service under the Scholarship or Loan Repayment Program, the Secretary may make grants to, and enter into contracts with, public and nonprofit private entities (including health professions schools) for the conduct of programs designed to prepare such individuals for the effective provision of primary health services in the health professional shortage areas to which the individuals are assigned.

(d) PROFESSIONAL DEVELOPMENT AND TRAINING.—

(1) IN GENERAL.—The Secretary shall assist Corps members in establishing and maintaining professional relationships and development opportunities, including by—

(A) establishing appropriate professional relationships between the Corps member involved and the health professions community of the geographic area with respect to which the member is assigned;

(B) establishing professional development, training, and mentorship linkages between the Corps member involved and the larger health professions community, including through distance learning, direct mentorship, and

development and implementation of training modules designed to meet the educational needs of offsite Corps members;

(C) establishing professional networks among Corps members; or

(D) engaging in other professional development, mentorship, and training activities for Corps members, at the discretion of the Secretary.

(2) ASSISTANCE IN ESTABLISHING PROFESSIONAL RELATIONSHIPS.—In providing such assistance under paragraph (1), the Secretary shall focus on establishing relationships with hospitals, with academic medical centers and health professions schools, with area health education centers under section 751, with health education and training centers under section 752, and with border health education and training centers under such section 752. Such assistance shall include assistance in obtaining faculty appointments at health professions schools.

(3) SUPPLEMENT NOT SUPPLANT.—Such efforts under this subsection shall supplement, not supplant, non-government efforts by professional health provider societies to establish and maintain professional relationships and development opportunities.

(e) TEMPORARY RELIEF FROM CORPS DUTIES.—

(1) IN GENERAL.—The Secretary shall, subject to paragraph (4), provide assistance to Corps members in establishing arrangements through which Corps members may, as appropriate, be provided temporary relief from duties in the Corps in order to pursue continuing education in the health professions, to participate in exchange programs with teaching centers, to attend professional conferences, or to pursue other interests, including vacations.

(2) ASSUMPTION OF DUTIES OF MEMBER.—

(A) Temporary relief under paragraph (1) may be provided only if the duties of the Corps member involved are assumed by another health professional. With respect to such temporary relief, the duties may be assumed by Corps members or by health professionals who are not Corps members, if the Secretary approves the professionals for such purpose. Any health professional so approved by the Secretary shall, during the period of providing such temporary relief, be deemed to be a Corps member for purposes of section 224 (including for purposes of the remedy described in such section), section 333(f)[39], and section 335(e).

(B) In carrying out paragraph (1), the Secretary shall provide for the formation and continued existence of a group of health professionals to provide temporary relief under such paragraph.

(3) RECRUITMENT FROM GENERAL HEALTH PROFESSIONS COMMUNITY.—In carrying out paragraph (1), the Secretary shall—

[39] So in law. As a result of the amendments made by section 103(b) of Public Law 101–597 (104 Stat. 3015), there is no subsection (f) in section 333. (Subsection (e) of section 333, like sections 224 and 335(e), establishes a right for Corps members.)

(A) encourage health professionals who are not Corps members to enter into arrangements under which the health professionals temporarily assume the duties of Corps members for purposes of paragraph (1); and

(B) with respect to the entities to which Corps members have been assigned under section 333, encourage the entities to facilitate the development of arrangements described in subparagraph (A).

(4) LIMITATION.—In carrying out paragraph (1), the Secretary may not, except as provided in paragraph (5), obligate any amounts (other than for incidental expenses) for the purpose of—

(A) compensating a health professional who is not a Corps member for assuming the duties of a Corps member; or

(B) paying the costs of a vacation, or other interests that a Corps member may pursue during the period of temporary relief under such paragraph.

(5) SOLE PROVIDERS OF HEALTH SERVICES.—In the case of any Corps member who is the sole provider of health services in the geographic area involved, the Secretary may, from amounts appropriated under section 338, obligate on behalf of the member such sums as the Secretary determines to be necessary for purposes of providing temporary relief under paragraph (1).

(f) DETERMINATIONS REGARDING EFFECTIVE SERVICE.—In carrying out subsection (a) and sections 338A(d) and 338B(d), the Secretary shall carry out activities to determine—

(1) the characteristics of physicians, dentists, and other health professionals who are more likely to remain in practice in health professional shortage areas after the completion of the period of service in the Corps;

(2) the characteristics of health manpower shortage areas[40], and of entities seeking assignments of Corps members, that are more likely to retain Corps members after the members have completed the period of service in the Corps; and

(3) the appropriate conditions for the assignment and utilization in health manpower shortage areas of certified nurse practitioners, certified nurse midwives, and physician assistants.

ANNUAL REPORTS.

SEC. 336A.**[**254i**]** The Secretary shall submit an annual report to Congress, and shall include in such report with respect to the previous calendar year—

(1) the number, identity, and priority of all health professional shortage areas designated in such year and the number of health professional shortage areas which the Secretary estimates will be designated in the subsequent year;

[40] So in law. Probably should be "health professional shortage areas". See section 401 of Public Law 101–597 (104 Stat. 3035).

(2) the number of applications filed under section 333 in such year for assignment of Corps members and the action taken on each such application;

(3) the number and types of Corps members assigned in such year to health professional shortage areas, the number and types of additional Corps members which the Secretary estimates will be assigned to such areas in the subsequent year, and the need for additional members for the Corps;

(4) the recruitment efforts engaged in for the Corps in such year and the number of qualified individuals who applied for service in the Corps in such year;

(5) the number of patients seen and the number of patient visits recorded during such year with respect to each health professional shortage area to which a Corps member was assigned during such year;

(6) the number of Corps members who elected, and the number of Corps members who did not elect, to continue to provide health services in health professional shortage areas after termination of their service in the Corps and the reasons (as reported to the Secretary) of members who did not elect for not making such election;

(7) the results of evaluations and determinations made under section 333(a)(1)(D) during such year; and

(8) the amount charged during such year for health services provided by Corps members, the amount which was collected in such year by entities in accordance with section 334, and the amount which was paid to the Secretary in such year under such agreements[41].

NATIONAL ADVISORY COUNCIL.

SEC. 337.[254j] (a) There is established a council to be known as the National Advisory Council on the National Health Service Corps (hereinafter in this section referred to as the "Council"). The Council shall be composed of fifteen members appointed by the Secretary. The Council shall consult with, advise, and make recommendations to, the Secretary with respect to his responsibilities in carrying out this subpart (other than section 338G), and shall review and comment upon regulations promulgated by the Secretary under this subpart.

(b)(1) Members of the Council shall be appointed for a term of three years, except that any member appointed to fill a vacancy occurring prior to the expiration of the term for which the member's predecessor was appointed shall be appointed for the remainder of such term. No member shall be removed, except for cause.

(2) Members of the Council (other than members who are officers or employees of the United States), while attending meetings or conferences thereof or otherwise serving on the business of the Council, shall be entitled to receive for each day (including travel-time) in which they are so serving compensation at a rate fixed by

[41] There is no antecedent reference to "agreements". Formerly, paragraph (8) contained the clause ", the amount which was collected in such year by entities in accordance with agreements under section 334,". Section 307(b) of Public Law 107–251 (116 Stat. 1649) struck "agreements under" in that clause.

the Secretary (but not to exceed the daily equivalent of the annual rate of basic pay in effect for grade GS–18 of the General Schedule); and while so serving away from their homes or regular places of business all members may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5 of the United States Code for persons in the Government service employed intermittently.

(c) Section 14 of the Federal Advisory Committee Act shall not apply with respect to the Council.

AUTHORIZATION OF APPROPRIATION.

SEC. 338.[254k] (a) For the purpose of carrying out this subpart, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2008 through 2012.

(b) An appropriation under an authorization under subsection (a) for any fiscal year may be made at any time before that fiscal year and may be included in an Act making an appropriation under an authorization under subsection (a) for another fiscal year; but no funds may be made available from any appropriation under such authorization for obligation under sections 331 through 335, section 336A, and section 337 before the fiscal year for which such appropriation is authorized.

Subpart III—Scholarship Program and Loan Repayment Program

NATIONAL HEALTH SERVICE CORPS SCHOLARSHIP PROGRAM.

SEC. 338A.[254*l*] (a) The Secretary shall establish the National Health Service Corps Scholarship Program to assure, with respect to the provision of primary health services pursuant to section 331(a)(2)—

(1) an adequate supply of physicians, dentists, behavioral and mental health professionals, certified nurse midwives, certified nurse practitioners, and physician assistants; and

(2) if needed by the Corps, an adequate supply of other health professionals.

(b) To be eligible to participate in the Scholarship Program, an individual must—

(1) be accepted for enrollment, or be enrolled, as a full-time student (A) in an accredited (as determined by the Secretary) educational institution in a State and (B) in a course of study or program, offered by such institution and approved by the Secretary, leading to a degree in medicine, osteopathic medicine, dentistry, or other health profession, or an appropriate degree from a graduate program of behavioral and mental health;

(2) be eligible for, or hold, an appointment as a commissioned officer in the Regular or Reserve Corps of the Service or be eligible for selection for civilian service in the Corps;

(3) submit an application to participate in the Scholarship Program; and

(4) sign and submit to the Secretary, at the time of submittal of such application, a written contract (described in subsection (f)) to accept payment of a scholarship and to serve (in accordance with this subpart) for the applicable period of obligated service in a health professional shortage area.

(c)(1) In disseminating application forms and contract forms to individuals desiring to participate in the Scholarship Program, the Secretary shall include with such forms—

(A) a fair summary of the rights and liabilities of an individual whose application is approved (and whose contract is accepted) by the Secretary, including in the summary a clear explanation of the damages to which the United States is entitled under section 338E in the case of the individual's breach of the contract; and

(B) information respecting meeting a service obligation through private practice under an agreement under section 338D and such other information as may be necessary for the individual to understand the individual's prospective participation in the Scholarship Program and service in the Corps, including a statement of all factors considered in approving applications for participation in the Program and in making assignments for participants in the Program.

(2) The application form, contract form, and all other information furnished by the Secretary under this subpart shall be written in a manner calculated to be understood by the average individual applying to participate in the Scholarship Program. The Secretary shall make such application forms, contract forms, and other information available to individuals desiring to participate in the Scholarship Program on a date sufficiently early to insure that such individuals have adequate time to carefully review and evaluate such forms and information.

(3)(A) The Secretary shall distribute to health professions schools materials providing information on the Scholarship Program and shall encourage the schools to disseminate the materials to the students of the schools.

(B)(i) In the case of any health professional whose period of obligated service under the Scholarship Program is nearing completion, the Secretary shall encourage the individual to remain in a health professional shortage area and to continue providing primary health services.

(ii) During the period in which a health professional is planning and making the transition to private practice from obligated service under the Scholarship Program, the Secretary may provide assistance to the professional regarding such transition if the professional is remaining in a health professional shortage area and is continuing to provide primary health services.

(C) In the case of entities to which participants in the Scholarship Program are assigned under section 333, the Secretary shall encourage the entities to provide options with respect to assisting the participants in remaining in the health professional shortage areas involved, and in continuing to provide primary health services, after the period of obligated service under the Scholarship Program is completed. The options with respect to which the Secretary provides such encouragement may include options regarding

the sharing of a single employment position in the health professions by 2 or more health professionals, and options regarding the recruitment of couples where both of the individuals are health professionals.

(d)(1) Subject to section 333A, in providing contracts under the Scholarship Program—

(A) the Secretary shall consider the extent of the demonstrated interest of the applicants for the contracts in providing primary health services;

(B) the Secretary, in considering applications from individuals accepted for enrollment or enrolled in dental school, shall consider applications from all individuals accepted for enrollment or enrolled in any accredited dental school in a State; and

(C) may consider such other factors regarding the applicants as the Secretary determines to be relevant to selecting qualified individuals to participate in such Program.

(2) In providing contracts under the Scholarship Program, the Secretary shall give priority—

(A) first, to any application for such a contract submitted by an individual who has previously received a scholarship under this section or under section 758;

(B) second, to any application for such a contract submitted by an individual who has characteristics that increase the probability that the individual will continue to serve in a health professional shortage area after the period of obligated service pursuant to subsection (f) is completed; and

(C) third, subject to subparagraph (B), to any application for such a contract submitted by an individual who is from a disadvantaged background.

(e)(1) An individual becomes a participant in the Scholarship Program only upon the Secretary's approval of the individual's application submitted under subsection (b)(3) and the Secretary's acceptance of the contract submitted by the individual under subsection (b)(4).

(2) The Secretary shall provide written notice to an individual promptly upon the Secretary's approving, under paragraph (1), of the individual's participation in the Scholarship Program.

(f) The written contract (referred to in this subpart) between the Secretary and an individual shall contain—

(1) an agreement that—

(A) subject to paragraph (2), the Secretary agrees (i) to provide the individual with a scholarship (described in subsection (g)) in each such school year or years for a period of years (not to exceed four school years) determined by the individual, during which period the individual is pursuing a course of study described in subsection (b)(1)(B), and (ii) to accept (subject to the availability of appropriated funds for carrying out sections 331 through 335 and section 337) the individual into the Corps (or for equivalent service as otherwise provided in this subpart); and

(B) subject to paragraph (2), the individual agrees—

(i) to accept provision of such a scholarship to the individual;

(ii) to maintain enrollment in a course of study described in subsection (b)(1)(B) until the individual completes the course of study;

(iii) while enrolled in such course of study, to maintain an acceptable level of academic standing (as determined under regulations of the Secretary by the educational institution offering such course of study);

(iv) if pursuing a degree from a school of medicine or osteopathic medicine, to complete a residency in a specialty that the Secretary determines is consistent with the needs of the Corps; and

(v) to serve for a time period (hereinafter in the subpart referred to as the "period of obligated service") equal to—

(I) one year for each school year for which the individual was provided a scholarship under the Scholarship Program, or

(II) two years,

whichever is greater, as a provider of primary health services in a health professional shortage area (designated under section 332) to which he is assigned by the Secretary as a member of the Corps, or as otherwise provided in this subpart;

(2) a provision that any financial obligation of the United States arising out of a contract entered into under this subpart and any obligation of the individual which is conditioned thereon, is contingent upon funds being appropriated for scholarships under this subpart and to carry out the purposes of sections 331 through 335 and sections 337 and 338;

(3) a statement of the damages to which the United States is entitled, under section 338E for the individual's breach of the contract; and

(4) such other statements of the rights and liabilities of the Secretary and of the individual, not inconsistent with the provisions of this subpart.

(g)(1) A scholarship provided to a student for a school year under a written contract under the Scholarship Program shall consist of—

(A) payment to, or (in accordance with paragraph (2)) on behalf of, the student of the amount (except as provided in section 711) of—

(i) the tuition of the student in such school year; and

(ii) all other reasonable educational expenses, including fees, books, and laboratory expenses, incurred by the student in such school year; and

(B) payment to the student of a stipend of $400 per month (adjusted in accordance with paragraph (3)) for each of the 12 consecutive months beginning with the first month of such school year.

(2) The Secretary may contract with an educational institution, in which a participant in the Scholarship Program is enrolled, for the payment to the educational institution of the amounts of tui-

tion and other reasonable educational expenses described in paragraph (1)(A). Payment to such an educational institution may be made without regard to section 3648 of the Revised Statutes (31 U.S.C. 529).

(3) The amount of the monthly stipend, specified in paragraph (1)(B) and as previously adjusted (if at all) in accordance with this paragraph, shall be increased by the Secretary for each school year ending in a fiscal year beginning after September 30, 1978, by an amount (rounded to the next highest multiple of $1) equal to the amount of such stipend multiplied by the overall percentage (under section 5303 of title 5, United States Code) of the adjustment (if such adjustment is an increase) in the rates of pay under the General Schedule made effective in the fiscal year in which such school year ends.

(h) Notwithstanding any other provision of law, individuals who have entered into written contracts with the Secretary under this section, while undergoing academic training, shall not be counted against any employment ceiling affecting the Department.

SEC. 338B.[254l–1] NATIONAL HEALTH SERVICE CORPS LOAN REPAYMENT PROGRAM.

(a) ESTABLISHMENT.—The Secretary shall establish a program to be known as the National Health Service Corps Loan Repayment Program to assure, with respect to the provision of primary health services pursuant to section 331(a)(2)—

(1) an adequate supply of physicians, dentists, behavioral and mental health professionals, certified nurse midwives, certified nurse practitioners, and physician assistants; and

(2) if needed by the Corps, an adequate supply of other health professionals.

(b) ELIGIBILITY.—To be eligible to participate in the Loan Repayment Program, an individual must—

(1)(A) have a degree in medicine, osteopathic medicine, dentistry, or another health profession, or an appropriate degree from a graduate program of behavioral and mental health, or be certified as a nurse midwife, nurse practitioner, or physician assistant;

(B) be enrolled in an approved graduate training program in medicine, osteopathic medicine, dentistry, behavioral and mental health, or other health profession; or

(C) be enrolled as a full-time student—

(i) in an accredited (as determined by the Secretary) educational institution in a State; and

(ii) in the final year of a course of a study or program, offered by such institution and approved by the Secretary, leading to a degree in medicine, osteopathic medicine, dentistry, or other health profession;

(2) be eligible for, or hold, an appointment as a commissioned officer in the Regular or Reserve Corps of the Service or be eligible for selection for civilian service in the Corps; and

(3) submit to the Secretary an application for a contract described in subsection (f) (relating to the payment by the Secretary of the educational loans of the individual in consideration of the individual serving for a period of obligated service).

(c) APPLICATION, CONTRACT, AND INFORMATION REQUIREMENTS.—

(1) SUMMARY AND INFORMATION.—In disseminating application forms and contract forms to individuals desiring to participate in the Loan Repayment Program, the Secretary shall include with such forms—

(A) a fair summary of the rights and liabilities of an individual whose application is approved (and whose contract is accepted) by the Secretary, including in the summary a clear explanation of the damages to which the United States is entitled under section 338E in the case of the individual's breach of the contract; and

(B) information respecting meeting a service obligation through private practice under an agreement under section 338D and such other information as may be necessary for the individual to understand the individual's prospective participation in the Loan Repayment Program and service in the Corps.

(2) UNDERSTANDABILITY.—The application form, contract form, and all other information furnished by the Secretary under this subpart shall be written in a manner calculated to be understood by the average individual applying to participate in the Loan Repayment Program.

(3) AVAILABILITY.—The Secretary shall make such application forms, contract forms, and other information available to individuals desiring to participate in the Loan Repayment Program on a date sufficiently early to ensure that such individuals have adequate time to carefully review and evaluate such forms and information.

(4) RECRUITMENT AND RETENTION.—

(A) The Secretary shall distribute to health professions schools materials providing information on the Loan Repayment Program and shall encourage the schools to disseminate the materials to the students of the schools.

(B)(i) In the case of any health professional whose period of obligated service under the Loan Repayment Program is nearing completion, the Secretary shall encourage the individual to remain in a health professional shortage area and to continue providing primary health services.

(ii) During the period in which a health professional is planning and making the transition to private practice from obligated service under the Loan Repayment Program, the Secretary may provide assistance to the professional regarding such transition if the professional is remaining in a health professional shortage area and is continuing to provide primary health services.

(C) In the case of entities to which participants in the Loan Repayment Program are assigned under section 333, the Secretary shall encourage the entities to provide options with respect to assisting the participants in remaining in the health professional shortage areas involved, and in continuing to provide primary health services, after the period of obligated service under the Loan Repayment Program is completed. The options with respect to which the

Secretary provides such encouragement may include options regarding the sharing of a single employment position in the health professions by 2 or more health professionals, and options regarding the recruitment of couples where both of the individuals are health professionals.

(d)(1) Subject to section 333A, in providing contracts under the Loan Repayment Program—

(A) the Secretary shall consider the extent of the demonstrated interest of the applicants for the contracts in providing primary health services; and

(B) may consider such other factors regarding the applicants as the Secretary determines to be relevant to selecting qualified individuals to participate in such Program.

(2) In providing contracts under the Loan Repayment Program, the Secretary shall give priority—

(A) to any application for such a contract submitted by an individual whose training is in a health profession or specialty determined by the Secretary to be needed by the Corps;

(B) to any application for such a contract submitted by an individual who has (and whose spouse, if any, has) characteristics that increase the probability that the individual will continue to serve in a health professional shortage area after the period of obligated service pursuant to subsection (f) is completed; and

(C) subject to subparagraph (B), to any application for such a contract submitted by an individual who is from a disadvantaged background.

(e) APPROVAL REQUIRED FOR PARTICIPATION.—An individual becomes a participant in the Loan Repayment Program only upon the Secretary and the individual entering into a written contract described in subsection (f).

(f) CONTENTS OF CONTRACTS.—The written contract (referred to in this subpart) between the Secretary and an individual shall contain—

(1) an agreement that—

(A) subject to paragraph (3), the Secretary agrees—

(i) to pay on behalf of the individual loans in accordance with subsection (g); and

(ii) to accept (subject to the availability of appropriated funds for carrying out sections 331 through 335 and section 337) the individual into the Corps (or for equivalent service as otherwise provided in this subpart); and

(B) subject to paragraph (3), the individual agrees—

(i) to accept loan payments on behalf of the individual;

(ii) in the case of an individual described in subsection (b)(1)(C), to maintain enrollment in a course of study or training described in such subsection until the individual completes the course of study or training;

(iii) in the case of an individual described in subsection (b)(1)(C), while enrolled in such course of study or training, to maintain an acceptable level of aca-

demic standing (as determined under regulations of the Secretary by the educational institution offering such course of study or training); and

(iv) to serve for a time period (hereinafter in this subpart referred to as the "period of obligated service") equal to 2 years or such longer period as the individual may agree to, as a provider of primary health services in a health professional shortage area (designated under section 332) to which such individual is assigned by the Secretary as a member of the Corps or released under section 338D;

(2) a provision permitting the Secretary to extend for such longer additional periods, as the individual may agree to, the period of obligated service agreed to by the individual under paragraph (1)(B)(iv), including extensions resulting in an aggregate period of obligated service in excess of 4 years;

(3) a provision that any financial obligation of the United States arising out of a contract entered into under this subpart and any obligation of the individual that is conditioned thereon, is contingent on funds being appropriated for loan repayments under this subpart and to carry out the purposes of sections 331 through 335 and sections 337 and 338;

(4) a statement of the damages to which the United States is entitled, under section 338E for the individual's breach of the contract; and

(5) such other statements of the rights and liabilities of the Secretary and of the individual, not inconsistent with this subpart.

(g) PAYMENTS.—

(1) IN GENERAL.—A loan repayment provided for an individual under a written contract under the Loan Repayment Program shall consist of payment, in accordance with paragraph (2), on behalf of the individual of the principal, interest, and related expenses on government and commercial loans received by the individual regarding the undergraduate or graduate education of the individual (or both), which loans were made for—

(A) tuition expenses;

(B) all other reasonable educational expenses, including fees, books, and laboratory expenses, incurred by the individual; or

(C) reasonable living expenses as determined by the Secretary.

(2) PAYMENTS FOR YEARS SERVED.—

(A) IN GENERAL.—For each year of obligated service that an individual contracts to serve under subsection (f) the Secretary may pay up to $50,000, plus, beginning with fiscal year 2012, an amount determined by the Secretary on an annual basis to reflect inflation, on behalf of the individual for loans described in paragraph (1). In making a determination of the amount to pay for a year of such service by an individual, the Secretary shall consider the extent to which each such determination—

(i) affects the ability of the Secretary to maximize the number of contracts that can be provided under the Loan Repayment Program from the amounts appropriated for such contracts;

(ii) provides an incentive to serve in health professional shortage areas with the greatest such shortages; and

(iii) provides an incentive with respect to the health professional involved remaining in a health professional shortage area, and continuing to provide primary health services, after the completion of the period of obligated service under the Loan Repayment Program.

(B) REPAYMENT SCHEDULE.—Any arrangement made by the Secretary for the making of loan repayments in accordance with this subsection shall provide that any repayments for a year of obligated service shall be made no later than the end of the fiscal year in which the individual completes such year of service.

(3) TAX LIABILITY.—For the purpose of providing reimbursements for tax liability resulting from payments under paragraph (2) on behalf of an individual—

(A) the Secretary shall, in addition to such payments, make payments to the individual in an amount equal to 39 percent of the total amount of loan repayments made for the taxable year involved; and

(B) may make such additional payments as the Secretary determines to be appropriate with respect to such purpose.

(4) PAYMENT SCHEDULE.—The Secretary may enter into an agreement with the holder of any loan for which payments are made under the Loan Repayment Program to establish a schedule for the making of such payments.

(h) EMPLOYMENT CEILING.—Notwithstanding any other provision of law, individuals who have entered into written contracts with the Secretary under this section, while undergoing academic or other training, shall not be counted against any employment ceiling affecting the Department.

OBLIGATED SERVICE.

SEC. 338C.[254m] (a) SERVICE IN FULL-TIME CLINICAL PRACTICE.—Except as provided in section 338D, each individual who has entered into a written contract with the Secretary under section 338A or 338B shall provide service in the full-time clinical practice of such individual's profession as a member of the Corps for the period of obligated service provided in such contract. The Secretary may treat teaching as clinical practice for up to 20 percent of such period of obligated service. Notwithstanding the preceding sentence, with respect to a member of the Corps participating in the teaching health centers graduate medical education program under section 340H, for the purpose of calculating time spent in full-time clinical practice under this section, up to 50 percent of time spent

teaching by such member may be counted toward his or her service obligation.

(b)(1) If an individual is required under subsection (a) to provide service as specified in section 338A(f)(1)(B)(v) or 338B(f)(1)(B)(iv) (hereinafter in this subsection referred to as "obligated service"), the Secretary shall, not later than ninety days before the date described in paragraph (5), determine if the individual shall provide such service—

(A) as a member of the Corps who is a commissioned officer in the Regular or Reserve Corps of the Service or who is a civilian employee of the United States, or

(B) as a member of the Corps who is not such an officer or employee,

and shall notify such individual of such determination.

(2) If the Secretary determines that an individual shall provide obligated service as a member of the Corps who is a commissioned officer in the Service or a civilian employee of the United States, the Secretary shall, not later than sixty days before the date described in paragraph (5), provide such individual with sufficient information regarding the advantages and disadvantages of service as such a commissioned officer or civilian employee to enable the individual to make a decision on an informed basis. To be eligible to provide obligated service as a commissioned officer in the Service, an individual shall notify the Secretary, not later than thirty days before the date described in paragraph (5), of the individual's desire to provide such service as such an officer. If an individual qualifies for an appointment as such an officer, the Secretary shall, as soon as possible after the date described in paragraph (5), appoint the individual as a commissioned officer of the Regular or Reserve Corps of the Service and shall designate the individual as a member of the Corps.

(3) If an individual provided notice by the Secretary under paragraph (2) does not qualify for appointment as a commissioned officer in the Service, the Secretary shall, as soon as possible after the date described in paragraph (5), appoint such individual as a civilian employee of the United States and designate the individual as a member of the Corps.

(4) If the Secretary determines that an individual shall provide obligated service as a member of the Corps who is not an employee of the United States, the Secretary shall, as soon as possible after the date described in paragraph (5), designate such individual as a member of the Corps to provide such service.

(5)(A) In the case of the Scholarship Program, the date referred to in paragraphs (1) through (4) shall be the date on which the individual completes the training required for the degree for which the individual receives the scholarship, except that—

(i) for an individual receiving such a degree after September 30, 2000, from a school of medicine or osteopathic medicine, such date shall be the date the individual completes a residency in a specialty that the Secretary determines is consistent with the needs of the Corps; and

(ii) at the request of an individual, the Secretary may, consistent with the needs of the Corps, defer such date until the

end of a period of time required for the individual to complete advanced training (including an internship or residency).

(B) No period of internship, residency, or other advanced clinical training shall be counted toward satisfying a period of obligated service under this subpart.

(C) In the case of the Loan Repayment Program, if an individual is required to provide obligated service under such Program, the date referred to in paragraphs (1) through (4)—

(i) shall be the date determined under subparagraph (A) in the case of an individual who is enrolled in the final year of a course of study;

(ii) shall, in the case of an individual who is enrolled in an approved graduate training program in medicine, osteopathic medicine, dentistry, or other health profession, be the date the individual completes such training program; and

(iii) shall, in the case of an individual who has a degree in medicine, osteopathic medicine, dentistry, or other health profession and who has completed graduate training, be the date the individual enters into an agreement with the Secretary under section 338B.

(c) An individual shall be considered to have begun serving a period of obligated service—

(1) on the date such individual is appointed as an officer in a Regular or Reserve Corps of the Service or is designated as a member of the Corps under subsection (b)(3) or (b)(4), or

(2) in the case of an individual who has entered into an agreement with the Secretary under section 338D, on the date specified in such agreement,

whichever is earlier.

(d) The Secretary shall assign individuals performing obligated service in accordance with a written contract under the Scholarship Program to health professional shortage areas in accordance with sections 331 through 335 and sections 337 and 338. If the Secretary determines that there is no need in a health professional shortage area (designated under section 332) for a member of the profession in which an individual is obligated to provide service under a written contract and if such individual is an officer in the Service or a civilian employee of the United States, the Secretary may detail such individual to serve his period of obligated service as a full-time member of such profession in such unit of the Department as the Secretary may determine.

PRIVATE PRACTICE.

SEC. 338D.[254n] (a) The Secretary shall, to the extent permitted by, and consistent with, the requirements of applicable State law, release an individual from all or part of his service obligation under section 338C(a) or under section 225 (as in effect on September 30, 1977) if the individual applies for such a release under this section and enters into a written agreement with the Secretary under which the individual agrees to engage for a period equal to the remaining period of his service obligation in the full-time private clinical practice (including service as a salaried em-

ployee in an entity directly providing health services) of his health profession—

(1) in the case of an individual who received a scholarship under the Scholarship Program or a loan repayment under the Loan Repayment Program and who is performing obligated service as a member of the Corps in a health professional shortage area on the date of his application for such a release, in the health professional shortage area in which such individual is serving on such date or in the case of an individual for whom a loan payment was made under the Loan Repayment Program and who is performing obligated service as a member of the Corps in a health professional shortage area on the date of the application of the individual for such a release, in the health professional shortage area selected by the Secretary; or

(2) in the case of any other individual, in a health professional shortage area (designated under section 332) selected by the Secretary.

(b)(1) The written agreement described in subsection (a) shall—

(A) provide that, during the period of private practice by an individual pursuant to the agreement, the individual shall comply with the requirements of section 334 that apply to entities; and

(B) contain such additional provisions as the Secretary may require to carry out the objectives of this section.

(2) The Secretary shall take such action as may be appropriate to ensure that the conditions of the written agreement prescribed by this subsection are adhered to.

(c) If an individual breaches the contract entered into under section 338A or 338B by failing (for any reason) to begin his service obligation in accordance with an agreement entered into under subsection (a) or to complete such service obligation, the Secretary may permit such individual to perform such service obligation as a member of the Corps.

(d) The Secretary may pay an individual who has entered into an agreement with the Secretary under subsection (a) an amount to cover all or part of the individual's expenses reasonably incurred in transporting himself, his family, and his possessions to the location of his private clinical practice.

(e) Upon the expiration of the written agreement under subsection (a), the Secretary may (notwithstanding any other provision of law) sell to the individual who has entered into an agreement with the Secretary under subsection (a), equipment and other property of the United States utilized by such individual in providing health services. Sales made under this subsection shall be made at the fair market value (as determined by the Secretary) of the equipment or such other property, except that the Secretary may make such sales for a lesser value to the individual if he determines that the individual is financially unable to pay the full market value.

(f) The Secretary may, out of appropriations authorized under section 338, pay to individuals participating in private practice

under this section the cost of such individual's malpractice insurance and the lesser of—

(1)(A) $10,000 in the first year of obligated service;

(B) $7,500 in the second year of obligated service;

(C) $5,000 in the third year of obligated service; and

(D) $2,500 in the fourth year of obligated service; or

(2) an amount determined by subtracting such individual's net income before taxes from the income the individual would have received as a member of the Corps for each such year of obligated service.

(g) The Secretary shall, upon request, provide to each individual released from service obligation under this section technical assistance to assist such individual in fulfilling his or her agreement under this section.

BREACH OF SCHOLARSHIP CONTRACT OR LOAN REPAYMENT CONTRACT.

SEC. 338E.[254o] (a)(1) An individual who has entered into a written contract with the Secretary under section 338A and who—

(A) fails to maintain an acceptable level of academic standing in the educational institution in which he is enrolled (such level determined by the educational institution under regulations of the Secretary);

(B) is dismissed from such educational institution for disciplinary reasons; or

(C) voluntarily terminates the training in such an educational institution for which he is provided a scholarship under such contract, before the completion of such training,

in lieu of any service obligation arising under such contract, shall be liable to the United States for the amount which has been paid to him, or on his behalf, under the contract.

(2) An individual who has entered into a written contract with the Secretary under section 338B and who—

(A) in the case of an individual who is enrolled in the final year of a course of study, fails to maintain an acceptable level of academic standing in the educational institution in which such individual is enrolled (such level determined by the educational institution under regulations of the Secretary) or voluntarily terminates such enrollment or is dismissed from such educational institution before completion of such course of study; or

(B) in the case of an individual who is enrolled in a graduate training program, fails to complete such training program and does not receive a waiver from the Secretary under section 338B(b)(1)(B)(ii),

in lieu of any service obligation arising under such contract shall be liable to the United States for the amount that has been paid on behalf of the individual under the contract.

(b)(1)(A) Except as provided in paragraph (2), if (for any reason not specified in subsection (a) or section 338G(d)) an individual breaches his written contract by failing to begin such individual's service obligation under section 338A in accordance with section 338C or 338D, to complete such service obligation, or to complete a required residency as specified in section 338A(f)(1)(B)(iv), the

United States shall be entitled to recover from the individual an amount determined in accordance with the formula

$$A=3\varphi(t-s/t)$$

in which "A" is the amount the United States is entitled to recover, "φ" is the sum of the amounts paid under this subpart to or on behalf of the individual and the interest on such amounts which would be payable if at the time the amounts were paid they were loans bearing interest at the maximum legal prevailing rate, as determined by the Treasurer of the United States; "t" is the total number of months in the individual's period of obligated service; and "s" is the number of months of such period served by him in accordance with section 338C or a written agreement under section 338D.

(B)(i) Any amount of damages that the United States is entitled to recover under this subsection or under subsection (c) shall, within the 1-year period beginning on the date of the breach of the written contract (or such longer period beginning on such date as specified by the Secretary), be paid to the United States. Amounts not paid within such period shall be subject to collection through deductions in Medicare payments pursuant to section 1892 of the Social Security Act.

(ii) If damages described in clause (i) are delinquent for 3 months, the Secretary shall, for the purpose of recovering such damages—

(I) utilize collection agencies contracted with by the Administrator of the General Services Administration; or

(II) enter into contracts for the recovery of such damages with collection agencies selected by the Secretary.

(iii) Each contract for recovering damages pursuant to this subsection shall provide that the contractor will, not less than once each 6 months, submit to the Secretary a status report on the success of the contractor in collecting such damages. Section 3718 of title 31, United States Code, shall apply to any such contract to the extent not inconsistent with this subsection.

(iv) To the extent not otherwise prohibited by law, the Secretary shall disclose to all appropriate credit reporting agencies information relating to damages of more than $100 that are entitled to be recovered by the United States under this subsection and that are delinquent by more than 60 days or such longer period as is determined by the Secretary.

(2) If an individual is released under section 753 from a service obligation under section 225 (as in effect on September 30, 1977) and if the individual does not meet the service obligation incurred under section 753, subsection (f) of such section 225 shall apply to such individual in lieu of paragraph (1) of this subsection.

(3) The Secretary may terminate a contract with an individual under section 338A if, not later than 30 days before the end of the school year to which the contract pertains, the individual—

(A) submits a written request for such termination; and

(B) repays all amounts paid to, or on behalf of, the individual under section 338A(g).

(c)(1) If (for any reason not specified in subsection (a) or section 338G(d)) an individual breaches the written contract of the individual under section 338B by failing either to begin such individual's service obligation in accordance with section 338C or 338D or to complete such service obligation, the United States shall be entitled to recover from the individual an amount equal to the sum of—

(A) the total of the amounts paid by the United States under section 338B(g) on behalf of the individual for any period of obligated service not served;

(B) an amount equal to the product of the number of months of obligated service that were not completed by the individual, multiplied by $7,500; and

(C) the interest on the amounts described in subparagraphs (A) and (B), at the maximum legal prevailing rate, as determined by the Treasurer of the United States, from the date of the breach;

except that the amount the United States is entitled to recover under this paragraph shall not be less than $31,000.

(2) The Secretary may terminate a contract with an individual under section 338B if, not later than 45 days before the end of the fiscal year in which the contract was entered into, the individual—

(A) submits a written request for such termination; and

(B) repays all amounts paid on behalf of the individual under section 338B(g).

(3) Damages that the United States is entitled to recover shall be paid in accordance with subsection (b)(1)(B).

(d)(1) Any obligation of an individual under the Scholarship Program (or a contract thereunder) or the Loan Repayment Program (or a contract thereunder) for service or payment of damages shall be canceled upon the death of the individual.

(2) The Secretary shall by regulation provide for the partial or total waiver or suspension of any obligation of service or payment by an individual under the Scholarship Program (or a contract thereunder) or the Loan Repayment Program (or a contract thereunder) whenever compliance by the individual is impossible or would involve extreme hardship to the individual and if enforcement of such obligation with respect to any individual would be unconscionable.

(3)(A) Any obligation of an individual under the Scholarship Program (or a contract thereunder) or the Loan Repayment Program (or a contract thereunder) for payment of damages may be released by a discharge in bankruptcy under title 11 of the United States Code only if such discharge is granted after the expiration of the 7-year period beginning on the first date that payment of such damages is required, and only if the bankruptcy court finds that nondischarge of the obligation would be unconscionable.

(B)(i) Subparagraph (A) shall apply to any financial obligation of an individual under the provision of law specified in clause (ii) to the same extent and in the same manner as such subparagraph applies to any obligation of an individual under the Scholarship or Loan Repayment Program (or contract thereunder) for payment of damages.

(ii) The provision of law referred to in clause (i) is subsection (f) of section 225 of this Act, as in effect prior to the repeal of such section by section 408(b)(1) of Public Law 94–484.

(e) Notwithstanding any other provision of Federal or State law, there shall be no limitation on the period within which suit may be filed, a judgment may be enforced, or an action relating to an offset or garnishment, or other action, may be initiated or taken by the Secretary, the Attorney General, or the head of another Federal agency, as the case may be, for the repayment of the amount due from an individual under this section.

(f) The amendment made by section 313(a)(4) of the Health Care Safety Net Amendments of 2002 (Public Law 107–251) shall apply to any obligation for which a discharge in bankruptcy has not been granted before the date that is 31 days after the date of enactment of such Act.

SEC. 338F.[254o–1] FUND REGARDING USE OF AMOUNTS RECOVERED FOR CONTRACT BREACH TO REPLACE SERVICES LOST AS RESULT OF BREACH.

(a) ESTABLISHMENT OF FUND.—There is established in the Treasury of the United States a fund to be known as the National Health Service Corps Member Replacement Fund (hereafter in this section referred to as the "Fund"). The Fund shall consist of such amounts as may be appropriated under subsection (b) to the Fund. Amounts appropriated for the Fund shall remain available until expended.

(b) AUTHORIZATION OF APPROPRIATIONS TO FUND.—For each fiscal year, there is authorized to be appropriated to the Fund an amount equal to the sum of—

(1) the amount collected during the preceding fiscal year by the Federal Government pursuant to the liability of individuals under section 338E for the breach of contracts entered into under section 338A or 338B;

(2) the amount by which grants under section 338I have, for such preceding fiscal year, been reduced under subsection (g)(2)(B) of such section; and

(3) the aggregate of the amount of interest accruing during the preceding fiscal year on obligations held in the Fund pursuant to subsection (d) and the amount of proceeds from the sale or redemption of such obligations during such fiscal year.

(c) USE OF FUND.—

(1) PAYMENTS TO CERTAIN HEALTH FACILITIES.—Amounts in the Fund and available pursuant to appropriations Act may, subject to paragraph (2), be expended by the Secretary to make payments to any entity—

(A) to which a Corps member has been assigned under section 333; and

(B) that has a need for a health professional to provide primary health services as a result of the Corps member having breached the contract entered into under section 338A or 338B by the individual.

(2) PURPOSE OF PAYMENTS.—An entity receiving payments pursuant to paragraph (1) may expend the payments to recruit and employ a health professional to provide primary health

services to patients of the entity, or to enter into a contract with such a professional to provide the services to the patients.

(d) INVESTMENT.—

(1) IN GENERAL.—The Secretary of the Treasury shall invest such amounts of the Fund as such Secretary determines are not required to meet current withdrawals from the Fund. Such investments may be made only in interest-bearing obligations of the United States. For such purpose, such obligations may be acquired on original issue at the issue price, or by purchase of outstanding obligations at the market price.

(2) SALE OF OBLIGATIONS.—Any obligation acquired by the Fund may be sold by the Secretary of the Treasury at the market price.

SPECIAL LOANS FOR FORMER CORPS MEMBERS TO ENTER PRIVATE PRACTICE.

SEC. 338G.[254p] (a) The Secretary may, out of appropriations authorized under section 338, make one loan to a Corps member who has agreed in writing—

(1) to engage in the private full-time clinical practice of the profession of the member in a health professional shortage area (designated under section 332) for a period of not less than 2 years which—

(A) in the case of a Corps member who is required to complete a period of obligated service under this subpart, begins not later than 1 year after the date on which such individual completes such period of obligated service; and

(B) in the case of an individual who is not required to complete a period of obligated service under this subpart, begins at such time as the Secretary considers appropriate;

(2) to conduct such practice in accordance with section 338D(b)(1); and

(3) to such additional conditions as the Secretary may require to carry out this section.

Such a loan shall be used to assist such individual in meeting the costs of beginning the practice of such individual's profession in accordance with such agreement, including the costs of acquiring equipment and renovating facilities for use in providing health services, and of hiring nurses and other personnel to assist in providing health services. Such loan may not be used for the purchase or construction of any building.

(b)(1) The amount of a loan under subsection (a) to an individual shall not exceed $25,000.

(2) The interest rate for any such loan shall not exceed an annual rate of 5 percent.

(c) The Secretary may not make a loan under this section unless an application therefor has been submitted to, and approved by, the Secretary. The Secretary shall, by regulation, set interest rates and repayment terms for loans under this section.

(d) If the Secretary determines that an individual has breached a written agreement entered into under subsection (a), he shall, as soon as practicable after making such determination notify the individual of such determination. If within 60 days after the date of

giving such notice, such individual is not practicing his profession in accordance with the agreement under such subsection and has not provided assurances satisfactory to the Secretary that he will not knowingly violate such agreement again, the United States shall be entitled to recover from such individual—

(1) in the case of an individual who has received a grant under this section (as in effect prior to October 1, 1984), an amount determined under section 338E(b), except that in applying the formula contained in such section "φ" shall be the sum of the amount of the grant made under subsection (a) to such individual and the interest on such amount which would be payable if at the time it was paid it was a loan bearing interest at the maximum legal prevailing rate, "t" shall be the number of months that such individual agreed to practice his profession under agreement, and "s" shall be the number of months that such individual practices his profession in accordance with such agreement; and

(2) in the case of an individual who has received a loan under this section, the full amount of the principal and interest owed by such individual under this section.

SEC. 338H.[254q] AUTHORIZATION OF APPROPRIATIONS.

(a) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section[42], there is authorized to be appropriated, out of any funds in the Treasury not otherwise appropriated, the following:

(1) For fiscal year 2010, $320,461,632.

(2) For fiscal year 2011, $414,095,394.

(3) For fiscal year 2012, $535,087,442.

(4) For fiscal year 2013, $691,431,432.

(5) For fiscal year 2014, $893,456,433.

(6) For fiscal year 2015, $1,154,510,336.

(7) For fiscal year 2016, and each subsequent fiscal year, the amount appropriated for the preceding fiscal year adjusted by the product of—

(A) one plus the average percentage increase in the costs of health professions education during the prior fiscal year; and

(B) one plus the average percentage change in the number of individuals residing in health professions shortage areas designated under section 333 during the prior fiscal year, relative to the number of individuals residing in such areas during the previous fiscal year.

(b) SCHOLARSHIPS FOR NEW PARTICIPANTS.—Of the amounts appropriated under subsection (a) for a fiscal year, the Secretary shall obligate not less than 10 percent for the purpose of providing contracts for—

(1) scholarships under this subpart to individuals who have not previously received such scholarships; or

(2) scholarships or loan repayments under the Loan Repayment Program under section 338B to individuals from disadvantaged backgrounds.

[42] The reference to "this section" in section 338H(a) probably should be a reference to "this subpart".

(c) SCHOLARSHIPS AND LOAN REPAYMENTS.—With respect to certification as a nurse practitioner, nurse midwife, or physician assistant, the Secretary shall, from amounts appropriated under subsection (a) for a fiscal year, obligate not less than a total of 10 percent for contracts for both scholarships under the Scholarship Program under section 338A and loan repayments under the Loan Repayment Program under section 338B to individuals who are entering the first year of a course of study or program described in section 338A(b)(1)(B) that leads to such a certification or individuals who are eligible for the loan repayment program as specified in section 338B(b) for a loan related to such certification.

SEC. 338I.[254q–1] GRANTS TO STATES FOR LOAN REPAYMENT PROGRAMS.

(a) IN GENERAL.—

(1) AUTHORITY FOR GRANTS.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, may make grants to States for the purpose of assisting the States in operating programs described in paragraph (2) in order to provide for the increased availability of primary health care services in health professional shortage areas. The National Advisory Council established under section 337 shall advise the Administrator regarding the program under this section.

(2) LOAN REPAYMENT PROGRAMS.—The programs referred to in paragraph (1) are, subject to subsection (c), programs of entering into contracts under which the State involved agrees to pay all or part of the principal, interest, and related expenses of the educational loans of health professionals in consideration of the professionals agreeing to provide primary health services in health professional shortage areas.

(3) DIRECT ADMINISTRATION BY STATE AGENCY.—The Secretary may not make a grant under paragraph (1) unless the State involved agrees that the program operated with the grant will be administered directly by a State agency.

(b) REQUIREMENT OF MATCHING FUNDS.—

(1) IN GENERAL.—The Secretary may not make a grant under subsection (a) unless the State agrees that, with respect to the costs of making payments on behalf of individuals under contracts made pursuant to paragraph (2) of such subsection, the State will make available (directly or through donations from public or private entities) non-Federal contributions in cash toward such costs in an amount equal to not less than $1 for each $1 of Federal funds provided in the grant.

(2) DETERMINATION OF AMOUNT OF NON-FEDERAL CONTRIBUTION.—In determining the amount of non-Federal contributions in cash that a State has provided pursuant to paragraph (1), the Secretary may not include any amounts provided to the State by the Federal Government.

(c) COORDINATION WITH FEDERAL PROGRAM.—

(1) ASSIGNMENTS FOR HEALTH PROFESSIONAL SHORTAGE AREAS UNDER FEDERAL PROGRAM.—The Secretary may not make a grant under subsection (a) unless the State involved agrees that, in carrying out the program operated with the grant, the State will assign health professionals participating

in the program only to public and nonprofit private entities located in and providing health services in health professional shortage areas.

(2) REMEDIES FOR BREACH OF CONTRACTS.—The Secretary may not make a grant under subsection (a) unless the State involved agrees that the contracts provided by the State pursuant to paragraph (2) of such subsection will provide remedies for any breach of the contracts by the health professionals involved.

(3) LIMITATION REGARDING CONTRACT INDUCEMENTS.—

(A) Except as provided in subparagraph (B), the Secretary may not make a grant under subsection (a) unless the State involved agrees that the contracts provided by the State pursuant to paragraph (2) of such subsection will not be provided on terms that are more favorable to health professionals than the most favorable terms that the Secretary is authorized to provide for contracts under the Loan Repayment Program under section 338B, including terms regarding—

(i) the annual amount of payments provided on behalf of the professionals regarding educational loans; and

(ii) the availability of remedies for any breach of the contracts by the health professionals involved.

(B) With respect to the limitation established in subparagraph (A) regarding the annual amount of payments that may be provided to a health professional under a contract provided by a State pursuant to subsection (a)(2), such limitation shall not apply with respect to a contract if—

(i) the excess of such annual payments above the maximum amount authorized in section 338B(g)(2)(A) for annual payments regarding contracts is paid solely from non-Federal contributions under subsection (b); and

(ii) the contract provides that the health professional involved will satisfy the requirement of obligated service under the contract solely through the provision of primary health services in a health professional shortage area that is receiving priority for purposes of section 333A(a)(1) and that is authorized to receive assignments under section 333 of individuals who are participating in the Scholarship Program under section 338A.

(d) RESTRICTIONS ON USE OF FUNDS.—The Secretary may not make a grant under subsection (a) unless the State involved agrees that the grant will not be expended—

(1) to conduct activities for which Federal funds are expended—

(A) within the State to provide technical or other nonfinancial assistance under subsection (f) of section 330;

(B) under a memorandum of agreement entered into with the State under subsection (h) of such section; or

(C) under a grant under section 338J; or

(2) for any purpose other than making payments on behalf of health professionals under contracts entered into pursuant to subsection (a)(2).

(e) REPORTS.—The Secretary may not make a grant under subsection (a) unless the State involved agrees—

(1) to submit to the Secretary such reports regarding the States loan repayment program, as are determined to be appropriate by the Secretary; and

(2) to submit such a report not later than January 10 of each fiscal year immediately following any fiscal year for which the State has received such a grant.

(f) REQUIREMENT OF APPLICATION.—The Secretary may not make a grant under subsection (a) unless an application for the grant is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out such subsection.

(g) NONCOMPLIANCE.—

(1) IN GENERAL.—The Secretary may not make payments under subsection (a) to a State for any fiscal year subsequent to the first fiscal year of such payments unless the Secretary determines that, for the immediately preceding fiscal year, the State has complied with each of the agreements made by the State under this section.

(2) REDUCTION IN GRANT RELATIVE TO NUMBER OF BREACHED CONTRACTS.—

(A) Before making a grant under subsection (a) to a State for a fiscal year, the Secretary shall determine the number of contracts provided by the State under paragraph (2) of such subsection with respect to which there has been an initial breach by the health professionals involved during the fiscal year preceding the fiscal year for which the State is applying to receive the grant.

(B) Subject to paragraph (3), in the case of a State with 1 or more initial breaches for purposes of subparagraph (A), the Secretary shall reduce the amount of a grant under subsection (a) to the State for the fiscal year involved by an amount equal to the sum of the expenditures of Federal funds made regarding the contracts involved and an amount representing interest on the amount of such expenditures, determined with respect to each contract on the basis of the maximum legal rate prevailing for loans made during the time amounts were paid under the contract, as determined by the Treasurer of the United States.

(3) WAIVER REGARDING REDUCTION IN GRANT.—The Secretary may waive the requirement established in paragraph (2)(B) with respect to the initial breach of a contract if the Secretary determines that such breach by the health professional involved was attributable solely to the professional having a serious illness.

(h) DEFINITIONS.—For purposes of this section, the term "State" means each of the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the United States Virgin Islands,

Guam, American Samoa, Palau, the Marshall Islands, and the Commonwealth of the Northern Mariana Islands.

(i) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—For the purpose of making grants under subsection (a), there are authorized to be appropriated $12,000,000 for fiscal year 2008, and such sums as may be necessary for each of fiscal years 2009 through 2012.

(2) AVAILABILITY.—Amounts appropriated under paragraph (1) shall remain available until expended.

(j) PUBLIC HEALTH LOAN REPAYMENT.—

(1) IN GENERAL.—The Secretary may award grants to States for the purpose of assisting such States in operating loan repayment programs under which such States enter into contracts to repay all or part of the eligible loans borrowed by, or on behalf of, individuals who agree to serve in State, local, or tribal health departments that serve health professional shortage areas or other areas at risk of a public health emergency, as designated by the Secretary.

(2) LOANS ELIGIBLE FOR REPAYMENT.—To be eligible for repayment under this subsection, a loan shall be a loan made, insured, or guaranteed by the Federal Government that is borrowed by, or on behalf of, an individual to pay the cost of attendance for a program of education leading to a degree appropriate for serving in a State, local, or tribal health department as determined by the Secretary and the chief executive officer of the State in which the grant is administered, at an institution of higher education (as defined in section 102 of the Higher Education Act of 1965), including principal, interest, and related expenses on such loan.

(3) APPLICABILITY OF EXISTING REQUIREMENTS.—With respect to awards made under paragraph (1)—

(A) the requirements of subsections (b), (f), and (g) shall apply to such awards; and

(B) the requirements of subsection (c) shall apply to such awards except that with respect to paragraph (1) of such subsection, the State involved may assign an individual only to public and nonprofit private entities that serve health professional shortage areas or areas at risk of a public health emergency, as determined by the Secretary.

(4) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this subsection, such sums as may be necessary for each of fiscal years 2007 through 2010.

SEC. 338J.[254r] GRANTS TO STATES FOR OPERATION OF OFFICES OF RURAL HEALTH.

(a) IN GENERAL.—The Secretary, action through the Director of the Office of Rural Health Policy (established in section 711 of the Social Security Act), may make grants to States for the purpose of improving health care in rural areas through the operation of State offices of rural health.

(b) REQUIREMENT OF MATCHING FUNDS.—

(1) IN GENERAL.—The Secretary may not make a grant under subsection (a) unless the State involved agrees, with respect to the costs to be incurred by the State in carrying out

the purpose described in such subsection, to provide non-Federal contributions toward such costs in an amount equal to—

(A) for the first fiscal year of payments under the grant, not less than $1 for each $3 of Federal funds provided in the grant;

(B) for any second fiscal year of such payments, not less than $1 for each $1 of Federal funds provided in the grant; and

(C) for any third fiscal year of such payments, not less than $3 for each $1 of Federal funds provided in the grant.

(2) DETERMINATION OF AMOUNT OF NON-FEDERAL CONTRIBUTION.—

(A) Subject to subparagraph (B), non-Federal contributions required in paragraph (1) may be in cash or in kind, fairly evaluated, including plant, equipment, or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

(B) The Secretary may not make a grant under subsection (a) unless the State involved agrees that—

(i) for the first fiscal year of payments under the grant, 100 percent or less of the non-Federal contributions required in paragraph (1) will be provided in the form of in-kind contributions;

(ii) for any second fiscal year of such payments, not more than 50 percent of such non-Federal contributions will be provided in the form of in-kind contributions; and

(iii) for any third fiscal year of such payments, such non-Federal contributions will be provided solely in the form of cash.

(c) CERTAIN REQUIRED ACTIVITIES.—The Secretary may not make a grant under subsection (a) unless the State involved agrees that activities carried out by an office operated pursuant to such subsection will include—

(1) establishing and maintaining within the State a clearinghouse for collecting and disseminating information on—

(A) rural health care issues;

(B) research findings relating to rural health care; and

(C) innovative approaches to the delivery of health care in rural areas;

(2) coordinating the activities carried out in the State that relate to rural health care, including providing coordination for the purpose of avoiding redundancy in such activities; and

(3) identifying Federal and State programs regarding rural health, and providing technical assistance to public and nonprofit private entities regarding participation in such programs.

(d) REQUIREMENT REGARDING ANNUAL BUDGET FOR OFFICE.—The Secretary may not make a grant under subsection (a) unless the State involved agrees that, for any fiscal year for which the State receives such a grant, the office operated pursuant to sub-

section (a) will be provided with an annual budget of not less than $50,000.

(e) CERTAIN USES OF FUNDS.—

(1) RESTRICTIONS.—The Secretary may not make a grant under subsection (a) unless the State involved agrees that—

(A) if research with respect to rural health is conducted pursuant to the grant, not more than 10 percent of the grant will be expended for such research; and

(B) the grant will not be expended—

(i) to provide health care (including providing cash payments regarding such care);

(ii) to conduct activities for which Federal funds are expended—

(I) within the State to provide technical and other nonfinancial assistance under subsection (f) of section 330[43];

(II) under a memorandum of agreement entered into with the State under subsection (h) of such section;[44] or

(III) under a grant under section 338I;

(iii) to purchase medical equipment, to purchase ambulances, aircraft, or other vehicles, or to purchase major communications equipment;

(iv) to purchase or improve real property; or

(v) to carry out any activity regarding a certificate of need.

(2) AUTHORITIES.—Activities for which a State may expend a grant under subsection (a) include—

(A) paying the costs of establishing an office of rural health for purposes of subsection (a);

(B) subject to paragraph (1)(B)(ii)(III), paying the costs of any activity carried out with respect to recruiting and retaining health professionals to serve in rural areas of the State; and

(C) providing grants and contracts to public and nonprofit private entities to carry out activities authorized in this section.

(f) REPORTS.—The Secretary may not make a grant under subsection (a) unless the State involved agrees—

(1) to submit to the Secretary reports containing such information as the Secretary may require regarding activities carried out under this section by the State; and

(2) to submit such a report not later than January 10 of each fiscal year immediately following any fiscal year for which the State has received such a grant.

(g) REQUIREMENT OF APPLICATION.—The Secretary may not make a grant under subsection (a) unless an application for the grant is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out such subsection.

[43] Probably should be "subsection (k)". See the amendment made by section 2 of Public Law 104–299 (110 Stat. 3626).

[44] Probably should be "subsection (m)". See the amendment referred to in footnote 1.

(h) NONCOMPLIANCE.—The Secretary may not make payments under subsection (a) to a State for any fiscal year subsequent to the first fiscal year of such payments unless the Secretary determines that, for the immediately preceding fiscal year, the State has complied with each of the agreements made by the State under this section.

(i) DEFINITIONS.—For purposes of this section, the term "State" means each of the several States.

(j) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—For the purpose of making grants under subsection (a), there are authorized to be appropriated $3,000,000 for fiscal year 1991, $4,000,000 for fiscal year 1992, $3,000,000 for fiscal year 1993, and such sums as may be necessary for each of the fiscal years 1998 through 2002.

(2) AVAILABILITY.—Amounts appropriated under paragraph (1) shall remain available until expended.

(k) TERMINATION OF PROGRAM.—No grant may be made under this section after the aggregate amounts appropriated under subsection (j)(1) are equal to $36,000,000.

SEC. 338K.[254s] NATIVE HAWAIIAN HEALTH SCHOLARSHIPS.

(a) Subject to the availability of funds appropriated under the authority of subsection (d), the Secretary shall provide scholarship assistance, pursuant to a contract with the Papa Ola Lokahi, to students who—

(1) meet the requirements of section 338A(b), and

(2) are Native Hawaiians.

(b)(1) The scholarship assistance provided under subsection (a) shall be provided under the same terms and subject to the same conditions, regulations, and rules that apply to scholarship assistance provided under section 338A.

(2) The Native Hawaiian Health Scholarship program shall not be administered by or through the Indian Health Service.

(c) For purposes of this section, the term "Native Hawaiian" means any individual who is—

(1) a citizen of the United States,

(2) a resident of the State of Hawaii, and

(3) a descendant of the aboriginal people, who prior to 1778, occupied and exercised sovereignty in the area that now constitutes the State of Hawaii, as evidenced by—

(A) genealogical records,

(B) Kupuna (elders) or Kama'aina (long-term community residents) verification, or

(C) birth records of the State of Hawaii.

(d) There are authorized to be appropriated $1,800,000 for each of the fiscal years 1990, 1991, and 1992 for the purpose of funding the scholarship assistance provided under subsection (a).

SEC. 338L.[254t] DEMONSTRATION PROJECT.

(a) PROGRAM AUTHORIZED.—The Secretary shall establish a demonstration project to provide for the participation of individuals who are chiropractic doctors or pharmacists in the Loan Repayment Program described in section 338B.

(b) PROCEDURE.—An individual that receives assistance under this section with regard to the program described in section 338B

shall comply with all rules and requirements described in such section (other than subparagraphs (A) and (B) of section 338B(b)(1)) in order to receive assistance under this section.

(c) LIMITATIONS.—

(1) IN GENERAL.—The demonstration project described in this section shall provide for the participation of individuals who shall provide services in rural and urban areas.

(2) AVAILABILITY OF OTHER HEALTH PROFESSIONALS.—The Secretary may not assign an individual receiving assistance under this section to provide obligated service at a site unless—

(A) the Secretary has assigned a physician (as defined in section 1861(r) of the Social Security Act) or other health professional licensed to prescribe drugs to provide obligated service at such site under section 338C or 338D; and

(B) such physician or other health professional will provide obligated service at such site concurrently with the individual receiving assistance under this section.

(3) RULES OF CONSTRUCTION.—

(A) SUPERVISION OF INDIVIDUALS.—Nothing in this section shall be construed to require or imply that a physician or other health professional licensed to prescribe drugs must supervise an individual receiving assistance under the demonstration project under this section, with respect to such project.

(B) LICENSURE OF HEALTH PROFESSIONALS.—Nothing in this section shall be construed to supersede State law regarding licensure of health professionals.

(d) DESIGNATIONS.—The demonstration project described in this section, and any providers who are selected to participate in such project, shall not be considered by the Secretary in the designation of a health professional shortage area under section 332 during fiscal years 2002 through 2004.

(e) RULE OF CONSTRUCTION.—This section shall not be construed to require any State to participate in the project described in this section.

(f) REPORT.—

(1) IN GENERAL.—The Secretary shall evaluate the participation of individuals in the demonstration projects under this section and prepare and submit a report containing the information described in paragraph (2) to—

(A) the Committee on Health, Education, Labor, and Pensions of the Senate;

(B) the Subcommittee on Labor, Health and Human Services, and Education of the Committee on Appropriations of the Senate;

(C) the Committee on Energy and Commerce of the House of Representatives; and

(D) the Subcommittee on Labor, Health and Human Services, and Education of the Committee on Appropriations of the House of Representatives.

(2) CONTENT.—The report described in paragraph (1) shall detail—

(A) the manner in which the demonstration project described in this section has affected access to primary care services, patient satisfaction, quality of care, and health care services provided for traditionally underserved populations;

(B) how the participation of chiropractic doctors and pharmacists in the Loan Repayment Program might affect the designation of health professional shortage areas; and

(C) whether adding chiropractic doctors and pharmacists as permanent members of the National Health Service Corps would be feasible and would enhance the effectiveness of the National Health Service Corps.

(g) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—There are authorized to be appropriated to carry out this section, such sums as may be necessary for fiscal years 2002 through 2004.

(2) FISCAL YEAR 2005[45].—If the Secretary determines and certifies to Congress by not later than September 30, 2004, that the number of individuals participating in the demonstration project established under this section is insufficient for purposes of performing the evaluation described in subsection (f)(1), the authorization of appropriations under paragraph (1) shall be extended to include fiscal year 2005.

SEC. 338M.[254u] PUBLIC HEALTH DEPARTMENTS.

(a) IN GENERAL.—To the extent that funds are appropriated under subsection (e), the Secretary shall establish a demonstration project to provide for the participation of individuals who are eligible for the Loan Repayment Program described in section 338B and who agree to complete their service obligation in a State health department that provides a significant amount of service to health professional shortage areas or areas at risk of a public health emergency, as determined by the Secretary, or in a local or tribal health department that serves a health professional shortage area or an area at risk of a public health emergency.

(b) PROCEDURE.—To be eligible to receive assistance under subsection (a), with respect to the program described in section 338B, an individual shall—

(1) comply with all rules and requirements described in such section (other than section 338B(f)(1)(B)(iv)); and

(2) agree to serve for a time period equal to 2 years, or such longer period as the individual may agree to, in a State, local, or tribal health department, described in subsection (a).

(c) DESIGNATIONS.—The demonstration project described in subsection (a), and any healthcare providers who are selected to participate in such project, shall not be considered by the Secretary in the designation of health professional shortage areas under section 332 during fiscal years 2007 through 2010.

(d) REPORT.—Not later than 3 years after the date of enactment of this section, the Secretary shall submit a report to the rel-

[45] So in law. The figure in the heading for paragraph (2) was erroneously enacted so that "2005" appears in full figures. However, the version represented here in the pdf reflects this figure so that it conforms to the proper size for figures that appear in a paragraph or below header.

evant committees of Congress that evaluates the participation of individuals in the demonstration project under subsection (a), the impact of such participation on State, local, and tribal health departments, and the benefit and feasibility of permanently allowing such placements in the Loan Repayment Program.

(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, such sums as may be necessary for each of fiscal years 2007 through 2010.

Subpart IV—Home Health Services

HOME HEALTH SERVICES.

SEC. 339.[255] (a)(1) For the purpose of encouraging the establishment and initial operation of home health programs to provide home health services in areas in which such services are inadequate or not readily accessible, the Secretary may, in accordance with the provisions of this section, make grants to public and nonprofit private entities and loans to proprietary entities to meet the initial costs of establishing and operating such home health programs. Such grants and loans may include funds to provide training for paraprofessionals (including homemaker home health aides) to provide home health services.

(2) In making grants and loans under this subsection, the Secretary shall—

(A) consider the relative needs of the several States for home health services;

(B) give preference to areas in which a high percentage of the population proposed to be served is composed of individuals who are elderly, medically indigent, or disabled; and

(C) give special consideration to areas with inadequate means of transportation to obtain necessary health services.

(3)(A) No loan may be made to a proprietary entity under this section unless the application of such entity for such loan contains assurances satisfactory to the Secretary that—

(i) at the time the application is made the entity is fiscally sound;

(ii) the entity is unable to secure a loan for the project for which the application is submitted from non-Federal lenders at the rate of interest prevailing in the area in which the entity is located; and

(iii) during the period of the loan, such entity will remain fiscally sound.

(B) Loans under this section shall be made at an interest rate comparable to the rate of interest prevailing on the date the loan is made with respect to the marketable obligations of the United States of comparable maturities, adjusted to provide for administrative costs.

(4) Applications for grants and loans under this subsection shall be in such form and contain such information as the Secretary shall prescribe.

(5) There are authorized to be appropriated for grants and loans under this subsection $5,000,000 for each of the fiscal years ending on September 30, 1983, September 30, 1984, September 30, 1985, September 30, 1986, and September 30, 1987.

(b)(1) The Secretary may make grants to and enter into contracts with public and private entities to assist them in developing appropriate training programs for paraprofessionals (including homemaker home health aides) to provide home health services.

(2) Any program established with a grant or contract under this subsection to train homemaker home health aides shall—

(A) extend for at least forty hours, and consist of classroom instruction and at least twenty hours (in the aggregate) of supervised clinical instruction directed toward preparing students to deliver home health services;

(B) be carried out under appropriate professional supervision and be designed to train students to maintain or enhance the personal care of an individual in his home in a manner which promotes the functional independence of the individual; and

(C) include training in—

(i) personal care services designed to assist an individual in the activities of daily living such as bathing, exercising, personal grooming, and getting in and out of bed; and

(ii) household care services such as maintaining a safe living environment, light housekeeping, and assisting in providing good nutrition (by the purchasing and preparation of food).

(3) In making grants and entering into contracts under this subsection, special consideration shall be given to entities which establish or will establish programs to provide training for persons fifty years of age and older who wish to become paraprofessionals (including homemaker home health aides) to provide home health services.

(4) Applications for grants and contracts under this subsection shall be in such form and contain such information as the Secretary shall prescribe.

(5) There are authorized to be appropriated for grants and contracts under this subsection $2,000,000 for each of the fiscal years ending September 30, 1983, September 30, 1984, September 30, 1985, September 30, 1986, and September 30, 1987.

(c) The Secretary shall report to the Committee on Labor and Human Resources of the Senate and the Committee on Energy and Commerce of the House of Representatives on or before January 1, 1984, with respect to—

(1) the impact of grants made and contracts entered into under subsections (a) and (b) (as such subsections were in effect prior to October 1, 1981);

(2) the need to continue grants and loans under subsections (a) and (b) (as such subsections are in effect on the day after the date of enactment of the Orphan Drug Act); and

(3) the extent to which standards have been applied to the training of personnel who provide home health services.

(d) For purposes of this section, the term "home health services" has the meaning prescribed for the term by section 1861(m) of the Social Security Act.

Subpart V—Healthy Communities Access Program

SEC. 340.[256] GRANTS TO STRENGTHEN THE EFFECTIVENESS, EFFICIENCY, AND COORDINATION OF SERVICES FOR THE UNINSURED AND UNDERINSURED.

(a) IN GENERAL.—The Secretary may award grants to eligible entities to assist in the development of integrated health care delivery systems to serve communities of individuals who are uninsured and individuals who are underinsured—

(1) to improve the efficiency of, and coordination among, the providers providing services through such systems;

(2) to assist communities in developing programs targeted toward preventing and managing chronic diseases; and

(3) to expand and enhance the services provided through such systems.

(b) ELIGIBLE ENTITIES.—To be eligible to receive a grant under this section, an entity shall be an entity that—

(1) represents a consortium—

(A) whose principal purpose is to provide a broad range of coordinated health care services for a community defined in the entity's grant application as described in paragraph (2); and

(B) that includes at least one of each of the following providers that serve the community (unless such provider does not exist within the community, declines or refuses to participate, or places unreasonable conditions on their participation)—

(i) a Federally qualified health center (as defined in section 1861(aa) of the Social Security Act (42 U.S.C. 1395x(aa)));

(ii) a hospital with a low-income utilization rate (as defined in section 1923(b)(3) of the Social Security Act (42 U.S.C. 1396r–4(b)(3)), that is greater than 25 percent;

(iii) a public health department; and

(iv) an interested public or private sector health care provider or an organization that has traditionally served the medically uninsured and underserved; and

(2) submits to the Secretary an application, in such form and manner as the Secretary shall prescribe, that—

(A) defines a community or geographic area of uninsured and underinsured individuals;

(B) identifies the providers who will participate in the consortium's program under the grant, and specifies each provider's contribution to the care of uninsured and underinsured individuals in the community, including the volume of care the provider provides to beneficiaries under the medicare, medicaid, and State child health insurance programs and to patients who pay privately for services;

(C) describes the activities that the applicant and the consortium propose to perform under the grant to further the objectives of this section;

(D) demonstrates the consortium's ability to build on the current system (as of the date of submission of the ap-

plication) for serving a community or geographic area of uninsured and underinsured individuals by involving providers who have traditionally provided a significant volume of care for that community;

(E) demonstrates the consortium's ability to develop coordinated systems of care that either directly provide or ensure the prompt provision of a broad range of high-quality, accessible services, including, as appropriate, primary, secondary, and tertiary services, as well as substance abuse treatment and mental health services in a manner that assures continuity of care in the community or geographic area;

(F) provides evidence of community involvement in the development, implementation, and direction of the program that the entity proposes to operate;

(G) demonstrates the consortium's ability to ensure that individuals participating in the program are enrolled in public insurance programs for which the individuals are eligible or know of private insurance programs where available;

(H) presents a plan for leveraging other sources of revenue, which may include State and local sources and private grant funds, and integrating current and proposed new funding sources in a way to assure long-term sustainability of the program;

(I) describes a plan for evaluation of the activities carried out under the grant, including measurement of progress toward the goals and objectives of the program and the use of evaluation findings to improve program performance;

(J) demonstrates fiscal responsibility through the use of appropriate accounting procedures and appropriate management systems;

(K) demonstrates the consortium's commitment to serve the community without regard to the ability of an individual or family to pay by arranging for or providing free or reduced charge care for the poor; and

(L) includes such other information as the Secretary may prescribe.

(c) LIMITATIONS.—

(1) NUMBER OF AWARDS.—

(A) IN GENERAL.—For each of fiscal years 2003, 2004, 2005, and 2006, the Secretary may not make more than 35 new awards under subsection (a) (excluding renewals of such awards).

(B) RULE OF CONSTRUCTION.—This paragraph shall not be construed to affect awards made before fiscal year 2003.

(2) IN GENERAL.—An eligible entity may not receive a grant under this section (including with respect to any such grant made before fiscal year 2003) for more than 3 consecutive fiscal years, except that such entity may receive such a grant award for not more than 1 additional fiscal year if—

(A) the eligible entity submits to the Secretary a request for a grant for such an additional fiscal year;

(B) the Secretary determines that extraordinary circumstances (as defined in paragraph (3)) justify the granting of such request; and

(C) the Secretary determines that granting such request is necessary to further the objectives described in subsection (a).

(3) EXTRAORDINARY CIRCUMSTANCES.—

(A) IN GENERAL.—In paragraph (2), the term "extraordinary circumstances" means an event (or events) that is outside of the control of the eligible entity that has prevented the eligible entity from fulfilling the objectives described by such entity in the application submitted under subsection (b)(2).

(B) EXAMPLES.—Extraordinary circumstances include—

(i) natural disasters or other major disruptions to the security or health of the community or geographic area served by the eligible entity; or

(ii) a significant economic deterioration in the community or geographic area served by such eligible entity, that directly and adversely affects the entity receiving an award under subsection (a).

(d) PRIORITIES.—In awarding grants under this section, the Secretary—

(1) shall accord priority to applicants that demonstrate the extent of unmet need in the community involved for a more coordinated system of care; and

(2) may accord priority to applicants that best promote the objectives of this section, taking into consideration the extent to which the application involved—

(A) identifies a community whose geographical area has a high or increasing percentage of individuals who are uninsured;

(B) demonstrates that the applicant has included in its consortium providers, support systems, and programs that have a tradition of serving uninsured individuals and underinsured individuals in the community;

(C) shows evidence that the program would expand utilization of preventive and primary care services for uninsured and underinsured individuals and families in the community, including behavioral and mental health services, oral health services, or substance abuse services;

(D) proposes a program that would improve coordination between health care providers and appropriate social service providers;

(E) demonstrates collaboration with State and local governments;

(F) demonstrates that the applicant makes use of non-Federal contributions to the greatest extent possible; or

(G) demonstrates a likelihood that the proposed program will continue after support under this section ceases.

(e) USE OF FUNDS.—

(1) USE BY GRANTEES.—

(A) IN GENERAL.—Except as provided in paragraphs (2) and (3), a grantee may use amounts provided under this section only for—

(i) direct expenses associated with achieving the greater integration of a health care delivery system so that the system either directly provides or ensures the provision of a broad range of culturally competent services, as appropriate, including primary, secondary, and tertiary services, as well as substance abuse treatment and mental health services; and

(ii) direct patient care and service expansions to fill identified or documented gaps within an integrated delivery system.

(B) SPECIFIC USES.—The following are examples of purposes for which a grantee may use grant funds under this section, when such use meets the conditions stated in subparagraph (A):

(i) Increases in outreach activities and closing gaps in health care service.

(ii) Improvements to case management.

(iii) Improvements to coordination of transportation to health care facilities.

(iv) Development of provider networks and other innovative models to engage physicians in voluntary efforts to serve the medically underserved within a community.

(v) Recruitment, training, and compensation of necessary personnel.

(vi) Acquisition of technology for the purpose of coordinating care.

(vii) Improvements to provider communication, including implementation of shared information systems or shared clinical systems.

(viii) Development of common processes for determining eligibility for the programs provided through the system, including creating common identification cards and single sliding scale discounts.

(ix) Development of specific prevention and disease management tools and processes.

(x) Translation services.

(xi) Carrying out other activities that may be appropriate to a community and that would increase access by the uninsured to health care, such as access initiatives for which private entities provide non-Federal contributions to supplement the Federal funds provided through the grants for the initiatives.

(2) DIRECT PATIENT CARE LIMITATION.—Not more than 15 percent of the funds provided under a grant awarded under this section may be used for providing direct patient care and services.

(3) RESERVATION OF FUNDS FOR NATIONAL PROGRAM PURPOSES.—The Secretary may use not more than 3 percent of funds appropriated to carry out this section for providing technical assistance to grantees, obtaining assistance of experts

and consultants, holding meetings, developing of tools, disseminating of information, evaluation, and carrying out activities that will extend the benefits of programs funded under this section to communities other than the community served by the program funded.

(f) GRANTEE REQUIREMENTS.—

(1) EVALUATION OF EFFECTIVENESS.—A grantee under this section shall—

(A) report to the Secretary annually regarding—

(i) progress in meeting the goals and measurable objectives set forth in the grant application submitted by the grantee under subsection (b); and

(ii) the extent to which activities conducted by such grantee have—

(I) improved the effectiveness, efficiency, and coordination of services for uninsured and underinsured individuals in the communities or geographic areas served by such grantee;

(II) resulted in the provision of better quality health care for such individuals; and

(III) resulted in the provision of health care to such individuals at lower cost than would have been possible in the absence of the activities conducted by such grantee; and

(B) provide for an independent annual financial audit of all records that relate to the disposition of funds received through the grant.

(2) PROGRESS.—The Secretary may not renew an annual grant under this section for an entity for a fiscal year unless the Secretary is satisfied that the consortium represented by the entity has made reasonable and demonstrable progress in meeting the goals and measurable objectives set forth in the entity's grant application for the preceding fiscal year.

(g) MAINTENANCE OF EFFORT.—With respect to activities for which a grant under this section is authorized, the Secretary may award such a grant only if the applicant for the grant, and each of the participating providers, agree that the grantee and each such provider will maintain its expenditures of non-Federal funds for such activities at a level that is not less than the level of such expenditures during the fiscal year immediately preceding the fiscal year for which the applicant is applying to receive such grant.

(h) TECHNICAL ASSISTANCE.—The Secretary may, either directly or by grant or contract, provide any entity that receives a grant under this section with technical and other nonfinancial assistance necessary to meet the requirements of this section.

(i) EVALUATION OF PROGRAM.—Not later than September 30, 2005, the Secretary shall prepare and submit to the appropriate committees of Congress a report that describes the extent to which projects funded under this section have been successful in improving the effectiveness, efficiency, and coordination of services for uninsured and underinsured individuals in the communities or geographic areas served by such projects, including whether the projects resulted in the provision of better quality health care for such individuals, and whether such care was provided at lower

costs, than would have been provided in the absence of such projects.

(j) DEMONSTRATION AUTHORITY.—The Secretary may make demonstration awards under this section to historically black health professions schools for the purposes of—

(1) developing patient-based research infrastructure at historically black health professions schools, which have an affiliation, or affiliations, with any of the providers identified in subsection (b)(1)(B);

(2) establishment of joint and collaborative programs of medical research and data collection between historically black health professions schools and such providers, whose goal is to improve the health status of medically underserved populations; or

(3) supporting the research-related costs of patient care, data collection, and academic training resulting from such affiliations.

(k) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section such sums as may be necessary for each of fiscal years 2002 through 2006.

(l) DATE CERTAIN FOR TERMINATION OF PROGRAM.—Funds may not be appropriated to carry out this section after September 30, 2006.

SEC. 340A.[256a] PATIENT NAVIGATOR GRANTS.

(a) GRANTS.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, may make grants to eligible entities for the development and operation of demonstration programs to provide patient navigator services to improve health care outcomes. The Secretary shall coordinate with, and ensure the participation of, the Indian Health Service, the National Cancer Institute, the Office of Rural Health Policy, and such other offices and agencies as deemed appropriate by the Secretary, regarding the design and evaluation of the demonstration programs.

(b) USE OF FUNDS.—The Secretary shall require each recipient of a grant under this section to use the grant to recruit, assign, train, and employ patient navigators who have direct knowledge of the communities they serve to facilitate the care of individuals, including by performing each of the following duties:

(1) Acting as contacts, including by assisting in the coordination of health care services and provider referrals, for individuals who are seeking prevention or early detection services for, or who following a screening or early detection service are found to have a symptom, abnormal finding, or diagnosis of, cancer or other chronic disease.

(2) Facilitating the involvement of community organizations in assisting individuals who are at risk for or who have cancer or other chronic diseases to receive better access to high-quality health care services (such as by creating partnerships with patient advocacy groups, charities, health care centers, community hospice centers, other health care providers, or other organizations in the targeted community).

(3) Notifying individuals of clinical trials and, on request, facilitating enrollment of eligible individuals in these trials.

(4) Anticipating, identifying, and helping patients to overcome barriers within the health care system to ensure prompt diagnostic and treatment resolution of an abnormal finding of cancer or other chronic disease.

(5) Coordinating with the relevant health insurance ombudsman programs to provide information to individuals who are at risk for or who have cancer or other chronic diseases about health coverage, including private insurance, health care savings accounts, and other publicly funded programs (such as Medicare, Medicaid, health programs operated by the Department of Veterans Affairs or the Department of Defense, the State children's health insurance program, and any private or governmental prescription assistance programs).

(6) Conducting ongoing outreach to health disparity populations, including the uninsured, rural populations, and other medically underserved populations, in addition to assisting other individuals who are at risk for or who have cancer or other chronic diseases to seek preventative care.

(c) PROHIBITIONS.—

(1) REFERRAL FEES.—The Secretary shall require each recipient of a grant under this section to prohibit any patient navigator providing services under the grant from accepting any referral fee, kickback, or other thing of value in return for referring an individual to a particular health care provider.

(2) LEGAL FEES AND COSTS.—The Secretary shall prohibit the use of any grant funds received under this section to pay any fees or costs resulting from any litigation, arbitration, mediation, or other proceeding to resolve a legal dispute.

(d) GRANT PERIOD.—

(1) IN GENERAL.—Subject to paragraphs (2) and (3), the Secretary may award grants under this section for periods of not more than 3 years.

(2) EXTENSIONS.—Subject to paragraph (3), the Secretary may extend the period of a grant under this section. Each such extension shall be for a period of not more than 1 year.

(3) LIMITATIONS ON GRANT PERIOD.—In carrying out this section, the Secretary shall ensure that the total period of a grant does not exceed 4 years.

(e) APPLICATION.—

(1) IN GENERAL.—To seek a grant under this section, an eligible entity shall submit an application to the Secretary in such form, in such manner, and containing such information as the Secretary may require.

(2) CONTENTS.—At a minimum, the Secretary shall require each such application to outline how the eligible entity will establish baseline measures and benchmarks that meet the Secretary's requirements to evaluate program outcomes.

(3) MINIMUM CORE PROFICIENCIES.—The Secretary shall not award a grant to an entity under this section unless such entity provides assurances that patient navigators recruited, assigned, trained, or employed using grant funds meet minimum core proficiencies, as defined by the entity that submits

the application, that are tailored for the main focus or intervention of the navigator involved.

(f) UNIFORM BASELINE MEASURES.—The Secretary shall establish uniform baseline measures in order to properly evaluate the impact of the demonstration projects under this section.

(g) PREFERENCE.—In making grants under this section, the Secretary shall give preference to eligible entities that demonstrate in their applications plans to utilize patient navigator services to overcome significant barriers in order to improve health care outcomes in their respective communities.

(h) DUPLICATION OF SERVICES.—An eligible entity that is receiving Federal funds for activities described in subsection (b) on the date on which the entity submits an application under subsection (e) may not receive a grant under this section unless the entity can demonstrate that amounts received under the grant will be utilized to expand services or provide new services to individuals who would not otherwise be served.

(i) COORDINATION WITH OTHER PROGRAMS.—The Secretary shall ensure coordination of the demonstration grant program under this section with existing authorized programs in order to facilitate access to high-quality health care services.

(j) STUDY; REPORTS.—

(1) FINAL REPORT BY SECRETARY.—Not later than 6 months after the completion of the demonstration grant program under this section, the Secretary shall conduct a study of the results of the program and submit to the Congress a report on such results that includes the following:

(A) An evaluation of the program outcomes, including—

(i) quantitative analysis of baseline and benchmark measures; and

(ii) aggregate information about the patients served and program activities.

(B) Recommendations on whether patient navigator programs could be used to improve patient outcomes in other public health areas.

(2) INTERIM REPORTS BY SECRETARY.—The Secretary may provide interim reports to the Congress on the demonstration grant program under this section at such intervals as the Secretary determines to be appropriate.

(3) REPORTS BY GRANTEES.—The Secretary may require grant recipients under this section to submit interim and final reports on grant program outcomes.

(k) RULE OF CONSTRUCTION.—This section shall not be construed to authorize funding for the delivery of health care services (other than the patient navigator duties listed in subsection (b)).

(l) DEFINITIONS.—In this section:

(1) The term "eligible entity" means a public or nonprofit private health center (including a Federally qualified health center (as that term is defined in section 1861(aa)(4) of the Social Security Act)), a health facility operated by or pursuant to a contract with the Indian Health Service, a hospital, a cancer center, a rural health clinic, an academic health center, or a nonprofit entity that enters into a partnership or coordinates

referrals with such a center, clinic, facility, or hospital to provide patient navigator services.

(2) The term "health disparity population" means a population that, as determined by the Secretary, has a significant disparity in the overall rate of disease incidence, prevalence, morbidity, mortality, or survival rates as compared to the health status of the general population.

(3) The term "patient navigator" means an individual who has completed a training program approved by the Secretary to perform the duties listed in subsection (b).

(m) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—To carry out this section, there are authorized to be appropriated $2,000,000 for fiscal year 2006, $5,000,000 for fiscal year 2007, $8,000,000 for fiscal year 2008, $6,500,000 for fiscal year 2009, $3,500,000 for fiscal year 2010, and such sums as may be necessary for each of fiscal years 2011 through 2015.

(2) AVAILABILITY.—The amounts appropriated pursuant to paragraph (1) shall remain available for obligation through the end of fiscal year 2015.

Subpart VII—Drug Pricing Agreements [46]

LIMITATION ON PRICES OF DRUGS PURCHASED BY COVERED ENTITIES.

SEC. 340B.[256b] (a) REQUIREMENTS FOR AGREEMENT WITH SECRETARY.—

(1) IN GENERAL.—The Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid (taking into account any rebate or discount, as provided by the Secretary) to the manufacturer for covered outpatient drugs (other than drugs described in paragraph (3)) purchased by a covered entity on or after the first day of the first month that begins after the date of the enactment of this section, does not exceed an amount equal to the average manufacturer price for the drug under title XIX of the Social Security Act in the preceding calendar quarter, reduced by the rebate percentage described in paragraph (2). Each such agreement shall require that the manufacturer furnish the Secretary with reports, on a quarterly basis, of the price for each covered outpatient drug subject to the agreement that, according to the manufacturer, represents the maximum price that covered entities may permissibly be required to pay for the drug (referred to in this section as the "ceiling price"), and shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price.

(2) REBATE PERCENTAGE DEFINED.—

(A) IN GENERAL.—For a covered outpatient drug purchased in a calendar quarter, the "rebate percentage" is the amount (expressed as a percentage) equal to—

[46] So in law. Former subpart VI was repealed by section 4(a)(3) of Public Law 104–299 (110 Stat. 3645).

(i) the average total rebate required under section 1927(c) of the Social Security Act with respect to the drug (for a unit of the dosage form and strength involved) during the preceding calendar quarter; divided by

(ii) the average manufacturer price for such a unit of the drug during such quarter.

(B) OVER THE COUNTER DRUGS.—

(i) IN GENERAL.—For purposes of subparagraph (A), in the case of over the counter drugs, the "rebate percentage" shall be determined as if the rebate required under section 1927(c) of the Social Security Act is based on the applicable percentage provided under section 1927(c)(3) of such Act.

(ii) DEFINITION.—The term "over the counter drug" means a drug that may be sold without a prescription and which is prescribed by a physician (or other persons authorized to prescribe such drug under State law).

(3) DRUGS PROVIDED UNDER STATE MEDICAID PLANS.—Drugs described in this paragraph are drugs purchased by the entity for which payment is made by the State under the State plan for medical assistance under title XIX of the Social Security Act.

(4) COVERED ENTITY DEFINED.—In this section, the term "covered entity" means an entity that meets the requirements described in paragraph (5) and is one of the following:

(A) A Federally-qualified health center (as defined in section 1905(l)(2)(B) of the Social Security Act).

(B) An entity receiving a grant under section 340A[47].

(C) A family planning project receiving a grant or contract under section 1001.

(D) An entity receiving a grant under subpart II of part C of title XXVI (relating to categorical grants for outpatient early intervention services for HIV disease).

(E) A State-operated AIDS drug purchasing assistance program receiving financial assistance under title XXVI.

(F) A black lung clinic receiving funds under section 427(a) of the Black Lung Benefits Act.

(G) A comprehensive hemophilia diagnostic treatment center receiving a grant under section 501(a)(2) of the Social Security Act.

(H) A Native Hawaiian Health Center receiving funds under the Native Hawaiian Health Care Act of 1988.

(I) An urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act.

(J) Any entity receiving assistance under title XXVI (other than a State or unit of local government or an entity described in subparagraph (D)), but only if the entity is certified by the Secretary pursuant to paragraph (7).

(K) An entity receiving funds under section 318 (relating to treatment of sexually transmitted diseases) or sec-

[47] See footnote on preceding page. See also footnote for section 217(a).

tion 317(j)(2) (relating to treatment of tuberculosis) through a State or unit of local government, but only if the entity is certified by the Secretary pursuant to paragraph (7).

(L) A subsection (d) hospital (as defined in section 1886(d)(1)(B) of the Social Security Act) that—

(i) is owned or operated by a unit of State or local government, is a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government, or is a private non-profit hospital which has a contract with a State or local government to provide health care services to low income individuals who are not entitled to benefits under title XVIII of the Social Security Act or eligible for assistance under the State plan under this title;

(ii) for the most recent cost reporting period that ended before the calendar quarter involved, had a disproportionate share adjustment percentage (as determined under section 1886(d)(5)(F) of the Social Security Act) greater than 11.75 percent or was described in section 1886(d)(5)(F)(i)(II) of such Act; and

(iii) does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement.

(M) A children's hospital excluded from the Medicare prospective payment system pursuant to section 1886(d)(1)(B)(iii) of the Social Security Act, or a free-standing cancer hospital excluded from the Medicare prospective payment system pursuant to section 1886(d)(1)(B)(v) of the Social Security Act, that would meet the requirements of subparagraph (L), including the disproportionate share adjustment percentage requirement under clause (ii) of such subparagraph, if the hospital were a subsection (d) hospital as defined by section 1886(d)(1)(B) of the Social Security Act.

(N) An entity that is a critical access hospital (as determined under section 1820(c)(2) of the Social Security Act), and that meets the requirements of subparagraph (L)(i).

(O) An entity that is a rural referral center, as defined by section 1886(d)(5)(C)(i) of the Social Security Act, or a sole community hospital, as defined by section 1886(d)(5)(C)(iii) of such Act, and that both meets the requirements of subparagraph (L)(i) and has a disproportionate share adjustment percentage equal to or greater than 8 percent.

(5) REQUIREMENTS FOR COVERED ENTITIES.—

(A) PROHIBITING DUPLICATE DISCOUNTS OR REBATES.—

(i) IN GENERAL.—A covered entity shall not request payment under title XIX of the Social Security Act for medical assistance described in section 1905(a)(12) of such Act with respect to a drug that is subject to an agreement under this section if the drug

is subject to the payment of a rebate to the State under section 1927 of such Act.

(ii) ESTABLISHMENT OF MECHANISM.—The Secretary shall establish a mechanism to ensure that covered entities comply with clause (i). If the Secretary does not establish a mechanism within 12 months under the previous sentence, the requirements of section 1927(a)(5)(C) of the Social Security Act shall apply.

(B) PROHIBITING RESALE OF DRUGS.—With respect to any covered outpatient drug that is subject to an agreement under this subsection, a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity.

(C) AUDITING.—A covered entity shall permit the Secretary and the manufacturer of a covered outpatient drug that is subject to an agreement under this subsection with the entity (acting in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits) to audit at the Secretary's or the manufacturer's expense the records of the entity that directly pertain to the entity's compliance with the requirements described in subparagraphs (A) or (B) with respect to drugs of the manufacturer.

(D) ADDITIONAL SANCTION FOR NONCOMPLIANCE.—If the Secretary finds, after audit as described in subparagraph (C) and after notice and hearing, that a covered entity is in violation of a requirement described in subparagraphs[48] (A) or (B), the covered entity shall be liable to the manufacturer of the covered outpatient drug that is the subject of the violation in an amount equal to the reduction in the price of the drug (as described in subparagraph (A)) provided under the agreement between the entity and the manufacturer under this paragraph.

(6) TREATMENT OF DISTINCT UNITS OF HOSPITALS.—In the case of a covered entity that is a distinct part of a hospital, the hospital shall not be considered a covered entity under this paragraph unless the hospital is otherwise a covered entity under this subsection.

(7) CERTIFICATION OF CERTAIN COVERED ENTITIES.—

(A) DEVELOPMENT OF PROCESS.—Not later than 60 days after the date of enactment of this subsection, the Secretary shall develop and implement a process for the certification of entities described in subparagraphs (J) and (K) of paragraph (4).

(B) INCLUSION OF PURCHASE INFORMATION.—The process developed under subparagraph (A) shall include a requirement that an entity applying for certification under this paragraph submit information to the Secretary concerning the amount such entity expended for covered outpatient drugs in the preceding year so as to assist the Sec-

[48] So in law. See section 602(a) of Public Law 102–585 (106 Stat. 4967). Probably should be "subparagraph".

retary in evaluating the validity of the entity's subsequent purchases of covered outpatient drugs at discounted prices.

(C) CRITERIA.—The Secretary shall make available to all manufacturers of covered outpatient drugs a description of the criteria for certification under this paragraph.

(D) LIST OF PURCHASERS AND DISPENSERS.—The certification process developed by the Secretary under subparagraph (A) shall include procedures under which each State shall, not later than 30 days after the submission of the descriptions under subparagraph (C), prepare and submit a report to the Secretary that contains a list of entities described in subparagraphs (J) and (K) of paragraph (4) that are located in the State.

(E) RECERTIFICATION.—The Secretary shall require the recertification of entities certified pursuant to this paragraph on a not more frequent than annual basis, and shall require that such entities submit information to the Secretary to permit the Secretary to evaluate the validity of subsequent purchases by such entities in the same manner as that required under subparagraph (B).

(8) DEVELOPMENT OF PRIME VENDOR PROGRAM.—The Secretary shall establish a prime vendor program under which covered entities may enter into contracts with prime vendors for the distribution of covered outpatient drugs. If a covered entity obtains drugs directly from a manufacturer, the manufacturer shall be responsible for the costs of distribution.

(9) NOTICE TO MANUFACTURERS.—The Secretary shall notify manufacturers of covered outpatient drugs and single State agencies under section 1902(a)(5) of the Social Security Act of the identities of covered entities under this paragraph, and of entities that no longer meet the requirements of paragraph (5) or that are no longer certified pursuant to paragraph (7).

(10) NO PROHIBITION ON LARGER DISCOUNT.—Nothing in this subsection shall prohibit a manufacturer from charging a price for a drug that is lower than the maximum price that may be charged under paragraph (1).

(b) OTHER DEFINITIONS [49].—

(1) IN GENERAL.—In this section, the terms "average manufacturer price", "covered outpatient drug", and "manufacturer" have the meaning given such terms in section 1927(k) of the Social Security Act.

(2) [50] COVERED DRUG.—In this section, the term "covered drug"—

(A) means a covered outpatient drug (as defined in section 1927(k)(2) of the Social Security Act); and

(B) includes, notwithstanding paragraph (3)(A) of section 1927(k) of such Act, a drug used in connection with an inpatient or outpatient service provided by a hospital

[49] The amendment made by section 7101(b)(2)(A) of Public Law 111–148 strikes "OTHER DEFINITION" and all that follows through "In this section" and inserts "OTHER DEFINITIONS.—

(1) IN GENERAL.—In this section".

The heading of such amendment should have been to strike "OTHER DEFINITIONS". The amendment made by such section has been carried out to reflect the probable intent of Congress.

[50] There are no references to the term "covered drug" in this section.

described in subparagraph (L), (M), (N), or (O) of subsection (a)(4) that is enrolled to participate in the drug discount program under this section.

(d)[51] IMPROVEMENTS IN PROGRAM INTEGRITY.—

(1) MANUFACTURER COMPLIANCE.—

(A) IN GENERAL.—From amounts appropriated under paragraph (4), the Secretary shall provide for improvements in compliance by manufacturers with the requirements of this section in order to prevent overcharges and other violations of the discounted pricing requirements specified in this section.

(B) IMPROVEMENTS.—The improvements described in subparagraph (A) shall include the following:

(i) The development of a system to enable the Secretary to verify the accuracy of ceiling prices calculated by manufacturers under subsection (a)(1) and charged to covered entities, which shall include the following:

(I) Developing and publishing through an appropriate policy or regulatory issuance, precisely defined standards and methodology for the calculation of ceiling prices under such subsection.

(II) Comparing regularly the ceiling prices calculated by the Secretary with the quarterly pricing data that is reported by manufacturers to the Secretary.

(III) Performing spot checks of sales transactions by covered entities.

(IV) Inquiring into the cause of any pricing discrepancies that may be identified and either taking, or requiring manufacturers to take, such corrective action as is appropriate in response to such price discrepancies.

(ii) The establishment of procedures for manufacturers to issue refunds to covered entities in the event that there is an overcharge by the manufacturers, including the following:

(I) Providing the Secretary with an explanation of why and how the overcharge occurred, how the refunds will be calculated, and to whom the refunds will be issued.

(II) Oversight by the Secretary to ensure that the refunds are issued accurately and within a reasonable period of time, both in routine instances of retroactive adjustment to relevant pricing data and exceptional circumstances such as

[51] In law, there is no subsection (c) in section 340B of the Public Health Service Act. Subsection (d) of section 340B of the Public Health Service, as in effect before the enactment of Public Law 111–148, was redesignated as subsection (c) by section 2501(f)(1)(C) of Public Law 111–148, amended to read by section 7101(d) of Public Law 111–148, and stricken by section 2302(2) of Public Law 111–152. Subsection (d) of section 340B of the Public Health Service, as currently in effect, is shown according to the probable intent of the Congress. Section 7102(a) of Public Law 111–148 does not execute because it amends to read a nonexistent subsection (d). Notably, section 2302(3) of Public Law 111–152 assumes that section 7102(a) of Public Law 111–148 executed properly and makes amendments to subsection (d).

erroneous or intentional overcharging for covered outpatient drugs.

(iii) The provision of access through the Internet website of the Department of Health and Human Services to the applicable ceiling prices for covered outpatient drugs as calculated and verified by the Secretary in accordance with this section, in a manner (such as through the use of password protection) that limits such access to covered entities and adequately assures security and protection of privileged pricing data from unauthorized re-disclosure.

(iv) The development of a mechanism by which—

(I) rebates and other discounts provided by manufacturers to other purchasers subsequent to the sale of covered outpatient drugs to covered entities are reported to the Secretary; and

(II) appropriate credits and refunds are issued to covered entities if such discounts or rebates have the effect of lowering the applicable ceiling price for the relevant quarter for the drugs involved.

(v) Selective auditing of manufacturers and wholesalers to ensure the integrity of the drug discount program under this section.

(vi) The imposition of sanctions in the form of civil monetary penalties, which—

(I) shall be assessed according to standards established in regulations to be promulgated by the Secretary not later than 180 days after the date of enactment of the Patient Protection and Affordable Care Act;

(II) shall not exceed $5,000 for each instance of overcharging a covered entity that may have occurred; and

(III) shall apply to any manufacturer with an agreement under this section that knowingly and intentionally charges a covered entity a price for purchase of a drug that exceeds the maximum applicable price under subsection (a)(1).

(2) COVERED ENTITY COMPLIANCE.—

(A) IN GENERAL.—From amounts appropriated under paragraph (4), the Secretary shall provide for improvements in compliance by covered entities with the requirements of this section in order to prevent diversion and violations of the duplicate discount provision and other requirements specified under subsection (a)(5).

(B) IMPROVEMENTS.—The improvements described in subparagraph (A) shall include the following:

(i) The development of procedures to enable and require covered entities to regularly update (at least annually) the information on the Internet website of the Department of Health and Human Services relating to this section.

(ii) The development of a system for the Secretary to verify the accuracy of information regarding covered entities that is listed on the website described in clause (i).

(iii) The development of more detailed guidance describing methodologies and options available to covered entities for billing covered outpatient drugs to State Medicaid agencies in a manner that avoids duplicate discounts pursuant to subsection (a)(5)(A).

(iv) The establishment of a single, universal, and standardized identification system by which each covered entity site can be identified by manufacturers, distributors, covered entities, and the Secretary for purposes of facilitating the ordering, purchasing, and delivery of covered outpatient drugs under this section, including the processing of chargebacks for such drugs.

(v) The imposition of sanctions, in appropriate cases as determined by the Secretary, additional to those to which covered entities are subject under subsection (a)(5)(D), through one or more of the following actions:

(I) Where a covered entity knowingly and intentionally violates subsection (a)(5)(B), the covered entity shall be required to pay a monetary penalty to a manufacturer or manufacturers in the form of interest on sums for which the covered entity is found liable under subsection (a)(5)(D), such interest to be compounded monthly and equal to the current short term interest rate as determined by the Federal Reserve for the time period for which the covered entity is liable.

(II) Where the Secretary determines a violation of subsection (a)(5)(B) was systematic and egregious as well as knowing and intentional, removing the covered entity from the drug discount program under this section and disqualifying the entity from re-entry into such program for a reasonable period of time to be determined by the Secretary.

(III) Referring matters to appropriate Federal authorities within the Food and Drug Administration, the Office of Inspector General of Department of Health and Human Services, or other Federal agencies for consideration of appropriate action under other Federal statutes, such as the Prescription Drug Marketing Act (21 U.S.C. 353).

(3) ADMINISTRATIVE DISPUTE RESOLUTION PROCESS.—

(A) IN GENERAL.—Not later than 180 days after the date of enactment of the Patient Protection and Affordable Care Act, the Secretary shall promulgate regulations to establish and implement an administrative process for the resolution of claims by covered entities that they have been overcharged for drugs purchased under this section,

and claims by manufacturers, after the conduct of audits as authorized by subsection (a)(5)(C), of violations of subsections (a)(5)(A) or (a)(5)(B), including appropriate procedures for the provision of remedies and enforcement of determinations made pursuant to such process through mechanisms and sanctions described in paragraphs (1)(B) and (2)(B).

(B) DEADLINES AND PROCEDURES.—Regulations promulgated by the Secretary under subparagraph (A) shall—

(i) designate or establish a decision-making official or decision-making body within the Department of Health and Human Services to be responsible for reviewing and finally resolving claims by covered entities that they have been charged prices for covered outpatient drugs in excess of the ceiling price described in subsection (a)(1), and claims by manufacturers that violations of subsection (a)(5)(A) or (a)(5)(B) have occurred;

(ii) establish such deadlines and procedures as may be necessary to ensure that claims shall be resolved fairly, efficiently, and expeditiously;

(iii) establish procedures by which a covered entity may discover and obtain such information and documents from manufacturers and third parties as may be relevant to demonstrate the merits of a claim that charges for a manufacturer's product have exceeded the applicable ceiling price under this section, and may submit such documents and information to the administrative official or body responsible for adjudicating such claim;

(iv) require that a manufacturer conduct an audit of a covered entity pursuant to subsection (a)(5)(C) as a prerequisite to initiating administrative dispute resolution proceedings against a covered entity;

(v) permit the official or body designated under clause (i), at the request of a manufacturer or manufacturers, to consolidate claims brought by more than one manufacturer against the same covered entity where, in the judgment of such official or body, consolidation is appropriate and consistent with the goals of fairness and economy of resources; and

(vi) include provisions and procedures to permit multiple covered entities to jointly assert claims of overcharges by the same manufacturer for the same drug or drugs in one administrative proceeding, and permit such claims to be asserted on behalf of covered entities by associations or organizations representing the interests of such covered entities and of which the covered entities are members.

(C) FINALITY OF ADMINISTRATIVE RESOLUTION.—The administrative resolution of a claim or claims under the regulations promulgated under subparagraph (A) shall be a final agency decision and shall be binding upon the par-

ties involved, unless invalidated by an order of a court of competent jurisdiction.

(4) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this subsection, such sums as may be necessary for fiscal year 2010 and each succeeding fiscal year.

(e)[52] EXCLUSION OF ORPHAN DRUGS FOR CERTAIN COVERED ENTITIES.—For covered entities described in subparagraph (M) (other than a children's hospital described in subparagraph (M)), (N), or (O) of subsection (a)(4), the term "covered outpatient drug" shall not include a drug designated by the Secretary under section 526 of the Federal Food, Drug, and Cosmetic Act for a rare disease or condition.

Subpart VIII—Bulk Purchases of Vaccines for Certain Programs

BULK PURCHASES OF VACCINES FOR CERTAIN PROGRAMS.

SEC. 340C.[256c] (a) AGREEMENTS FOR PURCHASES.—

(1) IN GENERAL.—Not later than 180 days after the date of the enactment of the Preventive Health Amendments of 1992[53], the Secretary, acting through the Director of the Centers for Disease Control and Prevention and in consultation with the Administrator of the Health Resources and Services Administration, shall enter into negotiations with manufacturers of vaccines for the purpose of establishing and maintaining agreements under which entities described in paragraph (2) may purchase vaccines from the manufacturers at the prices specified in the agreements.

(2) RELEVANT ENTITIES.—The entities referred to in paragraph (1) are entities that provide immunizations against vaccine-preventable diseases with assistance provided under section 330.

(b) NEGOTIATION OF PRICES.—In carrying out subsection (a), the Secretary shall, to the extent practicable, ensure that the prices provided for in agreements under such subsection are comparable to the prices provided for in agreements negotiated by the Secretary on behalf of grantees under section 317(j)(1).

(c) AUTHORITY OF SECRETARY.—In carrying out subsection (a), the Secretary, in the discretion of the Secretary, may enter into the agreements described in such subsection (and may decline to enter into such agreements), may modify such agreements, may extend such agreements, and may terminate such agreements.

(d) RULE OF CONSTRUCTION.—This section may not be construed as requiring any State to reduce or terminate the supply of vaccines provided by the State to any of the entities described in subsection (a)(2).

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[52] Subsection (e) is shown according to the probable intent of Congress. Section 2302(4) of Public Law 111–152 inserts subsection (e) "after subsection (d)". See note in section 340B(d) of the Public Health Service Act regarding the inclusion of subsection (d) to reflect the probable intent of Congress.

Section 204(a)(1) of Public Law 111–309 amends subsection (e) of section 340B (effective on the enactment of such Public Law).

[53] Enacted October 27, 1992.

BREAST AND CERVICAL CANCER INFORMATION.

SEC. 340D.[256d] (a) IN GENERAL.—As a condition of receiving grants, cooperative agreements, or contracts under this Act, each of the entities specified in subsection (c) shall, to the extent determined to be appropriate by the Secretary, make available information concerning breast and cervical cancer.

(b) CERTAIN AUTHORITIES.—In carrying out subsection (a), an entity specified in subsection (c)—

(1) may make the information involved available to such individuals as the entity determines appropriate;

(2) may, as appropriate, provide information under subsection (a) on the need for self-examination of the breasts and on the skills for such self-examinations;

(3) shall provide information under subsection (a) in the language and cultural context most appropriate to the individuals to whom the information is provided; and

(4) shall refer such clients as the entities determine appropriate for breast and cervical cancer screening, treatment, or other appropriate services.

(c) RELEVANT ENTITIES.—The entities specified in this subsection are the following:

(1) Entities receiving assistance under section 317F (relating to tuberculosis)[54].

(2) Entities receiving assistance under section 318 (relating to sexually transmitted diseases).

(3) Migrant health centers receiving assistance under section 329[55].

(4) Community health centers receiving assistance under section 330.

(5) Entities receiving assistance under section 330(h) (relating to homeless individuals).

(6) Entities receiving assistance under section 340A (relating to health services for residents of public housing).

(7) Entities providing services with assistance under title V or title XIX.

(8) Entities receiving assistance under section 1001 (relating to family planning).

(9) Entities receiving assistance under title XXVI (relating to services with respect to acquired immune deficiency syndrome).

(10) Non-Federal entities authorized under the Indian Self-Determination Act.

Subpart IX—Support of Graduate Medical Education Programs in Children's Hospitals

SEC. 340E.[256e] PROGRAM OF PAYMENTS TO CHILDREN'S HOSPITALS THAT OPERATE GRADUATE MEDICAL EDUCATION PROGRAMS.

(a) PAYMENTS.—The Secretary shall make two payments under this section to each children's hospital for each of fiscal years 2000

[54] The reference to section 317F is so in law. See section 2502(b) of Public Law 106–310 (114 Stat. 1163). Section 317E relates to tuberculosis, not section 317F.

[55] See footnote for section 217(a).

through 2005 and each of fiscal years 2007 through 2011, one for the direct expenses and the other for indirect expenses associated with operating approved graduate medical residency training programs. The Secretary shall promulgate regulations pursuant to the rulemaking requirements of title 5, United States Code, which shall govern payments made under this subpart.

(b) AMOUNT OF PAYMENTS.—

(1) IN GENERAL.—Subject to paragraphs (2) and (3), the amounts payable under this section to a children's hospital for an approved graduate medical residency training program for a fiscal year are each of the following amounts:

(A) DIRECT EXPENSE AMOUNT.—The amount determined under subsection (c) for direct expenses associated with operating approved graduate medical residency training programs.

(B) INDIRECT EXPENSE AMOUNT.—The amount determined under subsection (d) for indirect expenses associated with the treatment of more severely ill patients and the additional costs relating to teaching residents in such programs.

(2) CAPPED AMOUNT.—

(A) IN GENERAL.—The total of the payments made to children's hospitals under paragraph (1)(A) or paragraph (1)(B) in a fiscal year shall not exceed the funds appropriated under paragraph (1) or (2), respectively, of subsection (f) for such payments for that fiscal year.

(B) PRO RATA REDUCTIONS OF PAYMENTS FOR DIRECT EXPENSES.—If the Secretary determines that the amount of funds appropriated under subsection (f)(1) for a fiscal year is insufficient to provide the total amount of payments otherwise due for such periods under paragraph (1)(A), the Secretary shall reduce the amounts so payable on a pro rata basis to reflect such shortfall.

(3) ANNUAL REPORTING REQUIRED.—

(A) REDUCTION IN PAYMENT FOR FAILURE TO REPORT.—

(i) IN GENERAL.—The amount payable under this section to a children's hospital for a fiscal year (beginning with fiscal year 2008 and after taking into account paragraph (2)) shall be reduced by 25 percent if the Secretary determines that—

(I) the hospital has failed to provide the Secretary, as an addendum to the hospital's application under this section for such fiscal year, the report required under subparagraph (B) for the previous fiscal year; or

(II) such report fails to provide the information required under any clause of such subparagraph.

(ii) NOTICE AND OPPORTUNITY TO PROVIDE MISSING INFORMATION.—Before imposing a reduction under clause (i) on the basis of a hospital's failure to provide information described in clause (i)(II), the Secretary shall provide notice to the hospital of such failure and the Secretary's intention to impose such reduction and

shall provide the hospital with the opportunity to provide the required information within a period of 30 days beginning on the date of such notice. If the hospital provides such information within such period, no reduction shall be made under clause (i) on the basis of the previous failure to provide such information.

(B) ANNUAL REPORT.—The report required under this subparagraph for a children's hospital for a fiscal year is a report that includes (in a form and manner specified by the Secretary) the following information for the residency academic year completed immediately prior to such fiscal year:

(i) The types of resident training programs that the hospital provided for residents described in subparagraph (C), such as general pediatrics, internal medicine/pediatrics, and pediatric subspecialties, including both medical subspecialties certified by the American Board of Pediatrics (such as pediatric gastroenterology) and non-medical subspecialties approved by other medical certification boards (such as pediatric surgery).

(ii) The number of training positions for residents described in subparagraph (C), the number of such positions recruited to fill, and the number of such positions filled.

(iii) The types of training that the hospital provided for residents described in subparagraph (C) related to the health care needs of different populations, such as children who are underserved for reasons of family income or geographic location, including rural and urban areas.

(iv) The changes in residency training for residents described in subparagraph (C) which the hospital has made during such residency academic year (except that the first report submitted by the hospital under this subparagraph shall be for such changes since the first year in which the hospital received payment under this section), including—

(I) changes in curricula, training experiences, and types of training programs, and benefits that have resulted from such changes; and

(II) changes for purposes of training the residents in the measurement and improvement of the quality and safety of patient care.

(v) The numbers of residents described in subparagraph (C) who completed their residency training at the end of such residency academic year and care for children within the borders of the service area of the hospital or within the borders of the State in which the hospital is located. Such numbers shall be disaggregated with respect to residents who completed residencies in general pediatrics or internal medicine/pediatrics, subspecialty residencies, and dental residencies.

(C) RESIDENTS.—The residents described in this subparagraph are those who—

(i) are in full-time equivalent resident training positions in any training program sponsored by the hospital; or

(ii) are in a training program sponsored by an entity other than the hospital, but who spend more than 75 percent of their training time at the hospital.

(D) REPORT TO CONGRESS.—Not later than the end of fiscal year 2011, the Secretary, acting through the Administrator of the Health Resources and Services Administration, shall submit a report to the Congress—

(i) summarizing the information submitted in reports to the Secretary under subparagraph (B);

(ii) describing the results of the program carried out under this section; and

(iii) making recommendations for improvements to the program.

(c) AMOUNT OF PAYMENT FOR DIRECT GRADUATE MEDICAL EDUCATION.—

(1) IN GENERAL.—The amount determined under this subsection for payments to a children's hospital for direct graduate expenses relating to approved graduate medical residency training programs for a fiscal year is equal to the product of—

(A) the updated per resident amount for direct graduate medical education, as determined under paragraph (2); and

(B) the average number of full-time equivalent residents in the hospital's graduate approved medical residency training programs (as determined under section 1886(h)(4) of the Social Security Act during the fiscal year.

(2) UPDATED PER RESIDENT AMOUNT FOR DIRECT GRADUATE MEDICAL EDUCATION.—The updated per resident amount for direct graduate medical education for a hospital for a fiscal year is an amount determined as follows:

(A) DETERMINATION OF HOSPITAL SINGLE PER RESIDENT AMOUNT.—The Secretary shall compute for each hospital operating an approved graduate medical education program (regardless of whether or not it is a children's hospital) a single per resident amount equal to the average (weighted by number of full-time equivalent residents) of the primary care per resident amount and the non-primary care per resident amount computed under section 1886(h)(2) of the Social Security Act for cost reporting periods ending during fiscal year 1997.

(B) DETERMINATION OF WAGE AND NON-WAGE-RELATED PROPORTION OF THE SINGLE PER RESIDENT AMOUNT.—The Secretary shall estimate the average proportion of the single per resident amounts computed under subparagraph (A) that is attributable to wages and wage-related costs.

(C) STANDARDIZING PER RESIDENT AMOUNTS.—The Secretary shall establish a standardized per resident amount for each such hospital—

(i) by dividing the single per resident amount computed under subparagraph (A) into a wage-related portion and a non-wage-related portion by applying the proportion determined under subparagraph (B);

(ii) by dividing the wage-related portion by the factor applied under section 1886(d)(3)(E) of the Social Security Act for discharges occurring during fiscal year 1999 for the hospital's area; and

(iii) by adding the non-wage-related portion to the amount computed under clause (ii).

(D) DETERMINATION OF NATIONAL AVERAGE.—The Secretary shall compute a national average per resident amount equal to the average of the standardized per resident amounts computed under subparagraph (C) for such hospitals, with the amount for each hospital weighted by the average number of full-time equivalent residents at such hospital.

(E) APPLICATION TO INDIVIDUAL HOSPITALS.—The Secretary shall compute for each such hospital that is a children's hospital a per resident amount—

(i) by dividing the national average per resident amount computed under subparagraph (D) into a wage-related portion and a non-wage-related portion by applying the proportion determined under subparagraph (B);

(ii) by multiplying the wage-related portion by the factor applied under section 1886(d)(3)(E) of the Social Security Act for discharges occurring during the preceding fiscal year for the hospital's area; and

(iii) by adding the non-wage-related portion to the amount computed under clause (ii).

(F) UPDATING RATE.—The Secretary shall update such per resident amount for each such children's hospital by the estimated percentage increase in the consumer price index for all urban consumers during the period beginning October 1997 and ending with the midpoint of the Federal fiscal year for which payments are made.

(d) AMOUNT OF PAYMENT FOR INDIRECT MEDICAL EDUCATION.—

(1) IN GENERAL.—The amount determined under this subsection for payments to a children's hospital for indirect expenses associated with the treatment of more severely ill patients and the additional costs associated with the teaching of residents for a fiscal year is equal to an amount determined appropriate by the Secretary.

(2) FACTORS.—In determining the amount under paragraph (1), the Secretary shall—

(A) take into account variations in case mix among children's hospitals and the ratio of the number of full-time equivalent residents in the hospitals' approved graduate medical residency training programs to beds (but excluding beds or bassinets assigned to healthy newborn infants); and

(B) assure that the aggregate of the payments for indirect expenses associated with the treatment of more se-

verely ill patients and the additional costs related to the teaching of residents under this section in a fiscal year are equal to the amount appropriated for such expenses for the fiscal year involved under subsection (f)(2).

(e) MAKING OF PAYMENTS.—

(1) INTERIM PAYMENTS.—The Secretary shall determine, before the beginning of each fiscal year involved for which payments may be made for a hospital under this section, the amounts of the payments for direct graduate medical education and indirect medical education for such fiscal year and shall (subject to paragraph (2)) make the payments of such amounts in 12 equal interim installments during such period. Such interim payments to each individual hospital shall be based on the number of residents reported in the hospital's most recently filed Medicare cost report prior to the application date for the Federal fiscal year for which the interim payment amounts are established. In the case of a hospital that does not report residents on a Medicare cost report, such interim payments shall be based on the number of residents trained during the hospital's most recently completed Medicare cost report filing period.

(2) WITHHOLDING.—The Secretary shall withhold up to 25 percent from each interim installment for direct and indirect graduate medical education paid under paragraph (1) as necessary to ensure a hospital will not be overpaid on an interim basis.

(3) RECONCILIATION.—Prior to the end of each fiscal year, the Secretary shall determine any changes to the number of residents reported by a hospital in the application of the hospital for the current fiscal year to determine the final amount payable to the hospital for the current fiscal year for both direct expense and indirect expense amounts. Based on such determination, the Secretary shall recoup any overpayments made and pay any balance due to the extent possible. The final amount so determined shall be considered a final intermediary determination for the purposes of section 1878 of the Social Security Act and shall be subject to administrative and judicial review under that section in the same manner as the amount of payment under section 1186(d) of such Act is subject to review under such section.

(f) AUTHORIZATION OF APPROPRIATIONS.—

(1) DIRECT GRADUATE MEDICAL EDUCATION.—

(A) IN GENERAL.—There are hereby authorized to be appropriated, out of any money in the Treasury not otherwise appropriated, for payments under subsection (b)(1)(A)—

(i) for fiscal year 2000, $90,000,000;

(ii) for fiscal year 2001, $95,000,000;

(iii) for each of the fiscal years 2002 through 2005, such sums as may be necessary; and

(iv) for each of fiscal years 2007 through 2011, $110,000,000.

(B) CARRYOVER OF EXCESS.—The amounts appropriated under subparagraph (A) for fiscal year 2000 shall

remain available for obligation through the end of fiscal year 2001.

(2) INDIRECT MEDICAL EDUCATION.—There are hereby authorized to be appropriated, out of any money in the Treasury not otherwise appropriated, for payments under subsection (b)(1)(B)—

(A) for fiscal year 2000, $190,000,000;

(B) for fiscal year 2001, $190,000,000;

(C) for each of the fiscal years 2002 through 2005, such sums as may be necessary; and

(D) for each of fiscal years 2007 through 2011, $220,000,000.

(g) DEFINITIONS.—In this section:

(1) APPROVED GRADUATE MEDICAL RESIDENCY TRAINING PROGRAM.—The term "approved graduate medical residency training program" has the meaning given the term "approved medical residency training program" in section 1886(h)(5)(A) of the Social Security Act.

(2) CHILDREN'S HOSPITAL.—The term "children's hospital" means a hospital with a Medicare payment agreement and which is excluded from the Medicare inpatient prospective payment system pursuant to section 1886(d)(1)(B)(iii) of the Social Security Act and its accompanying regulations.

(3) DIRECT GRADUATE MEDICAL EDUCATION COSTS.—The term "direct graduate medical education costs" has the meaning given such term in section 1886(h)(5)(C) of the Social Security Act.

Subpart X—Primary Dental Programs

SEC. 340F.[256f] DESIGNATED DENTAL HEALTH PROFESSIONAL SHORTAGE AREA.

In this subpart, the term "designated dental health professional shortage area" means an area, population group, or facility that is designated by the Secretary as a dental health professional shortage area under section 332 or designated by the applicable State as having a dental health professional shortage.

SEC. 340G.[256g] GRANTS FOR INNOVATIVE PROGRAMS.

(a) GRANT PROGRAM AUTHORIZED.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, is authorized to award grants to States for the purpose of helping States develop and implement innovative programs to address the dental workforce needs of designated dental health professional shortage areas in a manner that is appropriate to the States' individual needs.

(b) STATE ACTIVITIES.—A State receiving a grant under subsection (a) may use funds received under the grant for—

(1) loan forgiveness and repayment programs for dentists who—

(A) agree to practice in designated dental health professional shortage areas;

(B) are dental school graduates who agree to serve as public health dentists for the Federal, State, or local government; and

(C) agree to—

(i) provide services to patients regardless of such patients' ability to pay; and

(ii) use a sliding payment scale for patients who are unable to pay the total cost of services;

(2) dental recruitment and retention efforts;

(3) grants and low-interest or no-interest loans to help dentists who participate in the medicaid program under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) to establish or expand practices in designated dental health professional shortage areas by equipping dental offices or sharing in the overhead costs of such practices;

(4) the establishment or expansion of dental residency programs in coordination with accredited dental training institutions in States without dental schools;

(5) programs developed in consultation with State and local dental societies to expand or establish oral health services and facilities in designated dental health professional shortage areas, including services and facilities for children with special needs, such as—

(A) the expansion or establishment of a community-based dental facility, free-standing dental clinic, consolidated health center dental facility, school-linked dental facility, or United States dental school-based facility;

(B) the establishment of a mobile or portable dental clinic; and

(C) the establishment or expansion of private dental services to enhance capacity through additional equipment or additional hours of operation;

(6) placement and support of dental students, dental residents, and advanced dentistry trainees;

(7) continuing dental education, including distance-based education;

(8) practice support through teledentistry conducted in accordance with State laws;

(9) community-based prevention services such as water fluoridation and dental sealant programs;

(10) coordination with local educational agencies within the State to foster programs that promote children going into oral health or science professions;

(11) the establishment of faculty recruitment programs at accredited dental training institutions whose mission includes community outreach and service and that have a demonstrated record of serving underserved States;

(12) the development of a State dental officer position or the augmentation of a State dental office to coordinate oral health and access issues in the State; and

(13) any other activities determined to be appropriate by the Secretary.

(c) APPLICATION.—

(1) IN GENERAL.—Each State desiring a grant under this section shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may reasonably require.

(2) ASSURANCES.—The application shall include assurances that the State will meet the requirements of subsection (d) and that the State possesses sufficient infrastructure to manage the activities to be funded through the grant and to evaluate and report on the outcomes resulting from such activities.

(d) MATCHING REQUIREMENT.—The Secretary may not make a grant to a State under this section unless that State agrees that, with respect to the costs to be incurred by the State in carrying out the activities for which the grant was awarded, the State will provide non-Federal contributions in an amount equal to not less than 40 percent of Federal funds provided under the grant. The State may provide the contributions in cash or in kind, fairly evaluated, including plant, equipment, and services and may provide the contributions from State, local, or private sources.

(e) REPORT.—Not later than 5 years after the date of enactment of the Health Care Safety Net Amendments of 2002, the Secretary shall prepare and submit to the appropriate committees of Congress a report containing data relating to whether grants provided under this section have increased access to dental services in designated dental health professional shortage areas.

(f) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $25,000,000 for the 5-fiscal year period beginning with fiscal year 2008.

SEC. 340G–1.[256g–1] DEMONSTRATION PROGRAM.

(a) IN GENERAL.—

(1) AUTHORIZATION.—The Secretary is authorized to award grants to 15 eligible entities to enable such entities to establish a demonstration program to establish training programs to train, or to employ, alternative dental health care providers in order to increase access to dental health care services in rural and other underserved communities.

(2) DEFINITION.—The term "alternative dental health care providers" includes community dental health coordinators, advance practice dental hygienists, independent dental hygienists, supervised dental hygienists, primary care physicians, dental therapists, dental health aides, and any other health professional that the Secretary determines appropriate.

(b) TIMEFRAME.—The demonstration projects funded under this section shall begin not later than 2 years after the date of enactment of this section, and shall conclude not later than 7 years after such date of enactment.

(c) ELIGIBLE ENTITIES.—To be eligible to receive a grant under subsection (a), an entity shall—

(1) be—

(A) an institution of higher education, including a community college;

(B) a public-private partnership;

(C) a federally qualified health center;

(D) an Indian Health Service facility or a tribe or tribal organization (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act);

(E) a State or county public health clinic, a health facility operated by an Indian tribe or tribal organization, or urban Indian organization providing dental services; or

(F) a public hospital or health system;

(2) be within a program accredited by the Commission on Dental Accreditation or within a dental education program in an accredited institution; and

(3) shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require.

(d) ADMINISTRATIVE PROVISIONS.—

(1) AMOUNT OF GRANT.—Each grant under this section shall be in an amount that is not less than $4,000,000 for the 5-year period during which the demonstration project being conducted.

(2) DISBURSEMENT OF FUNDS.—

(A) PRELIMINARY DISBURSEMENTS.—Beginning 1 year after the enactment of this section, the Secretary may disperse to any entity receiving a grant under this section not more than 20 percent of the total funding awarded to such entity under such grant, for the purpose of enabling the entity to plan the demonstration project to be conducted under such grant.

(B) SUBSEQUENT DISBURSEMENTS.—The remaining amount of grant funds not dispersed under subparagraph (A) shall be dispersed such that not less than 15 percent of such remaining amount is dispersed each subsequent year.

(e) COMPLIANCE WITH STATE REQUIREMENTS.—Each entity receiving a grant under this section shall certify that it is in compliance with all applicable State licensing requirements.

(f) EVALUATION.—The Secretary shall contract with the Director of the Institute of Medicine to conduct a study of the demonstration programs conducted under this section that shall provide analysis, based upon quantitative and qualitative data, regarding access to dental health care in the United States.

(g) CLARIFICATION REGARDING DENTAL HEALTH AIDE PROGRAM.—Nothing in this section shall prohibit a dental health aide training program approved by the Indian Health Service from being eligible for a grant under this section.

(h) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated such sums as may be necessary to carry out this section.

Subpart XI—Support of Graduate Medical Education in Qualified Teaching Health Centers

SEC. 340H.[256h] PROGRAM OF PAYMENTS TO TEACHING HEALTH CENTERS THAT OPERATE GRADUATE MEDICAL EDUCATION PROGRAMS.

(a) PAYMENTS.—Subject to subsection (h)(2), the Secretary shall make payments under this section for direct expenses and for indirect expenses to qualified teaching health centers that are listed as sponsoring institutions by the relevant accrediting body for expansion of existing or establishment of new approved graduate medical residency training programs.

(b) AMOUNT OF PAYMENTS.—

(1) IN GENERAL.—Subject to paragraph (2), the amounts payable under this section to qualified teaching health centers for an approved graduate medical residency training program for a fiscal year are each of the following amounts:

(A) DIRECT EXPENSE AMOUNT.—The amount determined under subsection (c) for direct expenses associated with sponsoring approved graduate medical residency training programs.

(B) INDIRECT EXPENSE AMOUNT.—The amount determined under subsection (d) for indirect expenses associated with the additional costs relating to teaching residents in such programs.

(2) CAPPED AMOUNT.—

(A) IN GENERAL.—The total of the payments made to qualified teaching health centers under paragraph (1)(A) or paragraph (1)(B) in a fiscal year shall not exceed the amount of funds appropriated under subsection (g) for such payments for that fiscal year.

(B) LIMITATION.—The Secretary shall limit the funding of full-time equivalent residents in order to ensure the direct and indirect payments as determined under subsection (c) and (d) do not exceed the total amount of funds appropriated in a fiscal year under subsection (g).

(c) AMOUNT OF PAYMENT FOR DIRECT GRADUATE MEDICAL EDUCATION.—

(1) IN GENERAL.—The amount determined under this subsection for payments to qualified teaching health centers for direct graduate expenses relating to approved graduate medical residency training programs for a fiscal year is equal to the product of—

(A) the updated national per resident amount for direct graduate medical education, as determined under paragraph (2); and

(B) the average number of full-time equivalent residents in the teaching health center's graduate approved medical residency training programs as determined under section 1886(h)(4) of the Social Security Act (without regard to the limitation under subparagraph (F) of such section) during the fiscal year.

(2) UPDATED NATIONAL PER RESIDENT AMOUNT FOR DIRECT GRADUATE MEDICAL EDUCATION.—The updated per resident

amount for direct graduate medical education for a qualified teaching health center for a fiscal year is an amount determined as follows:

(A) DETERMINATION OF QUALIFIED TEACHING HEALTH CENTER PER RESIDENT AMOUNT.—The Secretary shall compute for each individual qualified teaching health center a per resident amount—

(i) by dividing the national average per resident amount computed under section 340E(c)(2)(D) into a wage-related portion and a non-wage related portion by applying the proportion determined under subparagraph (B);

(ii) by multiplying the wage-related portion by the factor applied under section 1886(d)(3)(E) of the Social Security Act (but without application of section 4410 of the Balanced Budget Act of 1997 (42 U.S.C. 1395ww note)) during the preceding fiscal year for the teaching health center's area; and

(iii) by adding the non-wage-related portion to the amount computed under clause (ii).

(B) UPDATING RATE.—The Secretary shall update such per resident amount for each such qualified teaching health center as determined appropriate by the Secretary.

(d) AMOUNT OF PAYMENT FOR INDIRECT MEDICAL EDUCATION.—

(1) IN GENERAL.—The amount determined under this subsection for payments to qualified teaching health centers for indirect expenses associated with the additional costs of teaching residents for a fiscal year is equal to an amount determined appropriate by the Secretary.

(2) FACTORS.—In determining the amount under paragraph (1), the Secretary shall—

(A) evaluate indirect training costs relative to supporting a primary care residency program in qualified teaching health centers; and

(B) based on this evaluation, assure that the aggregate of the payments for indirect expenses under this section and the payments for direct graduate medical education as determined under subsection (c) in a fiscal year do not exceed the amount appropriated for such expenses as determined in subsection (g).

(3) INTERIM PAYMENT.—Before the Secretary makes a payment under this subsection pursuant to a determination of indirect expenses under paragraph (1), the Secretary may provide to qualified teaching health centers a payment, in addition to any payment made under subsection (c), for expected indirect expenses associated with the additional costs of teaching residents for a fiscal year, based on an estimate by the Secretary.

(e) CLARIFICATION REGARDING RELATIONSHIP TO OTHER PAYMENTS FOR GRADUATE MEDICAL EDUCATION.—Payments under this section—

(1) shall be in addition to any payments—

(A) for the indirect costs of medical education under section 1886(d)(5)(B) of the Social Security Act;

(B) for direct graduate medical education costs under section 1886(h) of such Act; and

(C) for direct costs of medical education under section 1886(k) of such Act;

(2) shall not be taken into account in applying the limitation on the number of total full-time equivalent residents under subparagraphs (F) and (G) of section 1886(h)(4) of such Act and clauses (v), (vi)(I), and (vi)(II) of section 1886(d)(5)(B) of such Act for the portion of time that a resident rotates to a hospital; and

(3) shall not include the time in which a resident is counted toward full-time equivalency by a hospital under paragraph (2) or under section 1886(d)(5)(B)(iv) of the Social Security Act, section 1886(h)(4)(E) of such Act, or section 340E of this Act.

(f) RECONCILIATION.—The Secretary shall determine any changes to the number of residents reported by a hospital in the application of the hospital for the current fiscal year to determine the final amount payable to the hospital for the current fiscal year for both direct expense and indirect expense amounts. Based on such determination, the Secretary shall recoup any overpayments made to pay any balance due to the extent possible. The final amount so determined shall be considered a final intermediary determination for the purposes of section 1878 of the Social Security Act and shall be subject to administrative and judicial review under that section in the same manner as the amount of payment under section 1186(d) of such Act is subject to review under such section.

(g) FUNDING.—To carry out this section, there are appropriated such sums as may be necessary, not to exceed $230,000,000, for the period of fiscal years 2011 through 2015.

(h) ANNUAL REPORTING REQUIRED.—

(1) ANNUAL REPORT.—The report required under this paragraph for a qualified teaching health center for a fiscal year is a report that includes (in a form and manner specified by the Secretary) the following information for the residency academic year completed immediately prior to such fiscal year:

(A) The types of primary care resident approved training programs that the qualified teaching health center provided for residents.

(B) The number of approved training positions for residents described in paragraph (4).

(C) The number of residents described in paragraph (4) who completed their residency training at the end of such residency academic year and care for vulnerable populations living in underserved areas.

(D) Other information as deemed appropriate by the Secretary.

(2) AUDIT AUTHORITY; LIMITATION ON PAYMENT.—

(A) AUDIT AUTHORITY.—The Secretary may audit a qualified teaching health center to ensure the accuracy and completeness of the information submitted in a report under paragraph (1).

(B) LIMITATION ON PAYMENT.—A teaching health center may only receive payment in a cost reporting period for

a number of such resident positions that is greater than the base level of primary care resident positions, as determined by the Secretary. For purposes of this subparagraph, the "base level of primary care residents" for a teaching health center is the level of such residents as of a base period.

(3) REDUCTION IN PAYMENT FOR FAILURE TO REPORT.—

(A) IN GENERAL.—The amount payable under this section to a qualified teaching health center for a fiscal year shall be reduced by at least 25 percent if the Secretary determines that—

(i) the qualified teaching health center has failed to provide the Secretary, as an addendum to the qualified teaching health center's application under this section for such fiscal year, the report required under paragraph (1) for the previous fiscal year; or

(ii) such report fails to provide complete and accurate information required under any subparagraph of such paragraph.

(B) NOTICE AND OPPORTUNITY TO PROVIDE ACCURATE AND MISSING INFORMATION.—Before imposing a reduction under subparagraph (A) on the basis of a qualified teaching health center's failure to provide complete and accurate information described in subparagraph (A)(ii), the Secretary shall provide notice to the teaching health center of such failure and the Secretary's intention to impose such reduction and shall provide the teaching health center with the opportunity to provide the required information within the period of 30 days beginning on the date of such notice. If the teaching health center provides such information within such period, no reduction shall be made under subparagraph (A) on the basis of the previous failure to provide such information.

(4) RESIDENTS.—The residents described in this paragraph are those who are in part-time or full-time equivalent resident training positions at a qualified teaching health center in any approved graduate medical residency training program.

(i) REGULATIONS.—The Secretary shall promulgate regulations to carry out this section.

(j) DEFINITIONS.—In this section:

(1) APPROVED GRADUATE MEDICAL RESIDENCY TRAINING PROGRAM.—The term "approved graduate medical residency training program" means a residency or other postgraduate medical training program—

(A) participation in which may be counted toward certification in a specialty or subspecialty and includes formal postgraduate training programs in geriatric medicine approved by the Secretary; and

(B) that meets criteria for accreditation (as established by the Accreditation Council for Graduate Medical Education, the American Osteopathic Association, or the American Dental Association).

(2) PRIMARY CARE RESIDENCY PROGRAM.—The term "primary care residency program" has the meaning given that term in section 749A.

(3) QUALIFIED TEACHING HEALTH CENTER.—The term "qualified teaching health center" has the meaning given the term "teaching health center" in section 749A.

Subpart XI—Community-Based Collaborative Care Network Program

SEC. 340H.[256i] COMMUNITY-BASED COLLABORATIVE CARE NETWORK PROGRAM.[56].

(a) IN GENERAL.—The Secretary may award grants to eligible entities to support community-based collaborative care networks that meet the requirements of subsection (b).

(b) COMMUNITY-BASED COLLABORATIVE CARE NETWORKS.—

(1) DESCRIPTION.—A community-based collaborative care network (referred to in this section as a "network") shall be a consortium of health care providers with a joint governance structure (including providers within a single entity) that provides comprehensive coordinated and integrated health care services (as defined by the Secretary) for low-income populations.

(2) REQUIRED INCLUSION.—A network shall include the following providers (unless such provider does not exist within the community, declines or refuses to participate, or places unreasonable conditions on their participation):

(A) A hospital that meets the criteria in section 1923(b)(1) of the Social Security Act; and

(B) All Federally qualified health centers (as defined in section 1861(aa) of the Social Security Act located in the community.

(3) PRIORITY.—In awarding grants, the Secretary shall give priority to networks that include—

(A) the capability to provide the broadest range of services to low-income individuals;

(B) the broadest range of providers that currently serve a high volume of low-income individuals; and

(C) a county or municipal department of health.

(c) APPLICATION.—

(1) APPLICATION.—A network described in subsection (b) shall submit an application to the Secretary.

(2) RENEWAL.—In subsequent years, based on the performance of grantees, the Secretary may provide renewal grants to prior year grant recipients.

(d) USE OF FUNDS.—

(1) USE BY GRANTEES.—Grant funds may be used for the following activities:

(A) Assist low-income individuals to—

(i) access and appropriately use health services;

(ii) enroll in health coverage programs; and

[56] So in law. Sections 5508(c) and 10333 of Public Law 111–148 added a subpart XI including adding two sections designated as section 340H).

(iii) obtain a regular primary care provider or a medical home.

(B) Provide case management and care management.

(C) Perform health outreach using neighborhood health workers or through other means.

(D) Provide transportation.

(E) Expand capacity, including through telehealth, after-hours services or urgent care.

(F) Provide direct patient care services.

(2) GRANT FUNDS TO HRSA GRANTEES.—The Secretary may limit the percent of grant funding that may be spent on direct care services provided by grantees of programs administered by the Health Resources and Services Administration or impose other requirements on such grantees deemed necessary.

(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section such sums as may be necessary for each of fiscal years 2011 through 2015.

PART E—NARCOTIC ADDICTS AND OTHER DRUG ABUSERS [57]

CARE AND TREATMENT.

SEC. 341.[257] (a) The Surgeon General is authorized to provide for the confinement, care, protection, treatment, and discipline of persons addicted to the use of habit-forming narcotic drugs who are civilly committed to treatment under the Narcotic Addict Rehabilitation Act of 1966, addicts and other persons with drug abuse and drug dependence problems who voluntarily submit themselves for treatment, and addicts convicted of offenses against the United States, including persons convicted by general courts-martial and consular courts. Such care and treatment shall be provided at hospitals of the Service especially equipped for the accommodation of such patients or elsewhere where authorized under other provisions of law, and shall be designed to rehabilitate such persons, to restore them to health, and, where necessary, to train them to be self-supporting and self-reliant; but nothing in this section or in this part shall be construed to limit the authority of the Surgeon General under other provisions of law to provide for the conditional release of patients and for aftercare under supervision. In carrying out this subsection, the Secretary shall establish in each hospital and other appropriate medical facility of the Service a treatment and rehabilitation program for drug addicts and other persons with drug abuse and drug dependence problems who are in the area served by such hospital or other facility; except that the requirement of this sentence shall not apply in the case of any such hospital or other facility with respect to which the Secretary determines that there is not sufficient need for such a program in such hospital or other facility.

(b) Upon the admittance to, and departure from, a hospital of the Service of a person who voluntarily submitted himself for treat-

[57] The probable intent of the Congress is that part E be repealed. Section 3405(a) of Public Law 106–310 (114 Stat. 1221) provides as follows: "Part E of title III (42 U.S.C. 257 et seq.) is repealed." No Act is identified as the subject of the amendment, but the citation given to the United States Code, section 257 of title 42, is the Code section that codifies section 341 of this Act (the first section in part E).

ment pursuant to the provisions of this section, and who at the time of his admittance to such hospital was a resident of the District of Columbia, the Surgeon General shall furnish to the Commissioners of the District of Columbia or their designated agent, the name, address, and such other pertinent information as may be useful in the rehabilitation to society of such person.

(c) The Secretary may enter into agreements with the Secretary of Veterans Affairs, the Secretary of Defense, and the head of any other department or agency of the Government under which agreements hospitals and other appropriate medical facilities of the Service may be used in treatment and rehabilitation programs provided by such department or agency for drug addicts and other persons with drug abuse and other drug dependence problems who are in areas served by such hospitals or other facilities.

EMPLOYMENT OF ADDICTS OR OTHER PERSONS WITH DRUG ABUSE AND DRUG DEPENDENCE PROBLEMS.

SEC. 342.[258] Narcotic addicts or other persons with drug abuse and drug dependence problems in hospitals of the Service designated for their care shall be employed in such manner and under such conditions as the Surgeon General may direct. In such hospitals the Surgeon General may, in his discretion, establish industries, plants, factories, or shops for the production and manufacture of articles, commodities, and supplies for the United States Government. The Secretary of the Treasury may require any Government department, establishment, or other institution, for whom appropriations are made directly or indirectly by the Congress of the United States, to purchase at current market prices, as determined by him or his authorized representative, such of the articles, commodities, or supplies so produced or manufactured as meet their specifications; and the Surgeon General shall provide for payment to the inmates or their dependents of such pecuniary earnings as he may deem proper. The Secretary shall establish a working-capital fund for such industries, plants, factories, and shops out of any funds appropriated for Public Health Service hospitals at which addicts or other persons with drug abuse and drug dependence problems are treated and cared for; and such fund shall be available for the purchase, repair, or replacement of machinery or equipment, for the purchase of raw materials and supplies, for the purchase of uniforms and other distinctive wearing apparel of employees in the performance of their official duties, and for the employment of necessary civilian officers and employees. The Surgeon General may provide for the disposal of products of the industrial activities conducted pursuant to this section, and the proceeds of any sales thereof shall be covered into the Treasury of the United States to the credit of the working-capital fund.

CONVICTS.

SEC. 343.[259] (a) The authority vested with the power to designate the place of confinement of a prisoner shall transfer to hospitals of the Service especially equipped for the accommodation of addicts or other persons with drug abuse and drug dependence problems, if accommodations are available, all addicts or other per-

sons with drug abuse and drug dependence problems who have been or are hereafter sentenced to confinement, or who are now or shall hereafter be confined, in any penal, correctional, disciplinary, or reformatory institution of the United States, including those addicts or other persons with drug abuse and drug dependence problems convicted of offenses against the United States who are confined in State and Territorial prisons, penitentiaries, and reformatories, except that no addict or other person with a drug abuse or other drug dependence problem shall be transferred to a hospital of the Service who, in the opinion of the officer authorized to direct the transfer, is not a proper subject for confinement in such an institution either because of the nature of the crime he has committed or because of his apparent incorrigibility. The authority vested with the power to designate the place of confinement of a prisoner shall transfer from a hospital of the Service to the institution from which he was received, or to such other institution as may be designated by the proper authority, any addict or other person with a drug abuse or other drug dependence problem whose presence at a hospital of the Service is detrimental to the well-being of the hospital or who does not continue to be a narcotic addict or other person with a drug abuse or other drug dependence problem. All transfers of such prisoners to or from a hospital of the Service shall be accompanied by necessary attendants as directed by the officer in charge of such hospital and the actual and necessary expenses incident to such transfers shall be paid from the appropriation for the maintenance of such Service hospital except to the extent that other Federal agencies are authorized or required by law to pay expenses incident to such transfers. When sentence is pronounced against any person whom the prosecuting officer believes to be an addict or other person with a drug abuse or other drug dependence problem such officer shall report to the authority vested with the power to designate the place of confinement, the name of such person, the reasons for his belief, all pertinent facts bearing on such addiction, drug abuse, or drug dependence and the nature of the offense committed. Whenever an alien addict or other person with a drug abuse or other drug dependence problem transferred to a Service hospital pursuant to this subsection is entitled to his discharge but is subject to deportation, in lieu of being returned to the penal institution from which he came he shall be deported by the authority vested by law with power over deportation.

(b)

(c) Not later than one month prior to the expiration of the sentence of any addict or other person with a drug abuse or other drug dependence problem confined in a Service hospital, he shall be examined by the Surgeon General or his authorized representative. If the Surgeon General believes the person to be discharged is still an addict or other person with a drug abuse or other drug dependence problem and that he may by further treatment in a Service hospital be cured of his addiction, drug abuse, or drug dependence the addict or other person with a drug abuse or other drug dependence problem shall be informed, in accordance with regulations, of the advisability of his submitting himself to further treatment. The addict or other person with a drug abuse or other drug dependence

problem may then apply in writing to the Surgeon General for further treatment in a Service hospital for a period not exceeding the maximum length of time considered necessary by the Surgeon General. Upon approval of the application by the Surgeon General or his authorized agent, the addict or other person with a drug abuse or other drug dependence problem may be given such further treatment as is necessary to cure him of his addiction, drug abuse, or drug dependence.

(d) Every person convicted of an offense against the United States, upon discharge, or upon release on parole or supervised release from a hospital of the Service, shall be furnished with the gratuities and transportation authorized by law to be furnished to prisoners upon release from a penal, correctional, disciplinary, or reformatory institution.

(e) Any court of the United States having the power to suspend the imposition or execution of sentence and to place a defendant on probation under any existing laws may impose as one of the conditions of such probation that the defendant, if an addict, or other person with a drug abuse or other drug dependence problem shall submit himself for treatment at a hospital of the Service especially equipped for the accommodation of addicts or other persons with drug abuse and drug dependence problems until discharged therefrom as cured and that he shall be admitted thereto for such purpose. Upon the discharge of any such probationer from a hospital of the Service, he shall be furnished with the gratuities and transportation authorized by law to be furnished to prisoners upon release from a penal, correctional, disciplinary, or reformatory institution. The actual and necessary expense incident to transporting such probationer to such hospital and to furnishing such transportation and gratuities shall be paid from the appropriation for the maintenance of such hospital except to the extent that other Federal agencies are authorized or required by law to pay the cost of such transportation: *Provided,* That where existing law vests a discretion in any officer as to the place to which transportation shall be furnished or as to the amount of clothing and gratuities to be furnished, such discretion shall be exercised by the Surgeon General with respect to addicts or other persons with drug abuse and drug dependence problems discharged from hospitals of the Service.

VOLUNTARY PATIENTS.

SEC. 344.[260] (a) Any addict, or other person with a drug abuse or other drug dependence problem whether or not he shall have been convicted of an offense against the United States, may apply to the Surgeon General for admission to a hospital of the Service especially equipped for the accommodation of addicts or other persons with drug abuse and drug dependence problems.

(b) Any applicant shall be examined by the Surgeon General who shall determine whether the applicant is an addict, or other person with a drug abuse or other drug dependence problem whether by treatment in a hospital of the Service he may probably be cured of his addiction, drug abuse, or drug dependence and the estimated length of time necessary to effect his cure. The Surgeon General may, in his discretion, admit the applicant to a Service

hospital. No such addict or other person with drug abuse or other drug dependence problem shall be admitted unless he agrees to submit to treatment for the maximum amount of time estimated by the Surgeon General to be necessary to effect a cure, and unless suitable accommodations are available after all eligible addicts or other persons with drug abuse and drug dependence problems convicted of offenses against the United States have been admitted. Any such addict or other person with a drug abuse or other drug dependence problem may be required to pay for his subsistence, care, and treatment at rates fixed by the Surgeon General and amounts so paid shall be covered into the Treasury of the United States to the credit of the appropriation from which the expenditure for his subsistence, care, and treatment was made. Appropriations available for the care and treatment of addicts or other persons with drug abuse and drug dependence problems admitted to a hospital of the Service under this section shall be available, subject to regulations, for paying the cost of transportation to any place within the continental United States, including subsistence allowance while traveling, for any indigent addict or other person with a drug abuse or other drug dependence problem who is discharged as cured.

(c) Any addict or other person with a drug abuse or other drug dependence problem admitted for treatment under this section, including any addict, or other person with a drug abuse or other drug dependence problem not convicted of an offense, who voluntarily submits himself for treatment, may be confined in a hospital of the Service for a period not exceeding the maximum amount of time estimated by the Surgeon General as necessary to effect a cure of the addiction, drug abuse, or drug dependence or until such time as he ceases to be an addict or other person with a drug abuse or other drug dependence problem.

(d) Any addict or other person with a drug abuse or other drug dependence problem admitted for treatment under this section shall not thereby forfeit or abridge any of his rights as a citizen of the United States; nor shall such admission or treatment be used against him in any proceeding in any court; and the record of his voluntary commitment shall, except as otherwise provided by this Act, be confidential and shall not be divulged.

PERSONS COMMITTED FROM DISTRICT OF COLUMBIA.

SEC. 345.[260a] (a) The Surgeon General is authorized to admit for care and treatment in any hospital of the Service suitably equipped therefor, and thereafter to transfer between hospitals of the Service in accordance with section 321(b), any addict who is committed, under the provisions of the Act of June 24, 1953 (Public Law 76, Eighty-third Congress)[58], to the Service or to a hospital thereof for care and treatment and who the Surgeon General determines is a proper subject for care and treatment. No such addict shall be admitted unless (1) committed prior to July 1, 1958; and (2) at the time of commitment, the number of persons in hospitals of the Service who have been admitted pursuant to this subsection is less than 100; and (3) suitable accommodations are available

[58] 67 Stat. 77. Codified to section 24–601 et seq., D.C. Code.

after all eligible addicts convicted of offenses against the United States have been admitted.

(b) Any person admitted to a hospital of the Service pursuant to subsection (a) shall be discharged therefrom (1) upon order of the Superior Court of the District of Columbia, or (2) when he is found by the Surgeon General to be cured and rehabilitated. When any such person is so discharged, the Surgeon General shall give notice thereof to the Superior Court of the District of Columbia and shall deliver such person to such court for such further action as such court may deem necessary and proper under the provisions of the Act of June 24, 1953 (Public Law 76, Eighty-third Congress).

(c) With respect to the detention, transfer, parole, or discharge of any person committed to a hospital of the Service in accordance with subsection (a), the Surgeon General and the officer in charge of the hospital, in addition to authority otherwise vested in them, shall have such authority as may be conferred upon them, respectively, by the order of the committing court.

(d) The cost of providing care and treatment for persons admitted to a hospital of the Service pursuant to subsection (a) shall be a charge upon the District of Columbia and shall be paid by the District of Columbia to the Public Health Service, either in advance or otherwise, as may be determined by the Surgeon General. Such cost may be determined for each addict or on the basis of rates established for all or particular classes of patients, and shall include the cost of transportation to and from facilities of the Public Health Service. Moneys so paid to the Public Health Service shall be covered into the Treasury of the United States as miscellaneous receipts. Appropriations available for the care and treatment of addicts admitted to a hospital of the Service under this section shall be available, subject to regulations, for paying the cost of transportation to the District of Columbia, including subsistence allowance while traveling, for any such addict who is discharged.

PENALTIES.

SEC. 346.[261] (a) Any person not authorized by law or by the Surgeon General who introduces or attempts to introduce into or upon the grounds of any hospital of the Service at which addicts or other persons with drug abuse and drug dependence problems are treated and cared for, any habit-forming narcotic drug, or substance controlled under the Controlled Substances Act, weapon, or any other contraband article or thing, or any contraband letter or message intended to be received by an inmate thereof, shall be guilty of a felony and, upon conviction thereof, shall be punished by imprisonment for not more than ten years.

(b) It shall be unlawful for any person properly committed thereto to escape or attempt to escape from a hospital of the Service at which addicts or other persons with drug abuse and drug dependence problems are treated and cared for, and any such person upon apprehension and conviction in a United States court shall be punished by imprisonment for not more than five years, such sentence to begin upon the expiration of the sentence for which such person was originally confined.

(c) Any person who procures the escape of any person admitted to a hospital of the Service at which addicts or other persons with drug abuse and drug dependence problems are treated and cared for, or who advises, connives at, aids, or assists in such escape, or who conceals any such inmate after such escape, shall be punished upon conviction in a United States court by imprisonment in the penitentiary for not more than three years.

RELEASE OF PATIENTS.

SEC. 347.[261a] For purposes of this Act, an individual shall be deemed cured of his addiction, drug abuse, or drug dependence, and rehabilitated if the Surgeon General determines that he has received the maximum benefits of treatment and care by the Service for his addiction, drug abuse, or drug dependence, or if the Surgeon General determines that his further treatment and care for such purpose would be detrimental to the interests of the Service.

PART F—LICENSING—BIOLOGICAL PRODUCTS AND CLINICAL LABORATORIES [59]

Subpart 1—Biological Products

REGULATION OF BIOLOGICAL PRODUCTS [60].

SEC. 351.[262] (a)(1) No person shall introduce or deliver for introduction into interstate commerce any biological product unless—

(A) a biologics license under this subsection or subsection (k) is in effect for the biological product; and

(B) each package of the biological product is plainly marked with—

(i) the proper name of the biological product contained in the package;

(ii) the name, address, and applicable license number of the manufacturer of the biological product; and

(iii) the expiration date of the biological product.

(2)(A) The Secretary shall establish, by regulation, requirements for the approval, suspension, and revocation of biologics licenses.

(B) PEDIATRIC STUDIES.—A person that submits an application for a license under this paragraph shall submit to the Secretary as part of the application any assessments required under section 505B of the Federal Food, Drug, and Cosmetic Act.

(C) The Secretary shall approve a biologics license application—

[59] Section 511(d) of Public Law 104–132 (110 Stat. 1284) relates to the regulatory control of biological agents and includes a requirement that the Secretary "establish and maintain a list of each biological agent that has the potential to pose a severe threat to public health and safety".

[60] Section 123(f) of Public Law 105–115 (111 Stat. 2324) provides as follows:

"(f) SPECIAL RULE.—The Secretary of Health and Human Services shall take measures to minimize differences in the review and approval of products required to have approved biologics license applications under section 351 of the Public Health Service Act (42 U.S.C. 262) and products required to have approved new drug applications under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(1)).".

(i) on the basis of a demonstration that—

(I) the biological product that is the subject of the application is safe, pure, and potent; and

(II) the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent; and

(ii) if the applicant (or other appropriate person) consents to the inspection of the facility that is the subject of the application, in accordance with subsection (c).

(D) POSTMARKET STUDIES AND CLINICAL TRIALS; LABELING; RISK EVALUATION AND MITIGATION STRATEGY.—A person that submits an application for a license under this paragraph is subject to sections 505(o), 505(p), and 505–1 of the Federal Food, Drug, and Cosmetic Act.

(3) The Secretary shall prescribe requirements under which a biological product undergoing investigation shall be exempt from the requirements of paragraph (1).

(b) No person shall falsely label or mark any package or container of any biological product or alter any label or mark on the package or container of the biological product so as to falsify the label or mark.

(c) Any officer, agent, or employee of the Department of Health and Human Services, authorized by the Secretary for the purpose, may during all reasonable hours enter and inspect any establishment for the propagation or manufacture and preparation of any biological product.

(d)(1) Upon a determination that a batch, lot, or other quantity of a product licensed under this section presents an imminent or substantial hazard to the public health, the Secretary shall issue an order immediately ordering the recall of such batch, lot, or other quantity of such product. An order under this paragraph shall be issued in accordance with section 554 of title 5, United States Code.

(2) Any violation of paragraph (1) shall subject the violator to a civil penalty of up to $100,000 per day of violation. The amount of a civil penalty under this paragraph shall, effective December 1 of each year beginning 1 year after the effective date of this paragraph, be increased by the percent change in the Consumer Price Index for the base quarter of such year over the Consumer Price Index for the base quarter of the preceding year, adjusted to the nearest 1/10 of 1 percent. For purposes of this paragraph, the term "base quarter", as used with respect to a year, means the calendar quarter ending on September 30 of such year and the price index for a base quarter is the arithmetical mean of such index for the 3 months comprising such quarter.

(e) No person shall interfere with any officer, agent, or employee of the Service in the performance of any duty imposed upon him by this section or by regulations made by authority thereof.

(f) Any person who shall violate, or aid or abet in violating, any of the provisions of this section shall be punished upon conviction by a fine not exceeding $500 or by imprisonment not exceeding one year, or by both such fine and imprisonment, in the discretion of the court.

(g) Nothing contained in this Act shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of the Federal Food, Drug, and Cosmetic Act (U.S.C., 1940 edition, title 21, ch. 9).[61]

(h)[62] A partially processed biological product which—

(1) is not in a form applicable to the prevention, treatment, or cure of diseases or injuries of man;

(2) is not intended for sale in the United States; and

(3) is intended for further manufacture into final dosage form outside the United States,

shall be subject to no restriction on the export of the product under this Act or the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et. seq.) if the product is manufactured, processed, packaged, and held in conformity with current good manufacturing practice requirements or meets international manufacturing standards as certified by an international standards organization recognized by the Secretary and meets the requirements of section 801(e)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(e)).

(i) In this section:

(1) The term "biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.

(2) The term "biosimilar" or "biosimilarity", in reference to a biological product that is the subject of an application under subsection (k), means—

(A) that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components; and

(B) there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.

(3) The term "interchangeable" or "interchangeability", in reference to a biological product that is shown to meet the standards described in subsection (k)(4), means that the biological product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

(4) The term "reference product" means the single biological product licensed under subsection (a) against which a biological product is evaluated in an application submitted under subsection (k).

(j) The Federal Food, Drug, and Cosmetic Act, including the requirements under sections 505(o), 505(p), and 505–1 of such Act, applies to a biological product subject to regulation under this section, except that a product for which a license has been approved

[61] Codification remains chapter 9 of title 21, United States Code (§301 et seq.).

[62] Section 2102(d)(2) of title II of Public Law 104–134 (110 Stat. 1321-319) amended certain provisions in subsection (h). Subsequently, section 2104 of such Public Law (110 Stat. 1321-320) amended subsection (h) in its entirety. The above reflects only the latter amendment.

under subsection (a) shall not be required to have an approved application under section 505 of such Act.

(k) LICENSURE OF BIOLOGICAL PRODUCTS AS BIOSIMILAR OR INTERCHANGEABLE.—

(1) IN GENERAL.—Any person may submit an application for licensure of a biological product under this subsection.

(2) CONTENT.—

(A) IN GENERAL.—

(i) REQUIRED INFORMATION.—An application submitted under this subsection shall include information demonstrating that—

(I) the biological product is biosimilar to a reference product based upon data derived from—

(aa) analytical studies that demonstrate that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components;

(bb) animal studies (including the assessment of toxicity); and

(cc) a clinical study or studies (including the assessment of immunogenicity and pharmacokinetics or pharmacodynamics) that are sufficient to demonstrate safety, purity, and potency in 1 or more appropriate conditions of use for which the reference product is licensed and intended to be used and for which licensure is sought for the biological product;

(II) the biological product and reference product utilize the same mechanism or mechanisms of action for the condition or conditions of use prescribed, recommended, or suggested in the proposed labeling, but only to the extent the mechanism or mechanisms of action are known for the reference product;

(III) the condition or conditions of use prescribed, recommended, or suggested in the labeling proposed for the biological product have been previously approved for the reference product;

(IV) the route of administration, the dosage form, and the strength of the biological product are the same as those of the reference product; and

(V) the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent.

(ii) DETERMINATION BY SECRETARY.—The Secretary may determine, in the Secretary's discretion, that an element described in clause (i)(I) is unnecessary in an application submitted under this subsection.

(iii) ADDITIONAL INFORMATION.—An application submitted under this subsection—

(I) shall include publicly-available information regarding the Secretary's previous determination that the reference product is safe, pure, and potent; and

(II) may include any additional information in support of the application, including publicly-available information with respect to the reference product or another biological product.

(B) INTERCHANGEABILITY.—An application (or a supplement to an application) submitted under this subsection may include information demonstrating that the biological product meets the standards described in paragraph (4).

(3) EVALUATION BY SECRETARY.—Upon review of an application (or a supplement to an application) submitted under this subsection, the Secretary shall license the biological product under this subsection if—

(A) the Secretary determines that the information submitted in the application (or the supplement) is sufficient to show that the biological product—

(i) is biosimilar to the reference product; or

(ii) meets the standards described in paragraph (4), and therefore is interchangeable with the reference product; and

(B) the applicant (or other appropriate person) consents to the inspection of the facility that is the subject of the application, in accordance with subsection (c).

(4) SAFETY STANDARDS FOR DETERMINING INTERCHANGEABILITY.—Upon review of an application submitted under this subsection or any supplement to such application, the Secretary shall determine the biological product to be interchangeable with the reference product if the Secretary determines that the information submitted in the application (or a supplement to such application) is sufficient to show that—

(A) the biological product—

(i) is biosimilar to the reference product; and

(ii) can be expected to produce the same clinical result as the reference product in any given patient; and

(B) for a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch.

(5) GENERAL RULES.—

(A) ONE REFERENCE PRODUCT PER APPLICATION.—A biological product, in an application submitted under this subsection, may not be evaluated against more than 1 reference product.

(B) REVIEW.—An application submitted under this subsection shall be reviewed by the division within the Food and Drug Administration that is responsible for the review and approval of the application under which the reference product is licensed.

(C) RISK EVALUATION AND MITIGATION STRATEGIES.—The authority of the Secretary with respect to risk evaluation and mitigation strategies under the Federal Food, Drug, and Cosmetic Act shall apply to biological products licensed under this subsection in the same manner as such authority applies to biological products licensed under subsection (a).

(6) EXCLUSIVITY FOR FIRST INTERCHANGEABLE BIOLOGICAL PRODUCT.—Upon review of an application submitted under this subsection relying on the same reference product for which a prior biological product has received a determination of interchangeability for any condition of use, the Secretary shall not make a determination under paragraph (4) that the second or subsequent biological product is interchangeable for any condition of use until the earlier of—

(A) 1 year after the first commercial marketing of the first interchangeable biosimilar biological product to be approved as interchangeable for that reference product;

(B) 18 months after—

(i) a final court decision on all patents in suit in an action instituted under subsection (l)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or

(ii) the dismissal with or without prejudice of an action instituted under subsection (l)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or

(C)(i) 42 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has been sued under subsection (l)(6) and such litigation is still ongoing within such 42-month period; or

(ii) 18 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has not been sued under subsection (l)(6).

For purposes of this paragraph, the term "final court decision" means a final decision of a court from which no appeal (other than a petition to the United States Supreme Court for a writ of certiorari) has been or can be taken.

(7) EXCLUSIVITY FOR REFERENCE PRODUCT.—

(A) EFFECTIVE DATE OF BIOSIMILAR APPLICATION APPROVAL.—Approval of an application under this subsection may not be made effective by the Secretary until the date that is 12 years after the date on which the reference product was first licensed under subsection (a).

(B) FILING PERIOD.—An application under this subsection may not be submitted to the Secretary until the date that is 4 years after the date on which the reference product was first licensed under subsection (a).

(C) FIRST LICENSURE.—Subparagraphs (A) and (B) shall not apply to a license for or approval of—

(i) a supplement for the biological product that is the reference product; or

(ii) a subsequent application filed by the same sponsor or manufacturer of the biological product that is the reference product (or a licensor, predecessor in interest, or other related entity) for—

(I) a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength; or

(II) a modification to the structure of the biological product that does not result in a change in safety, purity, or potency.

(8) GUIDANCE DOCUMENTS.—

(A) IN GENERAL.—The Secretary may, after opportunity for public comment, issue guidance in accordance, except as provided in subparagraph (B)(i), with section 701(h) of the Federal Food, Drug, and Cosmetic Act with respect to the licensure of a biological product under this subsection. Any such guidance may be general or specific.

(B) PUBLIC COMMENT.—

(i) IN GENERAL.—The Secretary shall provide the public an opportunity to comment on any proposed guidance issued under subparagraph (A) before issuing final guidance.

(ii) INPUT REGARDING MOST VALUABLE GUIDANCE.—The Secretary shall establish a process through which the public may provide the Secretary with input regarding priorities for issuing guidance.

(C) NO REQUIREMENT FOR APPLICATION CONSIDERATION.—The issuance (or non-issuance) of guidance under subparagraph (A) shall not preclude the review of, or action on, an application submitted under this subsection.

(D) REQUIREMENT FOR PRODUCT CLASS-SPECIFIC GUIDANCE.—If the Secretary issues product class-specific guidance under subparagraph (A), such guidance shall include a description of—

(i) the criteria that the Secretary will use to determine whether a biological product is highly similar to a reference product in such product class; and

(ii) the criteria, if available, that the Secretary will use to determine whether a biological product meets the standards described in paragraph (4).

(E) CERTAIN PRODUCT CLASSES.—

(i) GUIDANCE.—The Secretary may indicate in a guidance document that the science and experience, as of the date of such guidance, with respect to a product or product class (not including any recombinant protein) does not allow approval of an application for a license as provided under this subsection for such product or product class.

(ii) MODIFICATION OR REVERSAL.—The Secretary may issue a subsequent guidance document under

subparagraph (A) to modify or reverse a guidance document under clause (i).

(iii) NO EFFECT ON ABILITY TO DENY LICENSE.—Clause (i) shall not be construed to require the Secretary to approve a product with respect to which the Secretary has not indicated in a guidance document that the science and experience, as described in clause (i), does not allow approval of such an application.

(l) PATENTS.—

(1) CONFIDENTIAL ACCESS TO SUBSECTION (k) APPLICATION.—

(A) APPLICATION OF PARAGRAPH.—Unless otherwise agreed to by a person that submits an application under subsection (k) (referred to in this subsection as the "subsection (k) applicant") and the sponsor of the application for the reference product (referred to in this subsection as the "reference product sponsor"), the provisions of this paragraph shall apply to the exchange of information described in this subsection.

(B) IN GENERAL.—

(i) PROVISION OF CONFIDENTIAL INFORMATION.—When a subsection (k) applicant submits an application under subsection (k), such applicant shall provide to the persons described in clause (ii), subject to the terms of this paragraph, confidential access to the information required to be produced pursuant to paragraph (2) and any other information that the subsection (k) applicant determines, in its sole discretion, to be appropriate (referred to in this subsection as the "confidential information").

(ii) RECIPIENTS OF INFORMATION.—The persons described in this clause are the following:

(I) OUTSIDE COUNSEL.—One or more attorneys designated by the reference product sponsor who are employees of an entity other than the reference product sponsor (referred to in this paragraph as the "outside counsel"), provided that such attorneys do not engage, formally or informally, in patent prosecution relevant or related to the reference product.

(II) IN-HOUSE COUNSEL.—One attorney that represents the reference product sponsor who is an employee of the reference product sponsor, provided that such attorney does not engage, formally or informally, in patent prosecution relevant or related to the reference product.

(iii) PATENT OWNER ACCESS.—A representative of the owner of a patent exclusively licensed to a reference product sponsor with respect to the reference product and who has retained a right to assert the patent or participate in litigation concerning the patent may be provided the confidential information, provided that the representative informs the reference product sponsor and the subsection (k) applicant of his

or her agreement to be subject to the confidentiality provisions set forth in this paragraph, including those under clause (ii).

(C) LIMITATION ON DISCLOSURE.—No person that receives confidential information pursuant to subparagraph (B) shall disclose any confidential information to any other person or entity, including the reference product sponsor employees, outside scientific consultants, or other outside counsel retained by the reference product sponsor, without the prior written consent of the subsection (k) applicant, which shall not be unreasonably withheld.

(D) USE OF CONFIDENTIAL INFORMATION.—Confidential information shall be used for the sole and exclusive purpose of determining, with respect to each patent assigned to or exclusively licensed by the reference product sponsor, whether a claim of patent infringement could reasonably be asserted if the subsection (k) applicant engaged in the manufacture, use, offering for sale, sale, or importation into the United States of the biological product that is the subject of the application under subsection (k).

(E) OWNERSHIP OF CONFIDENTIAL INFORMATION.—The confidential information disclosed under this paragraph is, and shall remain, the property of the subsection (k) applicant. By providing the confidential information pursuant to this paragraph, the subsection (k) applicant does not provide the reference product sponsor or the outside counsel any interest in or license to use the confidential information, for purposes other than those specified in subparagraph (D).

(F) EFFECT OF INFRINGEMENT ACTION.—In the event that the reference product sponsor files a patent infringement suit, the use of confidential information shall continue to be governed by the terms of this paragraph until such time as a court enters a protective order regarding the information. Upon entry of such order, the subsection (k) applicant may redesignate confidential information in accordance with the terms of that order. No confidential information shall be included in any publicly-available complaint or other pleading. In the event that the reference product sponsor does not file an infringement action by the date specified in paragraph (6), the reference product sponsor shall return or destroy all confidential information received under this paragraph, provided that if the reference product sponsor opts to destroy such information, it will confirm destruction in writing to the subsection (k) applicant.

(G) RULE OF CONSTRUCTION.—Nothing in this paragraph shall be construed—

(i) as an admission by the subsection (k) applicant regarding the validity, enforceability, or infringement of any patent; or

(ii) as an agreement or admission by the subsection (k) applicant with respect to the competency,

relevance, or materiality of any confidential information.

(H) EFFECT OF VIOLATION.—The disclosure of any confidential information in violation of this paragraph shall be deemed to cause the subsection (k) applicant to suffer irreparable harm for which there is no adequate legal remedy and the court shall consider immediate injunctive relief to be an appropriate and necessary remedy for any violation or threatened violation of this paragraph.

(2) SUBSECTION (k) APPLICATION INFORMATION.—Not later than 20 days after the Secretary notifies the subsection (k) applicant that the application has been accepted for review, the subsection (k) applicant—

(A) shall provide to the reference product sponsor a copy of the application submitted to the Secretary under subsection (k), and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application; and

(B) may provide to the reference product sponsor additional information requested by or on behalf of the reference product sponsor.

(3) LIST AND DESCRIPTION OF PATENTS.—

(A) LIST BY REFERENCE PRODUCT SPONSOR.—Not later than 60 days after the receipt of the application and information under paragraph (2), the reference product sponsor shall provide to the subsection (k) applicant—

(i) a list of patents for which the reference product sponsor believes a claim of patent infringement could reasonably be asserted by the reference product sponsor, or by a patent owner that has granted an exclusive license to the reference product sponsor with respect to the reference product, if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application; and

(ii) an identification of the patents on such list that the reference product sponsor would be prepared to license to the subsection (k) applicant.

(B) LIST AND DESCRIPTION BY SUBSECTION (k) APPLICANT.—Not later than 60 days after receipt of the list under subparagraph (A), the subsection (k) applicant—

(i) may provide to the reference product sponsor a list of patents to which the subsection (k) applicant believes a claim of patent infringement could reasonably be asserted by the reference product sponsor if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application;

(ii) shall provide to the reference product sponsor, with respect to each patent listed by the reference product sponsor under subparagraph (A) or listed by the subsection (k) applicant under clause (i)—

(I) a detailed statement that describes, on a claim by claim basis, the factual and legal basis of the opinion of the subsection (k) applicant that such patent is invalid, unenforceable, or will not be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application; or

(II) a statement that the subsection (k) applicant does not intend to begin commercial marketing of the biological product before the date that such patent expires; and

(iii) shall provide to the reference product sponsor a response regarding each patent identified by the reference product sponsor under subparagraph (A)(ii).

(C) DESCRIPTION BY REFERENCE PRODUCT SPONSOR.—Not later than 60 days after receipt of the list and statement under subparagraph (B), the reference product sponsor shall provide to the subsection (k) applicant a detailed statement that describes, with respect to each patent described in subparagraph (B)(ii)(I), on a claim by claim basis, the factual and legal basis of the opinion of the reference product sponsor that such patent will be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application and a response to the statement concerning validity and enforceability provided under subparagraph (B)(ii)(I).

(4) PATENT RESOLUTION NEGOTIATIONS.—

(A) IN GENERAL.—After receipt by the subsection (k) applicant of the statement under paragraph (3)(C), the reference product sponsor and the subsection (k) applicant shall engage in good faith negotiations to agree on which, if any, patents listed under paragraph (3) by the subsection (k) applicant or the reference product sponsor shall be the subject of an action for patent infringement under paragraph (6).

(B) FAILURE TO REACH AGREEMENT.—If, within 15 days of beginning negotiations under subparagraph (A), the subsection (k) applicant and the reference product sponsor fail to agree on a final and complete list of which, if any, patents listed under paragraph (3) by the subsection (k) applicant or the reference product sponsor shall be the subject of an action for patent infringement under paragraph (6), the provisions of paragraph (5) shall apply to the parties.

(5) PATENT RESOLUTION IF NO AGREEMENT.—

(A) NUMBER OF PATENTS.—The subsection (k) applicant shall notify the reference product sponsor of the number of patents that such applicant will provide to the reference product sponsor under subparagraph (B)(i)(I).

(B) EXCHANGE OF PATENT LISTS.—

(i) IN GENERAL.—On a date agreed to by the subsection (k) applicant and the reference product sponsor, but in no case later than 5 days after the subsection (k) applicant notifies the reference product sponsor under subparagraph (A), the subsection (k)

applicant and the reference product sponsor shall simultaneously exchange—

(I) the list of patents that the subsection (k) applicant believes should be the subject of an action for patent infringement under paragraph (6); and

(II) the list of patents, in accordance with clause (ii), that the reference product sponsor believes should be the subject of an action for patent infringement under paragraph (6).

(ii) NUMBER OF PATENTS LISTED BY REFERENCE PRODUCT SPONSOR.—

(I) IN GENERAL.—Subject to subclause (II), the number of patents listed by the reference product sponsor under clause (i)(II) may not exceed the number of patents listed by the subsection (k) applicant under clause (i)(I).

(II) EXCEPTION.—If a subsection (k) applicant does not list any patent under clause (i)(I), the reference product sponsor may list 1 patent under clause (i)(II).

(6) IMMEDIATE PATENT INFRINGEMENT ACTION.—

(A) ACTION IF AGREEMENT ON PATENT LIST.—If the subsection (k) applicant and the reference product sponsor agree on patents as described in paragraph (4), not later than 30 days after such agreement, the reference product sponsor shall bring an action for patent infringement with respect to each such patent.

(B) ACTION IF NO AGREEMENT ON PATENT LIST.—If the provisions of paragraph (5) apply to the parties as described in paragraph (4)(B), not later than 30 days after the exchange of lists under paragraph (5)(B), the reference product sponsor shall bring an action for patent infringement with respect to each patent that is included on such lists.

(C) NOTIFICATION AND PUBLICATION OF COMPLAINT.—

(i) NOTIFICATION TO SECRETARY.—Not later than 30 days after a complaint is served to a subsection (k) applicant in an action for patent infringement described under this paragraph, the subsection (k) applicant shall provide the Secretary with notice and a copy of such complaint.

(ii) PUBLICATION BY SECRETARY.—The Secretary shall publish in the Federal Register notice of a complaint received under clause (i).

(7) NEWLY ISSUED OR LICENSED PATENTS.—In the case of a patent that—

(A) is issued to, or exclusively licensed by, the reference product sponsor after the date that the reference product sponsor provided the list to the subsection (k) applicant under paragraph (3)(A); and

(B) the reference product sponsor reasonably believes that, due to the issuance of such patent, a claim of patent infringement could reasonably be asserted by the reference

product sponsor if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application,

not later than 30 days after such issuance or licensing, the reference product sponsor shall provide to the subsection (k) applicant a supplement to the list provided by the reference product sponsor under paragraph (3)(A) that includes such patent, not later than 30 days after such supplement is provided, the subsection (k) applicant shall provide a statement to the reference product sponsor in accordance with paragraph (3)(B), and such patent shall be subject to paragraph (8).

(8) NOTICE OF COMMERCIAL MARKETING AND PRELIMINARY INJUNCTION.—

(A) NOTICE OF COMMERCIAL MARKETING.—The subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k).

(B) PRELIMINARY INJUNCTION.—After receiving the notice under subparagraph (A) and before such date of the first commercial marketing of such biological product, the reference product sponsor may seek a preliminary injunction prohibiting the subsection (k) applicant from engaging in the commercial manufacture or sale of such biological product until the court decides the issue of patent validity, enforcement, and infringement with respect to any patent that is—

(i) included in the list provided by the reference product sponsor under paragraph (3)(A) or in the list provided by the subsection (k) applicant under paragraph (3)(B); and

(ii) not included, as applicable, on—

(I) the list of patents described in paragraph (4); or

(II) the lists of patents described in paragraph (5)(B).

(C) REASONABLE COOPERATION.—If the reference product sponsor has sought a preliminary injunction under subparagraph (B), the reference product sponsor and the subsection (k) applicant shall reasonably cooperate to expedite such further discovery as is needed in connection with the preliminary injunction motion.

(9) LIMITATION ON DECLARATORY JUDGMENT ACTION.—

(A) SUBSECTION (k) APPLICATION PROVIDED.—If a subsection (k) applicant provides the application and information required under paragraph (2)(A), neither the reference product sponsor nor the subsection (k) applicant may, prior to the date notice is received under paragraph (8)(A), bring any action under section 2201 of title 28, United States Code, for a declaration of infringement, validity, or enforceability of any patent that is described in clauses (i) and (ii) of paragraph (8)(B).

(B) SUBSEQUENT FAILURE TO ACT BY SUBSECTION (k) APPLICANT.—If a subsection (k) applicant fails to complete an action required of the subsection (k) applicant under paragraph (3)(B)(ii), paragraph (5), paragraph (6)(C)(i), paragraph (7), or paragraph (8)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28, United States Code, for a declaration of infringement, validity, or enforceability of any patent included in the list described in paragraph (3)(A), including as provided under paragraph (7).

(C) SUBSECTION (k) APPLICATION NOT PROVIDED.—If a subsection (k) applicant fails to provide the application and information required under paragraph (2)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28, United States Code, for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product.

(m) PEDIATRIC STUDIES.—

(1) APPLICATION OF CERTAIN PROVISIONS.—The provisions of subsections (a), (d), (e), (f), (h), (i), (j), (k), (l), (n), and (p) of section 505A of the Federal Food, Drug, and Cosmetic Act shall apply with respect to the extension of a period under paragraphs (2) and (3) to the same extent and in the same manner as such provisions apply with respect to the extension of a period under subsection (b) or (c) of section 505A of the Federal Food, Drug, and Cosmetic Act.

(2) MARKET EXCLUSIVITY FOR NEW BIOLOGICAL PRODUCTS.—If, prior to approval of an application that is submitted under subsection (a), the Secretary determines that information relating to the use of a new biological product in the pediatric population may produce health benefits in that population, the Secretary makes a written request for pediatric studies (which shall include a timeframe for completing such studies), the applicant agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe, and the reports thereof are submitted and accepted in accordance with section 505A(d)(3) of the Federal Food, Drug, and Cosmetic Act—

(A) the periods for such biological product referred to in subsection (k)(7) are deemed to be 4 years and 6 months rather than 4 years and 12 years and 6 months rather than 12 years; and

(B) if the biological product is designated under section 526 for a rare disease or condition, the period for such biological product referred to in section 527(a) is deemed to be 7 years and 6 months rather than 7 years.

(3) MARKET EXCLUSIVITY FOR ALREADY-MARKETED BIOLOGICAL PRODUCTS.—If the Secretary determines that information relating to the use of a licensed biological product in the pediatric population may produce health benefits in that population and makes a written request to the holder of an approved application under subsection (a) for pediatric studies (which shall include a timeframe for completing such studies),

the holder agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe, and the reports thereof are submitted and accepted in accordance with section 505A(d)(3) of the Federal Food, Drug, and Cosmetic Act—

(A) the periods for such biological product referred to in subsection (k)(7) are deemed to be 4 years and 6 months rather than 4 years and 12 years and 6 months rather than 12 years; and

(B) if the biological product is designated under section 526 for a rare disease or condition, the period for such biological product referred to in section 527(a) is deemed to be 7 years and 6 months rather than 7 years.

(4) EXCEPTION.—The Secretary shall not extend a period referred to in paragraph (2)(A), (2)(B), (3)(A), or (3)(B) if the determination under section 505A(d)(3) is made later than 9 months prior to the expiration of such period.

SEC. 351A.[262a] ENHANCED CONTROL OF DANGEROUS BIOLOGICAL AGENTS AND TOXINS.[63].

(a) REGULATORY CONTROL OF CERTAIN BIOLOGICAL AGENTS AND TOXINS.—

(1) LIST OF BIOLOGICAL AGENTS AND TOXINS.—

(A) IN GENERAL.—The Secretary shall by regulation establish and maintain a list of each biological agent and each toxin that has the potential to pose a severe threat to public health and safety.

(B) CRITERIA.—In determining whether to include an agent or toxin on the list under subparagraph (A), the Secretary shall—

(i) consider—

(I) the effect on human health of exposure to the agent or toxin;

(II) the degree of contagiousness of the agent or toxin and the methods by which the agent or toxin is transferred to humans;

(III) the availability and effectiveness of pharmacotherapies and immunizations to treat and prevent any illness resulting from infection by the agent or toxin; and

(IV) any other criteria, including the needs of children and other vulnerable populations, that the Secretary considers appropriate; and

(ii) consult with appropriate Federal departments and agencies and with scientific experts representing appropriate professional groups, including groups with pediatric expertise.

[63] A program is carried out by the Secretary of Agriculture with respect to each biological agent and each toxin that the Secretary determines has the potential to pose a severe threat to animal or plant health, or to animal or plant products. Such program has requirements and authorities similar to those established in section 351A above. See subtitle B of title II of Public Law 107–188 (section 211 et seq.; 116 Stat. 647). Subtitle C of such title (section 221 et seq.; 116 Stat. 657) relates to interagency coordination of the two programs.

(2) BIENNIAL REVIEW.—The Secretary shall review and republish the list under paragraph (1) biennially, or more often as needed, and shall by regulation revise the list as necessary in accordance with such paragraph.

(b) REGULATION OF TRANSFERS OF LISTED AGENTS AND TOXINS.—The Secretary shall by regulation provide for—

(1) the establishment and enforcement of safety procedures for the transfer of listed agents and toxins, including measures to ensure—

(A) proper training and appropriate skills to handle such agents and toxins; and

(B) proper laboratory facilities to contain and dispose of such agents and toxins;

(2) the establishment and enforcement of safeguard and security measures to prevent access to such agents and toxins for use in domestic or international terrorism or for any other criminal purpose;

(3) the establishment of procedures to protect the public safety in the event of a transfer or potential transfer of such an agent or toxin in violation of the safety procedures established under paragraph (1) or the safeguard and security measures established under paragraph (2); and

(4) appropriate availability of biological agents and toxins for research, education, and other legitimate purposes.

(c) POSSESSION AND USE OF LISTED AGENTS AND TOXINS.—The Secretary shall by regulation provide for the establishment and enforcement of standards and procedures governing the possession and use of listed agents and toxins, including the provisions described in paragraphs (1) through (4) of subsection (b), in order to protect the public health and safety.

(d) REGISTRATION; IDENTIFICATION; DATABASE.—

(1) REGISTRATION.—Regulations under subsections (b) and (c) shall require registration with the Secretary of the possession, use, and transfer of listed agents and toxins, and shall include provisions to ensure that persons seeking to register under such regulations have a lawful purpose to possess, use, or transfer such agents and toxins, including provisions in accordance with subsection (e)(6).

(2) IDENTIFICATION; DATABASE.—Regulations under subsections (b) and (c) shall require that registration include (if available to the person registering) information regarding the characterization of listed agents and toxins to facilitate their identification, including their source. The Secretary shall maintain a national database that includes the names and locations of registered persons, the listed agents and toxins such persons are possessing, using, or transferring, and information regarding the characterization of such agents and toxins.

(e) SAFEGUARD AND SECURITY REQUIREMENTS FOR REGISTERED PERSONS.—

(1) IN GENERAL.—Regulations under subsections (b) and (c) shall include appropriate safeguard and security requirements for persons possessing, using, or transferring a listed agent or toxin commensurate with the risk such agent or toxin poses to public health and safety (including the risk of use in domestic

or international terrorism). The Secretary shall establish such requirements in collaboration with the Secretary of Homeland Security and the Attorney General, and shall ensure compliance with such requirements as part of the registration system under such regulations.

(2) LIMITING ACCESS TO LISTED AGENTS AND TOXINS.—Requirements under paragraph (1) shall include provisions to ensure that registered persons—

(A) provide access to listed agents and toxins to only those individuals whom the registered person involved determines have a legitimate need to handle or use such agents and toxins;

(B) submit the names and other identifying information for such individuals to the Secretary and the Attorney General, promptly after first determining that the individuals need access under subparagraph (A), and periodically thereafter while the individuals have such access, not less frequently than once every five years;

(C) deny access to such agents and toxins by individuals whom the Attorney General has identified as restricted persons; and

(D) limit or deny access to such agents and toxins by individuals whom the Attorney General has identified as within any category under paragraph (3)(B)(ii), if limiting or denying such access by the individuals involved is determined appropriate by the Secretary, in consultation with the Attorney General.

(3) SUBMITTED NAMES; USE OF DATABASES BY ATTORNEY GENERAL.—

(A) IN GENERAL.—Upon the receipt of names and other identifying information under paragraph (2)(B), the Attorney General shall, for the sole purpose of identifying whether the individuals involved are within any of the categories specified in subparagraph (B), promptly use criminal, immigration, national security, and other electronic databases that are available to the Federal Government and are appropriate for such purpose.

(B) CERTAIN INDIVIDUALS.—For purposes of subparagraph (A), the categories specified in this subparagraph regarding an individual are that—

(i) the individual is a restricted person; or

(ii) the individual is reasonably suspected by any Federal law enforcement or intelligence agency of—

(I) committing a crime set forth in section 2332b(g)(5) of title 18, United States Code;

(II) knowing involvement with an organization that engages in domestic or international terrorism (as defined in section 2331 of such title 18) or with any other organization that engages in intentional crimes of violence; or

(III) being an agent of a foreign power (as defined in section 1801 of title 50, United States Code).

(C) NOTIFICATION BY ATTORNEY GENERAL REGARDING SUBMITTED NAMES.—After the receipt of a name and other identifying information under paragraph (2)(B), the Attorney General shall promptly notify the Secretary whether the individual is within any of the categories specified in subparagraph (B).

(4) NOTIFICATIONS BY SECRETARY.—The Secretary, after receiving notice under paragraph (3) regarding an individual, shall promptly notify the registered person involved of whether the individual is granted or denied access under paragraph (2). If the individual is denied such access, the Secretary shall promptly notify the individual of the denial.

(5) EXPEDITED REVIEW.—Regulations under subsections (b) and (c) shall provide for a procedure through which, upon request to the Secretary by a registered person who submits names and other identifying information under paragraph (2)(B) and who demonstrates good cause, the Secretary may, as determined appropriate by the Secretary—

(A) request the Attorney General to expedite the process of identification under paragraph (3)(A) and notification of the Secretary under paragraph (3)(C); and

(B) expedite the notification of the registered person by the Secretary under paragraph (4).

(6) PROCESS REGARDING PERSONS SEEKING TO REGISTER.—

(A) INDIVIDUALS.—Regulations under subsections (b) and (c) shall provide that an individual who seeks to register under either of such subsections is subject to the same processes described in paragraphs (2) through (4) as apply to names and other identifying information submitted to the Attorney General under paragraph (2)(B). Paragraph (5) does not apply for purposes of this subparagraph.

(B) OTHER PERSONS.—Regulations under subsections (b) and (c) shall provide that, in determining whether to deny or revoke registration by a person other than an individual, the Secretary shall submit the name of such person to the Attorney General, who shall use criminal, immigration, national security, and other electronic databases available to the Federal Government, as appropriate for the purpose of promptly notifying the Secretary whether the person, or, where relevant, the individual who owns or controls such person, is a restricted person or is reasonably suspected by any Federal law enforcement or intelligence agency of being within any category specified in paragraph (3)(B)(ii) (as applied to persons, including individuals). Such regulations shall provide that a person who seeks to register under either of such subsections is subject to the same processes described in paragraphs (2) and (4) as apply to names and other identifying information submitted to the Attorney General under paragraph (2)(B). Paragraph (5) does not apply for purposes of this subparagraph. The Secretary may exempt Federal, State, or local governmental agencies from the requirements of this subparagraph.

(7) REVIEW.—

(A) ADMINISTRATIVE REVIEW.—

(i) IN GENERAL.—Regulations under subsections (b) and (c) shall provide for an opportunity for a review by the Secretary—

(I) when requested by the individual involved, of a determination under paragraph (2) to deny the individual access to listed agents and toxins; and

(II) when requested by the person involved, of a determination under paragraph (6) to deny or revoke registration for such person.

(ii) EX PARTE REVIEW.—During a review under clause (i), the Secretary may consider information relevant to the review ex parte to the extent that disclosure of the information could compromise national security or an investigation by any law enforcement agency.

(iii) FINAL AGENCY ACTION.—The decision of the Secretary in a review under clause (i) constitutes final agency action for purposes of section 702 of title 5, United States Code.

(B) CERTAIN PROCEDURES.—

(i) SUBMISSION OF EX PARTE MATERIALS IN JUDICIAL PROCEEDINGS.—When reviewing a decision of the Secretary under subparagraph (A), and upon request made ex parte and in writing by the United States, a court, upon a sufficient showing, may review and consider ex parte documents containing information the disclosure of which could compromise national security or an investigation by any law enforcement agency. If the court determines that portions of the documents considered ex parte should be disclosed to the person involved to allow a response, the court shall authorize the United States to delete from such documents specified items of information the disclosure of which could compromise national security or an investigation by any law enforcement agency, or to substitute a summary of the information to which the person may respond. Any order by the court authorizing the disclosure of information that the United States believes could compromise national security or an investigation by any law enforcement agency shall be subject to the processes set forth in subparagraphs (A) and (B)(i) of section 2339B(f)(5) of title 18, United States Code (relating to interlocutory appeal and expedited consideration).

(ii) DISCLOSURE OF INFORMATION.—In a review under subparagraph (A), and in any judical proceeding conducted pursuant to such review, neither the Secretary nor the Attorney General may be required to disclose to the public any information that under subsection (h) shall not be disclosed under section 552 of title 5, United States Code.

(8) NOTIFICATIONS REGARDING THEFT OR LOSS OF AGENTS.—Requirements under paragraph (1) shall include the prompt notification of the Secretary, and appropriate Federal, State, and local law enforcement agencies, of the theft or loss of listed agents and toxins.

(9) TECHNICAL ASSISTANCE FOR REGISTERED PERSONS.—The Secretary, in consultation with the Attorney General, may provide technical assistance to registered persons to improve security of the facilities of such persons.

(f) INSPECTIONS.—The Secretary shall have the authority to inspect persons subject to regulations under subsection (b) or (c) to ensure their compliance with such regulations, including prohibitions on restricted persons and other provisions of subsection (e).

(g) EXEMPTIONS.—

(1) CLINICAL OR DIAGNOSTIC LABORATORIES.—Regulations under subsections (b) and (c) shall exempt clinical or diagnostic laboratories and other persons who possess, use, or transfer listed agents or toxins that are contained in specimens presented for diagnosis, verification, or proficiency testing, provided that—

(A) the identification of such agents or toxins is reported to the Secretary, and when required under Federal, State, or local law, to other appropriate authorities; and

(B) such agents or toxins are transferred or destroyed in a manner set forth by the Secretary by regulation.

(2) PRODUCTS.—

(A) IN GENERAL.—Regulations under subsections (b) and (c) shall exempt products that are, bear, or contain listed agents or toxins and are cleared, approved, licensed, or registered under any of the Acts specified in subparagraph (B), unless the Secretary by order determines that applying additional regulation under subsection (b) or (c) to a specific product is necessary to protect public health and safety.

(B) RELEVANT LAWS.—For purposes of subparagraph (A), the Acts specified in this subparagraph are the following:

(i) The Federal Food, Drug, and Cosmetic Act.

(ii) Section 351 of this Act.

(iii) The Act commonly known as the Virus-Serum-Toxin Act (the eighth paragraph under the heading "Bureau of Animal Industry" in the Act of March 4, 1913; 21 U.S.C. 151–159).

(iv) The Federal Insecticide, Fungicide, and Rodenticide Act.

(C) INVESTIGATIONAL USE.—

(i) IN GENERAL.—The Secretary may exempt an investigational product that is, bears, or contains a listed agent or toxin from the applicability of provisions of regulations under subsection (b) or (c) when such product is being used in an investigation authorized under any Federal Act and the Secretary determines that applying additional regulation under subsection

(b) or (c) to such product is not necessary to protect public health and safety.

(ii) CERTAIN PROCESSES.—Regulations under subsections (b) and (c) shall set forth the procedures for applying for an exemption under clause (i). In the case of investigational products authorized under any of the Acts specified in subparagraph (B), the Secretary shall make a determination regarding a request for an exemption not later than 14 days after the first date on which both of the following conditions have been met by the person requesting the exemption:

(I) The person has submitted to the Secretary an application for the exemption meeting the requirements established by the Secretary.

(II) The person has notified the Secretary that the investigation has been authorized under such an Act.

(3) PUBLIC HEALTH EMERGENCIES.—The Secretary may temporarily exempt a person from the applicability of the requirements of this section, in whole or in part, if the Secretary determines that such exemption is necessary to provide for the timely participation of the person in a response to a domestic or foreign public health emergency (whether determined under section 319(a) or otherwise) that involves a listed agent or toxin. With respect to the emergency involved, such exemption for a person may not exceed 30 days, except that the Secretary, after review of whether such exemption remains necessary, may provide one extension of an additional 30 days.

(4) AGRICULTURAL EMERGENCIES.—Upon request of the Secretary of Agriculture, after the granting by such Secretary of an exemption under section 212(g)(1)(D) of the Agricultural Bioterrorism Protection Act of 2002 pursuant to a finding that there is an agricultural emergency, the Secretary of Health and Human Services may temporarily exempt a person from the applicability of the requirements of this section, in whole or in part, to provide for the timely participation of the person in a response to the agricultural emergency. With respect to the emergency involved, the exemption under this paragraph for a person may not exceed 30 days, except that upon request of the Secretary of Agriculture, the Secretary of Health and Human Services may, after review of whether such exemption remains necessary, provide one extension of an additional 30 days.

(h) DISCLOSURE OF INFORMATION.—

(1) NONDISCLOSURE OF CERTAIN INFORMATION.—No Federal agency specified in paragraph (2) shall disclose under section 552 of title 5, United States Code, any of the following:

(A) Any registration or transfer documentation submitted under subsections (b) and (c) for the possession, use, or transfer of a listed agent or toxin; or information derived therefrom to the extent that it identifies the listed agent or toxin possessed, used, or transferred by a specific registered person or discloses the identity or location of a specific registered person.

(B) The national database developed pursuant to subsection (d), or any other compilation of the registration or transfer information submitted under subsections (b) and (c) to the extent that such compilation discloses site-specific registration or transfer information.

(C) Any portion of a record that discloses the site-specific or transfer-specific safeguard and security measures used by a registered person to prevent unauthorized access to listed agents and toxins.

(D) Any notification of a release of a listed agent or toxin submitted under subsections (b) and (c), or any notification of theft or loss submitted under such subsections.

(E) Any portion of an evaluation or report of an inspection of a specific registered person conducted under subsection (f) that identifies the listed agent or toxin possessed by a specific registered person or that discloses the identity or location of a specific registered person if the agency determines that public disclosure of the information would endanger public health or safety.

(2) COVERED AGENCIES.—For purposes of paragraph (1) only, the Federal agencies specified in this paragraph are the following:

(A) The Department of Health and Human Services, the Department of Justice, the Department of Agriculture, and the Department of Transportation.

(B) Any Federal agency to which information specified in paragraph (1) is transferred by any agency specified in subparagraph (A) of this paragraph.

(C) Any Federal agency that is a registered person, or has a sub-agency component that is a registered person.

(D) Any Federal agency that awards grants or enters into contracts or cooperative agreements involving listed agents and toxins to or with a registered person, and to which information specified in paragraph (1) is transferred by any such registered person.

(3) OTHER EXEMPTIONS.—This subsection may not be construed as altering the application of any exemptions to public disclosure under section 552 of title 5, United States Code, except as to subsection 552(b)(3) of such title, to any of the information specified in paragraph (1).

(4) RULE OF CONSTRUCTION.—Except as specifically provided in paragraph (1), this subsection may not be construed as altering the authority of any Federal agency to withhold under section 552 of title 5, United States Code, or the obligation of any Federal agency to disclose under section 552 of title 5, United States Code, any information, including information relating to—

(A) listed agents and toxins, or individuals seeking access to such agents and toxins;

(B) registered persons, or persons seeking to register their possession, use, or transfer of such agents and toxins;

(C) general safeguard and security policies and requirements under regulations under subsections (b) and (c); or

(D) summary or statistical information concerning registrations, registrants, denials or revocations of registrations, listed agents and toxins, inspection evaluations and reports, or individuals seeking access to such agents and toxins.

(5) DISCLOSURES TO CONGRESS; OTHER DISCLOSURES.—This subsection may not be construed as providing any authority—

(A) to withhold information from the Congress or any committee or subcommittee thereof; or

(B) to withhold information from any person under any other Federal law or treaty.

(i) CIVIL MONEY PENALTY.—[64]

(1) IN GENERAL.—In addition to any other penalties that may apply under law, any person who violates any provision of regulations under subsection (b) or (c) shall be subject to the United States for a civil money penalty in an amount not exceeding $250,000 in the case of an individual and $500,000 in the case of any other person.

(2) APPLICABILITY OF CERTAIN PROVISIONS.—The provisions of section 1128A of the Social Security Act (other than subsections (a), (b), (h), and (i), the first sentence of subsection (c), and paragraphs (1) and (2) of subsection (f)) shall apply to a civil money penalty under paragraph (1) in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a) of such Act. The Secretary may delegate authority under this subsection in the same manner as provided in section 1128A(j)(2) of the Social Security Act, and such authority shall include all powers as contained in section 6 of the Inspector General Act of 1978 (5 U.S.C. App.).

(j) NOTIFICATION IN EVENT OF RELEASE.—Regulations under subsections (b) and (c) shall require the prompt notification of the Secretary by a registered person whenever a release, meeting criteria established by the Secretary, of a listed agent or toxin has occurred outside of the biocontainment area of a facility of the registered person. Upon receipt of such notification and a finding by the Secretary that the release poses a threat to public health or safety, the Secretary shall take appropriate action to notify relevant State and local public health authorities, other relevant Federal authorities, and, if necessary, other appropriate persons (including the public). If the released listed agent or toxin is an overlap agent or toxin (as defined in subsection (l)), the Secretary shall promptly notify the Secretary of Agriculture upon notification by the registered person.

(k) REPORTS.—The Secretary shall report to the Congress annually on the number and nature of notifications received under subsection (e)(8) (relating to theft or loss) and subsection (j) (relating to releases).

(l) DEFINITIONS.—For purposes of this section:

[64] Section 175b of title 18, United States Code, establishes criminal penalties relating to biological agents or toxins that are listed as select agents in Appendix A of part 72 of title 42, Code of Federal Regulations, pursuant to section 351A above, and are not exempted under subsection (h) of section 72.6, or Appendix A of part 72, of title 42, Code of Federal Regulations.

(1) The terms "biological agent" and "toxin" have the meanings given such terms in section 178 of title 18, United States Code.

(2) The term "listed agents and toxins" means biological agents and toxins listed pursuant to subsection (a)(1).

(3) The term "listed agents or toxins" means biological agents or toxins listed pursuant to subsection (a)(1).

(4) The term "overlap agents and toxins" means biological agents and toxins that—

(A) are listed pursuant to subsection (a)(1); and

(B) are listed pursuant to section 212(a)(1) of the Agricultural Bioterrorism Protection Act of 2002.

(5) The term "overlap agent or toxin" means a biological agent or toxin that—

(A) is listed pursuant to subsection (a)(1); and

(B) is listed pursuant to section 212(a)(1) of the Agricultural Bioterrorism Protection Act of 2002.

(6) The term "person" includes Federal, State, and local governmental entities.

(7) The term "registered person" means a person registered under regulations under subsection (b) or (c).

(8) The term "restricted person" has the meaning given such term in section 175b of title 18, United States Code.

(m) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2002 through 2007.

PREPARATION OF BIOLOGICAL PRODUCTS.

SEC. 352.[263] (a) The Service may prepare for its own use any product described in section 351 and any product necessary to carrying out any of the purposes of section 301.

(b) The Service may prepare any product described in section 351 for the use of other Federal departments or agencies, and public or private agencies and individuals engaged in work in the field of medicine when such product is not available from establishments licensed under such section.

Subpart 2—Clinical Laboratories

CERTIFICATION OF LABORATORIES.

SEC. 353.[263a] (a) DEFINITION.—As used in this section, the term "laboratory" or "clinical laboratory" means a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.

(b) CERTIFICATE REQUIREMENT.—No person may solicit or accept materials derived from the human body for laboratory examination or other procedure unless there is in effect for the laboratory a certificate issued by the Secretary under this section applica-

ble to the category of examinations or procedures which includes such examination or procedure.

(c) ISSUANCE AND RENEWAL OF CERTIFICATES.—

(1) IN GENERAL.—The Secretary may issue or renew a certificate for a laboratory only if the laboratory meets the requirements of subsection (d).

(2) TERM.—A certificate issued under this section shall be valid for a period of 2 years or such shorter period as the Secretary may establish.

(d) REQUIREMENTS FOR CERTIFICATES.—

(1) IN GENERAL.—A laboratory may be issued a certificate or have its certificate renewed if—

(A) the laboratory submits (or if the laboratory is accredited under subsection (e), the accreditation body which accredited the laboratory submits), an application—

(i) in such form and manner as the Secretary shall prescribe,

(ii) that describes the characteristics of the laboratory examinations and other procedures performed by the laboratory including—

(I) the number and types of laboratory examinations and other procedures performed,

(II) the methodologies for laboratory examinations and other procedures employed, and

(III) the qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory examinations and other procedures, and

(iii) that contains such other information as the Secretary may require to determine compliance with this section, and

the laboratory agrees to provide to the Secretary (or if the laboratory is accredited, to the accreditation body which accredited it) a description of any change in the information submitted under clause (ii) not later than 6 months after the change was put into effect,

(B) the laboratory provides the Secretary—

(i) with satisfactory assurances that the laboratory will be operated in accordance with standards issued by the Secretary under subsection (f), or

(ii) with proof of accreditation under subsection (e),

(C) the laboratory agrees to permit inspections by the Secretary under subsection (g),

(D) the laboratory agrees to make records available and submit reports to the Secretary as the Secretary may reasonably require, and

(E) the laboratory agrees to treat proficiency testing samples in the same manner as it treats materials derived from the human body referred to it for laboratory examinations or other procedures in the ordinary course of business, except that no proficiency testing sample shall be re-

ferred to another laboratory for analysis as prohibited under subsection (i)(4).

(2) REQUIREMENTS FOR CERTIFICATES OF WAIVER.—

(A) IN GENERAL.—A laboratory which only performs laboratory examinations and procedures described in paragraph (3) shall be issued a certificate of waiver or have its certificate of waiver renewed if—

(i) the laboratory submits an application—

(I) in such form and manner as the Secretary shall prescribe,

(II) that describes the characteristics of the laboratory examinations and other procedures performed by the laboratory, including the number and types of laboratory examinations and other procedures performed, the methodologies for laboratory examinations and other procedures employed, and the qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory examinations and other procedures, and

(III) that contains such other information as the Secretary may reasonably require to determine compliance with this section, and

(ii) the laboratory agrees to make records available and submit reports to the Secretary as the Secretary may require.

(B) CHANGES.—If a laboratory makes changes in the examinations and other procedures performed by it only with respect to examinations and procedures which are described in paragraph (3), the laboratory shall report such changes to the Secretary not later than 6 months after the change has been put into effect. If a laboratory proposes to make changes in the examinations and procedures performed by it such that the laboratory will perform an examination or procedure not described in paragraph (3), the laboratory shall report such change to the Secretary before the change takes effect.

(C) EFFECT.—Subsections (f) and (g) shall not apply to a laboratory to which has been issued a certificate of waiver.

(3) EXAMINATIONS AND PROCEDURES.—The examinations and procedures identified in paragraph (2) are laboratory examinations and procedures that have been approved by the Food and Drug Administration for home use or that, as determined by the Secretary, are simple laboratory examinations and procedures that have an insignificant risk of an erroneous result, including those that—

(A) employ methodologies that are so simple and accurate as to render the likelihood of erroneous results by the user negligible, or

(B) the Secretary has determined pose no unreasonable risk of harm to the patient if performed incorrectly.

(4) DEFINITION.—As used in this section, the term "certificate" includes a certificate of waiver issued under paragraph (2).

(e) ACCREDITATION.—

(1) IN GENERAL.—A laboratory may be accredited for purposes of obtaining a certificate if the laboratory—

(A) meets the standards of an approved accreditation body, and

(B) authorizes the accreditation body to submit to the Secretary (or such State agency as the Secretary may designate) such records or other information as the Secretary may require.

(2) APPROVAL OF ACCREDITATION BODIES.—

(A) IN GENERAL.—The Secretary may approve a private nonprofit organization to be an accreditation body for the accreditation of laboratories if—

(i) using inspectors qualified to evaluate the methodologies used by the laboratories in performing laboratory examinations and other procedures, the accreditation body agrees to inspect a laboratory for purposes of accreditation with such frequency as determined by Secretary,[65]

(ii) the standards applied by the body in determining whether or not to accredit a laboratory are equal to or more stringent than the standards issued by the Secretary under subsection (f),

(iii) there is adequate provision for assuring that the standards of the accreditation body continue to be met by the laboratory,

(iv) in the case of any laboratory accredited by the body which has had its accreditation denied, suspended, withdrawn, or revoked or which has had any other action taken against it by the accrediting body, the accrediting body agrees to submit to the Secretary the name of such laboratory within 30 days of the action taken,

(v) the accreditation body agrees to notify the Secretary at least 30 days before it changes its standards, and

(vi) if the accreditation body has its approval withdrawn by the Secretary, the body agrees to notify each laboratory accredited by the body of the withdrawal within 10 days of the withdrawal.

(B) CRITERIA AND PROCEDURES.—The Secretary shall promulgate criteria and procedures for approving an accreditation body and for withdrawing such approval if the Secretary determines that the accreditation body does not meet the requirements of subparagraph (A).

(C) EFFECT OF WITHDRAWAL OF APPROVAL.—If the Secretary withdraws the approval of an accreditation body under subparagraph (B), the certificate of any laboratory accredited by the body shall continue in effect for 60 days

[65] So in law. Probably should be "the Secretary".

after the laboratory receives notification of the withdrawal of the approval, except that the Secretary may extend such period for a laboratory if it determines that the laboratory submitted an application for accreditation or a certificate in a timely manner after receipt of the notification of the withdrawal of approval. If an accreditation body withdraws or revokes the accreditation of a laboratory, the certificate of the laboratory shall continue in effect—

(i) for 45 days after the laboratory receives notice of the withdrawal or revocation of the accreditation, or

(ii) until the effective date of any action taken by the Secretary under subsection (i).

(D) EVALUATIONS.—The Secretary shall evaluate annually the performance of each approved accreditation body by—

(i) inspecting under subsection (g) a sufficient number of the laboratories accredited by such body to allow a reasonable estimate of the performance of such body, and

(ii) such other means as the Secretary determines appropriate.

(3) REPORT.—The Secretary shall annually prepare and submit, to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate, a report that describes the results of the evaluation conducted under paragraph (2)(D).

(f)[66] STANDARDS.—

(1) IN GENERAL.—The Secretary shall issue standards to assure consistent performance by laboratories issued a certificate under this section of valid and reliable laboratory examinations and other procedures. Such standards shall require each laboratory issued a certificate under this section—

(A) to maintain a quality assurance and quality control program adequate and appropriate for the validity and reliability of the laboratory examinations and other procedures of the laboratory and to meet requirements relating to the proper collection, transportation, and storage of specimens and the reporting of results,

(B) to maintain records, equipment, and facilities necessary for the proper and effective operation of the laboratory,

(C) in performing and carrying out its laboratory examinations and other procedures, to use only personnel meeting such qualifications as the Secretary may establish for the direction, supervision, and performance of examinations and procedures within the laboratory, which qualifications shall take into consideration competency, training, experience, job performance, and education and which qualifications shall, as appropriate, be different on the basis of the type of examinations and procedures being

[66] Section 3 of Public Law 100–578 provides that, with respect to subsection (g)(1) and subsections (h) through (m), any reference made in any of such subsections to the standards established under subsection (f) "shall be considered a reference to the standards established under subsection (d) [of section 353], as in effect on December 31, 1988.".

performed by the laboratory and the risks and consequences of erroneous results associated with such examinations and procedures,

(D) to qualify under a proficiency testing program meeting the standards established by the Secretary under paragraph (3), and

(E) to meet such other requirements as the Secretary determines necessary to assure consistent performance by such laboratories of accurate and reliable laboratory examinations and procedures.

(2) CONSIDERATIONS.—In developing the standards to be issued under paragraph (1), the Secretary shall, within the flexibility provided under subparagraphs (A) through (E) of paragraph (1), take into consideration—

(A) the examinations and procedures performed and the methodologies employed,

(B) the degree of independent judgment involved,

(C) the amount of interpretation involved,

(D) the difficulty of the calculations involved,

(E) the calibration and quality control requirements of the instruments used,

(F) the type of training required to operate the instruments used in the methodology, and

(G) such other factors as the Secretary considers relevant.

(3) PROFICIENCY TESTING PROGRAM.—

(A) IN GENERAL.—The Secretary shall establish standards for the proficiency testing programs for laboratories issued a certificate under this section which are conducted by the Secretary, conducted by an organization approved under subparagraph (C), or conducted by an approved accrediting body. The standards shall require that a laboratory issued a certificate under this section be tested for each examination and procedure conducted within a category of examinations or procedures for which it has received a certificate, except for examinations and procedures for which the Secretary has determined that a proficiency test cannot reasonably be developed. The testing shall be conducted on a quarterly basis, except where the Secretary determines for technical and scientific reasons that a particular examination or procedure may be tested less frequently (but not less often than twice per year).

(B) CRITERIA.—The standards established under subparagraph (A) shall include uniform criteria for acceptable performance under a proficiency testing program, based on the available technology and the clinical relevance of the laboratory examination or other procedure subject to such program. The criteria shall be established for all examinations and procedures and shall be uniform for each examination and procedure. The standards shall also include a system for grading proficiency testing performance to determine whether a laboratory has performed acceptably for a particular quarter and acceptably for a particular exam-

ination or procedure or category of examination or procedure over a period of successive quarters.

(C) APPROVED PROFICIENCY TESTING PROGRAMS.—For the purpose of administering proficiency testing programs which meet the standards established under subparagraph (A), the Secretary shall approve a proficiency testing program offered by a private nonprofit organization or a State if the program meets the standards established under subparagraph (A) and the organization or State provides technical assistance to laboratories seeking to qualify under the program. The Secretary shall evaluate each program approved under this subparagraph annually to determine if the program continues to meet the standards established under subparagraph (A) and shall withdraw the approval of any program that no longer meets such standards.

(D) ON-SITE [67] TESTING.—The Secretary shall perform, or shall direct a program approved under subparagraph (C) to perform, onsite proficiency testing to assure compliance with the requirements of subsection (d)(5) [68]. The Secretary shall perform, on an onsite or other basis, proficiency testing to evaluate the performance of a proficiency testing program approved under subparagraph (C) and to assure quality performance by a laboratory.

(E) TRAINING, TECHNICAL ASSISTANCE, AND ENHANCED PROFICIENCY TESTING.—The Secretary may, in lieu of or in addition to actions authorized under subsection (h), (i), or (j), require any laboratory which fails to perform acceptably on an individual examination and procedure or a category of examination and procedures—

(i) to undertake training and to obtain the necessary technical assistance to meet the requirements of the proficency [69] testing program,

(ii) to enroll in a program of enhanced proficiency testing, or

(iii) to undertake any combination of the training, technical assistance, or testing described in clauses (i) and (ii).

(F) TESTING RESULTS.—The Secretary shall establish a system to make the results of the proficiency testing programs subject to the standards established by the Secretary under subparagraph (A) available, on a reasonable basis, upon request of any person. The Secretary shall include with results made available under this subparagraph such explanatory information as may be appropriate to assist in the interpretation of such results.

(4) NATIONAL STANDARDS FOR QUALITY ASSURANCE IN CYTOLOGY SERVICES.—

(A) ESTABLISHMENT.—The Secretary shall establish national standards for quality assurance in cytology services designed to assure consistent performance by laboratories of valid and reliable cytological services.

[67] So in law. Probably should not be hyphenated. Compare with text of subparagraph (D).
[68] So in law. Probably should be "(d)(1)(E)".
[69] So in law. Probably should be "proficiency".

(B) STANDARDS.—The standards established under subparagraph (A) shall include—

(i) the maximum number of cytology slides that any individual may screen in a 24-hour period,

(ii) requirements that a clinical laboratory maintain a record of (I) the number of cytology slides screened during each 24-hour period by each individual who examines cytology slides for the laboratory, and (II) the number of hours devoted during each 24-hour period to screening cytology slides by such individual,

(iii) criteria for requiring rescreening of cytological preparations, such as (I) random rescreening of cytology specimens determined to be in the benign category, (II) focused rescreening of such preparations in high risk groups, and (III) for each abnormal cytological result, rescreening of all prior cytological specimens for the patient, if available,

(iv) periodic confirmation and evaluation of the proficiency of individuals involved in screening or interpreting cytological preparations, including announced and unannounced on-site[70] proficiency testing of such individuals, with such testing to take place, to the extent practicable, under normal working conditions,

(v) procedures for detecting inadequately prepared slides, for assuring that no cytological diagnosis is rendered on such slides, and for notifying referring physicians of such slides,

(vi) requirements that all cytological screening be done on the premises of a laboratory that is certified under this section,

(vii) requirements for the retention of cytology slides by laboratories for such periods of time as the Secretary considers appropriate, and

(viii) standards requiring periodic inspection of cytology services by persons capable of evaluating the quality of cytology services.

(g) INSPECTIONS.—

(1) IN GENERAL.—The Secretary may, on an announced or unannounced basis, enter and inspect, during regular hours of operation, laboratories which have been issued a certificate under this section. In conducting such inspections the Secretary shall have access to all facilities, equipment, materials, records, and information that the Secretary determines have a bearing on whether the laboratory is being operated in accordance with this section. As part of such an inspection the Secretary may copy any such material or require to it be[71] submitted to the Secretary. An inspection under this paragraph may be made only upon presenting identification to the owner, operator, or agent in charge of the laboratory being inspected.

[70] See footnote 1 for paragraph (3)(D).
[71] So in law. Probably should be "require it to be".

(2) COMPLIANCE WITH REQUIREMENTS AND STANDARDS.—The Secretary shall conduct inspections of laboratories under paragraph (1) to determine their compliance with the requirements of subsection (d) and the standards issued under subsection (f). Inspections of laboratories not accredited under subsection (e) shall be conducted on a biennial basis or with such other frequency as the Secretary determines to be necessary to assure compliance with such requirements and standards. Inspections of laboratories accredited under subsection (e) shall be conducted on such basis as the Secretary determines is necessary to assure compliance with such requirements and standards.

(h) INTERMEDIATE SANCTIONS.—

(1) IN GENERAL.—If the Secretary determines that a laboratory which has been issued a certificate under this section no longer substantially meets the requirements for the issuance of a certificate, the Secretary may impose intermediate sanctions in lieu of the actions authorized by subsection (i).

(2) TYPES OF SANCTIONS.—The intermediate sanctions which may be imposed under paragraph (1) shall consist of—

(A) directed plans of correction,

(B) civil money penalties in an amount not to exceed $10,000 for each violation listed in subsection (i)(1) or for each day of substantial noncompliance with the requirements of this section,

(C) payment for the costs of onsite monitoring, or

(D) any combination of the actions described in subparagraphs (A), (B), and (C).

(3) PROCEDURES.—The Secretary shall develop and implement procedures with respect to when and how each of the intermediate sanctions is to be imposed under paragraph (1). Such procedures shall provide for notice to the laboratory and a reasonable opportunity to respond to the proposed sanction and appropriate procedures for appealing determinations relating to the imposition of intermediate sanctions [72]

(i) SUSPENSION, REVOCATION, AND LIMITATION.—

(1) IN GENERAL.—Except as provided in paragraph (2), the certificate of a laboratory issued under this section may be suspended, revoked, or limited if the Secretary finds, after reasonable notice and opportunity for hearing to the owner or operator of the laboratory, that such owner or operator or any employee of the laboratory—

(A) has been guilty of misrepresentation in obtaining the certificate,

(B) has performed or represented the laboratory as entitled to perform a laboratory examination or other procedure which is not within a category of laboratory examinations or other procedures authorized in the certificate,

(C) has failed to comply with the requirements of subsection (d) or the standards prescribed by the Secretary under subsection (f),

[72] So in law. The sentence lacks a period.

(D) has failed to comply with reasonable requests of the Secretary for—

(i) any information or materials, or

(ii) work on materials,

that the Secretary concludes is necessary to determine the laboratory's continued eligibility for its certificate or continued compliance with the Secretary's standards under subsection (f),

(E) has refused a reasonable request of the Secretary, or any Federal officer or employee duly designated by the Secretary, for permission to inspect the laboratory and its operations and pertinent records during the hours the laboratory is in operation,

(F) has violated or aided and abetted in the violation of any provisions of this section or of any regulation promulgated thereunder, or

(G) has not complied with an intermediate sanction imposed under subsection (h).

(2) ACTION BEFORE A HEARING.—If the Secretary determines that—

(A) the failure of a laboratory to comply with the standards of the Secretary under subsection (f) presents an imminent and serious risk to human health, or

(B) a laboratory has engaged in an action described in subparagraph (D) or (E) of paragraph (1),

the Secretary may suspend or limit the certificate of the laboratory before holding a hearing under paragraph (1) regarding such failure or refusal. The opportunity for a hearing shall be provided no later than 60 days from the effective date of the suspension or limitation. A suspension or limitation under this paragraph shall stay in effect until the decision of the Secretary made after the hearing under paragraph (1).

(3) INELIGIBILITY TO OWN OR OPERATE LABORATORIES AFTER REVOCATION.—No person who has owned or operated a laboratory which has had its certificate revoked may, within 2 years of the revocation of the certificate, own or operate a laboratory for which a certificate has been issued under this section, except that if the revocation occurs pursuant to paragraph (4) the Secretary may substitute intermediate sanctions under subsection (h) instead of the 2-year prohibition against ownership or operation which would otherwise apply under this paragraph. The certificate of a laboratory which has been excluded from participation under the medicare program under title XVIII of the Social Security Act because of actions relating to the quality of the laboratory shall be suspended for the period the laboratory is so excluded.

(4) IMPROPER REFERRALS.—Any laboratory that the Secretary determines intentionally refers its proficiency testing samples to another laboratory for analysis may have its certificate revoked for at least one year and shall be subject to appropriate fines and penalties as provided for in subsection (h).

(j) INJUNCTIONS.—Whenever the Secretary has reason to believe that continuation of any activity by a laboratory would constitute a significant hazard to the public health the Secretary may

bring suit in the district court of the United States for the district in which such laboratory is situated to enjoin continuation of such activity. Upon proper showing, a temporary injunction or restraining order against continuation of such activity pending issuance of a final order under this subsection shall be granted without bond by such court.

(k) JUDICIAL REVIEW.—

(1) PETITION.—Any laboratory which has had an intermediate sanction imposed under subsection (h) or has had its certificate suspended, revoked, or limited under subsection (i) may, at any time within 60 days after the date the action of the Secretary under subsection (i) or (h) becomes final, file a petition with the United States court of appeals for the circuit wherein the laboratory has its principal place of business for judicial review of such action. As soon as practicable after receipt of the petition, the clerk of the court shall transmit a copy of the petition to the Secretary or other officer designated by the Secretary for that purpose. As soon as practicable after receipt of the copy, the Secretary shall file in the court the record on which the action of the Secretary is based, as provided in section 2112 of title 28, United States Code.

(2) ADDITIONAL EVIDENCE.—If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence (and evidence in rebuttal of such additional evidence) to be taken before the Secretary, and to be adduced upon the hearing in such manner and upon such terms and conditions as the court may deem proper. The Secretary may modify the findings of the Secretary as to the facts, or make new findings, by reason of the additional evidence so taken, and the Secretary shall file such modified or new findings, and the recommendations of the Secretary, if any, for the modification or setting aside of his original action, with the return of such additional evidence.

(3) JUDGMENT OF COURT.—Upon the filing of the petition referred to in paragraph (1), the court shall have jurisdiction to affirm the action, or to set it aside in whole or in part, temporarily or permanently. The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive.

(4) FINALITY OF JUDGMENT.—The judgment of the court affirming or setting aside, in whole or in part, any such action of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28, United States Code.

(l) SANCTIONS.—Any person who intentionally violates any requirement of this section or any regulation promulgated thereunder shall be imprisoned for not more than one year or fined under title 18, United States Code or both, except that if the conviction is for a second or subsequent violation of such a requirement such person

shall be imprisoned for not more than 3 years or fined in accordance with title 18, United States Code or both.

(m) FEES.—

(1) CERTIFICATE FEES.—The Secretary shall require payment of fees for the issuance and renewal of certificates, except that the Secretary shall only require a nominal fee for the issuance and renewal of certificates of waiver.

(2) ADDITIONAL FEES.—The Secretary shall require the payment of fees for inspections of laboratories which are not accredited and for the cost of performing proficiency testing on laboratories which do not participate in proficiency testing programs approved under subsection (f)(3)(C).

(3) CRITERIA.—

(A) FEES UNDER PARAGRAPH (1).—Fees imposed under paragraph (1) shall be sufficient to cover the general costs of administering this section, including evaluating and monitoring proficiency testing programs approved under subsection (f) and accrediting bodies and implementing and monitoring compliance with the requirements of this section.

(B) FEES UNDER PARAGRAPH (2).—Fees imposed under paragraph (2) shall be sufficient to cover the cost of the Secretary in carrying out the inspections and proficiency testing described in paragraph (2).

(C) FEES IMPOSED UNDER PARAGRAPHS (1) AND (2).—Fees imposed under paragraphs (1) and (2) shall vary by group or classification of laboratory, based on such considerations as the Secretary determines are relevant, which may include the dollar volume and scope of the testing being performed by the laboratories.

(n) INFORMATION.—On April 1, 1990 and annually thereafter, the Secretary shall compile and make available to physicians and the general public information, based on the previous calendar year, which the Secretary determines is useful in evaluating the performance of a laboratory, including—

(1) a list of laboratories which have been convicted under Federal or State laws relating to fraud and abuse, false billings, or kickbacks,

(2) a list of laboratories—

(A) which have had their certificates revoked, suspended, or limited under subsection (i), or

(B) which have been the subject of a sanction under subsection (l),

together with a statement of the reasons for the revocation, suspension, limitation, or sanction,

(3) a list of laboratories subject to intermediate sanctions under subsection (h) together with a statement of the reasons for the sanctions,

(4) a list of laboratories whose accreditation has been withdrawn or revoked together with a statement of the reasons for the withdrawal or revocation,

(5) a list of laboratories against which the Secretary has taken action under subsection (j) together with a statement of the reasons for such action, and

(6) a list of laboratories which have been excluded from participation under title XVIII or XIX of the Social Security Act.

The information to be compiled under paragraphs (1) through (6) shall be information for the calendar year preceding the date the information is to be made available to the public and shall be accompanied by such explanatory information as may be appropriate to assist in the interpretation of the information compiled under such paragraphs.

(o) DELEGATION.—In carrying out this section, the Secretary may, pursuant to agreement, use the services or facilities of any Federal or State or local public agency or nonprofit private organization, and may pay therefor in advance or by way of reimbursement, and in such installments, as the Secretary may determine.

(p) STATE LAWS.—

(1) Except as provided in paragraph (2), nothing in this section shall be construed as affecting the power of any State to enact and enforce laws relating to the matters covered by this section to the extent that such laws are not inconsistent with this section or with the regulations issued under this section.

(2) If a State enacts laws relating to matters covered by this section which provide for requirements equal to or more stringent than the requirements of this section or than the regulations issued under this section, the Secretary may exempt clinical laboratories in that State from compliance with this section.

(q) CONSULTATIONS.—In carrying out this section, the Secretary shall consult with appropriate private organizations and public agencies.

Subpart 3—Mammography Facilities

SEC. 354.[263b] CERTIFICATION OF MAMMOGRAPHY FACILITIES.

(a) DEFINITIONS.—As used in this section:

(1) ACCREDITATION BODY.—The term "accreditation body" means a body that has been approved by the Secretary under subsection (e)(1)(A) to accredit mammography facilities.

(2) CERTIFICATE.—The term "certificate" means the certificate described in subsection (b)(1).

(3) FACILITY.—

(A) IN GENERAL.—The term "facility" means a hospital, outpatient department, clinic, radiology practice, or mobile unit, an office of a physician, or other facility as determined by the Secretary, that conducts breast cancer screening or diagnosis through mammography activities. Such term does not include a facility of the Department of Veterans Affairs.

(B) ACTIVITIES.—For the purposes of this section, the activities of a facility include the operation of equipment to produce the mammogram, the processing of the film, the initial interpretation of the mammogram and the viewing conditions for that interpretation. Where procedures such as the film processing, or the interpretation of the mam-

mogram are performed in a location different from where the mammogram is performed, the facility performing the mammogram shall be responsible for meeting the quality standards described in subsection (f).

(4) INSPECTION.—The term "inspection" means an onsite evaluation of the facility by the Secretary, or State or local agency on behalf of the Secretary.

(5) MAMMOGRAM.—The term "mammogram" means a radiographic image produced through mammography.

(6) MAMMOGRAPHY.—The term "mammography" means radiography of the breast.

(7) SURVEY.—The term "survey" means an onsite physics consultation and evaluation performed by a medical physicist as described in subsection (f)(1)(E).

(8) REVIEW PHYSICIAN.—The term "review physician" means a physician as prescribed by the Secretary under subsection (f)(1)(D) who meets such additional requirements as may be established by an accreditation body under subsection (e) and approved by the Secretary to review clinical images under subsection (e)(1)(B)(i) on behalf of the accreditation body.

(b) CERTIFICATE REQUIREMENT.—

(1) CERTIFICATE.—No facility may conduct an examination or procedure described in paragraph (2) involving mammography after October 1, 1994, unless the facility obtains—

(A) a certificate or a temporary renewal certificate—

(i) that is issued, and, if applicable, renewed, by the Secretary in accordance with paragraphs[73] (1) or (2) of subsection (c);

(ii) that is applicable to the examination or procedure to be conducted; and

(iii) that is displayed prominently in such facility; or

(B) a provisional certificate or a limited provisional certificate—

(i) that is issued by the Secretary in accordance with paragraphs (3) and (4) of subsection (c);

(ii) that is applicable to the examination or procedure to be conducted; and

(iii) that is displayed prominently in such facility.

The reference to a certificate in this section includes a temporary renewal certificate, provisional certificate, or a[74] limited provisional certificate.

(2) EXAMINATION OR PROCEDURE.—A facility shall obtain a certificate in order to—

(A) operate radiological equipment that is used to image the breast;

(B) provide for the interpretation of a mammogram produced by such equipment at the facility or under arrangements with a qualified individual at a facility dif-

[73] So in law. Probably should be "paragraph". See section 2(1)(A)(ii) of Public Law 108–365 (118 Stat. 1738).

[74] So in law. The article "a" appears before both "temporary renewal certificate" and "limited provisional certificate". See section 2(1)(C) of Public Law 108–365 (118 Stat. 1738).

ferent from where the mammography examination is performed; and

(C) provide for the processing of film produced by such equipment at the facility or under arrangements with a qualified individual at a facility different from where the mammography examination is performed.

(c) ISSUANCE AND RENEWAL OF CERTIFICATES.—

(1) IN GENERAL.—The Secretary may issue or renew a certificate for a facility if the person or agent described in subsection (d)(1)(A) meets the applicable requirements of subsection (d)(1) with respect to the facility. The Secretary may issue or renew a certificate under this paragraph for not more than 3 years.

(2) TEMPORARY RENEWAL CERTIFICATE.—The Secretary may issue a temporary renewal certificate, for a period of not to exceed 45 days, to a facility seeking reaccreditation if the accreditation body has issued an accreditation extension, for a period of not to exceed 45 days, for any of the following:

(A) The facility has submitted the required materials to the accreditation body within the established time frames for the submission of such materials but the accreditation body is unable to complete the reaccreditation process before the certification expires.

(B) The facility has acquired additional or replacement equipment, or has had significant personnel changes or other unforeseen situations that have caused the facility to be unable to meet reaccreditation timeframes, but in the opinion of the accreditation body have not compromised the quality of mammography.

(3) LIMITED PROVISIONAL CERTIFICATE.—The Secretary may, upon the request of an accreditation body, issue a limited provisional certificate to an entity to enable the entity to conduct examinations for educational purposes while an onsite visit from an accreditation body is in progress. Such certificate shall be valid only during the time the site visit team from the accreditation body is physically in the facility, and in no case shall be valid for longer than 72 hours. The issuance of a certificate under this paragraph, shall not preclude the entity from qualifying for a provisional certificate under paragraph (4).

(4) PROVISIONAL CERTIFICATE.—The Secretary may issue a provisional certificate for an entity to enable the entity to qualify as a facility. The applicant for a provisional certificate shall meet the requirements of subsection (d)(1), except providing information required by clauses (iii) and (iv) of subsection (d)(1)(A). A provisional certificate may be in effect no longer than 6 months from the date it is issued, except that it may be extended once for a period of not more than 90 days if the owner, lessor, or agent of the facility demonstrates to the Secretary that without such extension access to mammography in the geographic area served by the facility would be significantly reduced and if the owner, lessor, or agent of the facility will describe in a report to the Secretary steps that will be

taken to qualify the facility for certification under subsection (b)(1).

(d) APPLICATION FOR CERTIFICATE.—

(1) SUBMISSION.—The Secretary may issue or renew a certificate for a facility if—

(A) the person who owns or leases the facility or an authorized agent of the person, submits to the Secretary, in such form and manner as the Secretary shall prescribe, an application that contains at a minimum—

(i) a description of the manufacturer, model, and type of each x-ray machine, image receptor, and processor operated in the performance of mammography by the facility;

(ii) a description of the procedures currently used to provide mammography at the facility, including—

(I) the types of procedures performed and the number of such procedures performed in the prior 12 months;

(II) the methodologies for mammography; and

(III) the names and qualifications (educational background, training, and experience) of the personnel performing mammography and the physicians reading and interpreting the results from the procedures;

(iii) proof of on-site survey by a qualified medical physicist as described in subsection (f)(1)(E); and

(iv) proof of accreditation in such manner as the Secretary shall prescribe; and

(B) the person or agent submits to the Secretary—

(i) a satisfactory assurance that the facility will be operated in accordance with standards established by the Secretary under subsection (f) to assure the safety and accuracy of mammography;

(ii) a satisfactory assurance that the facility will—

(I) permit inspections under subsection (g);

(II) make such records and information available, and submit such reports, to the Secretary as the Secretary may require; and

(III) update the information submitted under subparagraph (A) or assurances submitted under this subparagraph on a timely basis as required by the Secretary; and

(iii) such other information as the Secretary may require.

An applicant shall not be required to provide in an application under subparagraph (A) any information which the applicant has supplied to the accreditation body which accredited the applicant, except as required by the Secretary.

(2) APPEAL.—If the Secretary denies an application for the certification of a facility submitted under paragraph (1)(A), the Secretary shall provide the owner or lessor of the facility or the agent of the owner or lessor who submitted such application—

(A) a statement of the grounds on which the denial is based, and

(B) an opportunity for an appeal in accordance with the procedures set forth in regulations of the Secretary published at part 498 of title 42, Code of Federal Regulations.

(3) EFFECT OF DENIAL.—If the application for the certification of a facility is denied, the facility may not operate unless the denial of the application is overturned at the conclusion of the administrative appeals process provided in the regulations referred to in paragraph (2)(B).

(e) ACCREDITATION.—

(1) APPROVAL OF ACCREDITATION BODIES.—

(A) IN GENERAL.—The Secretary may approve a private nonprofit organization or State agency to accredit facilities for purposes of subsection (d)(1)(A)(iv) if the accreditation body meets the standards for accreditation established by the Secretary as described in subparagraph (B) and provides the assurances required by subparagraph (C).

(B) STANDARDS.—The Secretary shall establish standards for accreditation bodies, including—

(i) standards that require an accreditation body to perform—

(I) a review of clinical images from each facility accredited by such body not less often than every 3 years which review will be made by qualified review physicians; and

(II) a review of a random sample of clinical images from such facilities in each 3-year period beginning October 1, 1994, which review will be made by qualified review physicians;

(ii) standards that prohibit individuals conducting the reviews described in clause (i) from maintaining any relationship to the facility undergoing review which would constitute a conflict of interest;

(iii) standards that limit the imposition of fees for accreditation to reasonable amounts;

(iv) standards that require as a condition of accreditation that each facility undergo a survey at least annually by a medical physicist as described in subsection (f)(1)(E) to ensure that the facility meets the standards described in subparagraphs (A) and (B) of subsection (f)(1);

(v) standards that require monitoring and evaluation of such survey, as prescribed by the Secretary;

(vi) standards that are equal to standards established under subsection (f) which are relevant to accreditation as determined by the Secretary; and

(vii) such additional standards as the Secretary may require.

(C) ASSURANCES.—The accrediting body shall provide the Secretary satisfactory assurances that the body will—

(i) comply with the standards as described in subparagraph (B);

(ii) comply with the requirements described in paragraph (4);

(iii) submit to the Secretary the name of any facility for which the accreditation body denies, suspends, or revokes accreditation;

(iv) notify the Secretary in a timely manner before the accreditation body changes the standards of the body;

(v) notify each facility accredited by the accreditation body if the Secretary withdraws approval of the accreditation body under paragraph (2) in a timely manner; and

(vi) provide such other additional information as the Secretary may require.

(D) REGULATIONS.—Not later than 9 months after the date of the enactment of this section, the Secretary shall promulgate regulations under which the Secretary may approve an accreditation body.

(2) WITHDRAWAL OF APPROVAL.—

(A) IN GENERAL.—The Secretary shall promulgate regulations under which the Secretary may withdraw the approval of an accreditation body if the Secretary determines that the accreditation body does not meet the standards under subparagraph (B) of paragraph (1), the requirements of clauses (i) through (vi) of subparagraph (C) of paragraph (1), or the requirements of paragraph (4).

(B) EFFECT OF WITHDRAWAL.—If the Secretary withdraws the approval of an accreditation body under subparagraph (A), the certificate of any facility accredited by the body shall continue in effect until the expiration of a reasonable period, as determined by the Secretary, for such facility to obtain another accreditation.

(3) ACCREDITATION.—To be accredited by an approved accreditation body a facility shall meet—

(A) the standards described in paragraph (1)(B) which the Secretary determines are applicable to the facility, and

(B) such other standards which the accreditation body may require.

(4) COMPLIANCE.—To ensure that facilities accredited by an accreditation body will continue to meet the standards of the accreditation body, the accreditation body shall—

(A) make onsite visits on an annual basis of a sufficient number of the facilities accredited by the body to allow a reasonable estimate of the performance of the body; and

(B) take such additional measures as the Secretary determines to be appropriate.

Visits made under subparagraph (A) shall be made after providing such notice as the Secretary may require.

(5) REVOCATION OF ACCREDITATION.—If an accreditation body revokes the accreditation of a facility, the certificate of the facility shall continue in effect until such time as may be determined by the Secretary.

(6) EVALUATION AND REPORT.—

(A) EVALUATION.—The Secretary shall evaluate annually the performance of each approved accreditation body by—

(i) inspecting under subsection (g)(2) a sufficient number of the facilities accredited by the body to allow a reasonable estimate of the performance of the body; and

(ii) such additional means as the Secretary determines to be appropriate.

(B) REPORT.—The Secretary shall annually prepare and submit to the Committee on Labor and Human Resources of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that describes the results of the evaluation conducted in accordance with subparagraph (A).

(f) QUALITY STANDARDS.—

(1) IN GENERAL.—The standards referred to in subsection (d)(1)(B)(i) are standards established by the Secretary which include—

(A) standards that require establishment and maintenance of a quality assurance and quality control program at each facility that is adequate and appropriate to ensure the reliability, clarity, and accuracy of interpretation of mammograms and standards for appropriate radiation dose;

(B) standards that require use of radiological equipment specifically designed for mammography, including radiologic standards and standards for other equipment and materials used in conjunction with such equipment;

(C) a requirement that personnel who perform mammography—

(i)(I) be licensed by a State to perform radiological procedures; or

(II) be certified as qualified to perform radiological procedures by an organization described in paragraph (2)(A); and

(ii) during the 2-year period beginning October 1, 1994, meet training standards for personnel who perform mammography or meet experience requirements which shall at a minimum include 1 year of experience in the performance of mammography; and

(iii) upon the expiration of such 2-year period meet minimum training standards for personnel who perform mammograms;

(D) a requirement that mammograms be interpreted by a physician who is certified as qualified to interpret radiological procedures, including mammography—

(i)(I) by a board described in paragraph (2)(B); or

(II) by a program that complies with the standards described in paragraph (2)(C); and

(ii) who meets training and continuing medical education requirements as established by the Secretary;

(E) a requirement that individuals who survey mammography facilities be medical physicists—

(i) licensed or approved by a State to perform such surveys, reviews, or inspections for mammography facilities;

(ii) certified in diagnostic radiological physics or certified as qualified to perform such surveys by a board as described in paragraph (2)(D); or

(iii) in the first 5 years after the date of the enactment of this section, who meet other criteria established by the Secretary which are comparable to the criteria described in clause (i) or (ii);

(F) a requirement that a medical physicist who is qualified in mammography as described in subparagraph (E) survey mammography equipment and oversee quality assurance practices at each facility;

(G) a requirement that—

(i) a facility that performs any mammogram—

(I) except as provided in subclause (II), maintain the mammogram in the permanent medical records of the patient for a period of not less than 5 years, or not less than 10 years if no subsequent mammograms of such patient are performed at the facility, or longer if mandated by State law; and

(II) upon the request of or on behalf of the patient, transfer the mammogram to a medical institution, to a physician of the patient, or to the patient directly; and

(ii)(I) a facility must assure the preparation of a written report of the results of any mammography examination signed by the interpreting physician;

(II) such written report shall be provided to the patient's physicians (if any);

(III) if such a physician is not available or if there is no such physician, the written report shall be sent directly to the patient; and

(IV) whether or not such a physician is available or there is no such physician, a summary of the written report shall be sent directly to the patient in terms easily understood by a lay person; and

(H) standards relating to special techniques for mammography of patients with breast implants.

Subparagraph (G) shall not be construed to limit a patient's access to the patient's medical records.

(2) CERTIFICATION OF PERSONNEL.—The Secretary shall by regulation—

(A) specify organizations eligible to certify individuals to perform radiological procedures as required by paragraph (1)(C);

(B) specify boards eligible to certify physicians to interpret radiological procedures, including mammography, as required by paragraph (1)(D);

(C) establish standards for a program to certify physicians described in paragraph (1)(D); and

(D) specify boards eligible to certify medical physicists who are qualified to survey mammography equipment and to oversee quality assurance practices at mammography facilities.

(g) INSPECTIONS.—

(1) ANNUAL INSPECTIONS.—

(A) IN GENERAL.—The Secretary may enter and inspect facilities to determine compliance with the certification requirements under subsection (b) and the standards established under subsection (f). The Secretary shall, if feasible, delegate to a State or local agency the authority to make such inspections.

(B) IDENTIFICATION.—The Secretary, or State or local agency acting on behalf of the Secretary, may conduct inspections only on presenting identification to the owner, operator, or agent in charge of the facility to be inspected.

(C) SCOPE OF INSPECTION.—In conducting inspections, the Secretary or State or local agency acting on behalf of the Secretary—

(i) shall have access to all equipment, materials, records, and information that the Secretary or State or local agency considers necessary to determine whether the facility is being operated in accordance with this section; and

(ii) may copy, or require the facility to submit to the Secretary or the State or local agency, any of the materials, records, or information.

(D) QUALIFICATIONS OF INSPECTORS.—Qualified individuals, as determined by the Secretary, shall conduct all inspections. The Secretary may request that a State or local agency acting on behalf of the Secretary designate a qualified officer or employee to conduct the inspections, or designate a qualified Federal officer or employee to conduct inspections. The Secretary shall establish minimum qualifications and appropriate training for inspectors and criteria for certification of inspectors in order to inspect facilities for compliance with subsection (f).

(E) FREQUENCY.—The Secretary or State or local agency acting on behalf of the Secretary shall conduct inspections under this paragraph of each facility not less often than annually, subject to paragraph (6).

(F) RECORDS AND ANNUAL REPORTS.—The Secretary or a State or local agency acting on behalf of the Secretary which is responsible for inspecting mammography facilities shall maintain records of annual inspections required under this paragraph for a period as prescribed by the Secretary. Such a State or local agency shall annually prepare and submit to the Secretary a report concerning the inspections carried out under this paragraph. Such reports shall include a description of the facilities inspected and the results of such inspections.

(2) INSPECTION OF ACCREDITED FACILITIES.—The Secretary shall inspect annually a sufficient number of the facilities accredited by an accreditation body to provide the Secretary with a reasonable estimate of the performance of such body.

(3) INSPECTION OF FACILITIES INSPECTED BY STATE OR LOCAL AGENCIES.—The Secretary shall inspect annually facilities inspected by State or local agencies acting on behalf of the Secretary to assure a reasonable performance by such State or local agencies.

(4) TIMING.—The Secretary, or State or local agency, may conduct inspections under paragraphs (1), (2), and (3), during regular business hours or at a mutually agreeable time and after providing such notice as the Secretary may prescribe, except that the Secretary may waive such requirements if the continued performance of mammography at such facility threatens the public health.

(5) LIMITED REINSPECTION.—Nothing in this section limits the authority of the Secretary to conduct limited reinspections of facilities found not to be in compliance with this section.

(6) DEMONSTRATION PROGRAM.—

(A) IN GENERAL.—The Secretary may establish a demonstration program under which inspections under paragraph (1) of selected facilities are conducted less frequently by the Secretary (or as applicable, by State or local agencies acting on behalf of the Secretary) than the interval specified in subparagraph (E) of such paragraph.

(B) REQUIREMENTS.—Any demonstration program under subparagraph (A) shall be carried out in accordance with the following:

(i) The program may not be implemented before April 1, 2001. Preparations for the program may be carried out prior to such date.

(ii) In carrying out the program, the Secretary may not select a facility for inclusion in the program unless the facility is substantially free of incidents of noncompliance with the standards under subsection (f). The Secretary may at any time provide that a facility will no longer be included in the program.

(iii) The number of facilities selected for inclusion in the program shall be sufficient to provide a statistically significant sample, subject to compliance with clause (ii).

(iv) Facilities that are selected for inclusion in the program shall be inspected at such intervals as the Secretary determines will reasonably ensure that the facilities are maintaining compliance with such standards.

(h) SANCTIONS.—

(1) IN GENERAL.—In order to promote voluntary compliance with this section, the Secretary may, in lieu of taking the actions authorized by subsection (i), impose one or more of the following sanctions:

(A) Directed plans of correction which afford a facility an opportunity to correct violations in a timely manner.

(B) Payment for the cost of onsite monitoring.

(2) PATIENT INFORMATION.—If the Secretary determines that the quality of mammography performed by a facility (whether or not certified pursuant to subsection (c)) was so inconsistent with the quality standards established pursuant to subsection (f) as to present a significant risk to individual or public health, the Secretary may require such facility to notify patients who received mammograms at such facility, and their referring physicians, of the deficiencies presenting such risk, the potential harm resulting, appropriate remedial measures, and such other relevant information as the Secretary may require.

(3) CIVIL MONEY PENALTIES.—The Secretary may assess civil money penalties in an amount not to exceed $10,000 for—

(A) failure to obtain a certificate as required by subsection (b),

(B) each failure by a facility to substantially comply with, or each day on which a facility fails to substantially comply with, the standards established under subsection (f) or the requirements described in subclauses (I) through (III) of subsection (d)(1)(B)(ii),

(C) each failure to notify a patient of risk as required by the Secretary pursuant to paragraph (2), and

(D) each violation, or for each aiding and abetting in a violation of, any provision of, or regulation promulgated under, this section by an owner, operator, or any employee of a facility required to have a certificate.

(4) PROCEDURES.—The Secretary shall develop and implement procedures with respect to when and how each of the sanctions is to be imposed under paragraphs (1) through (3). Such procedures shall provide for notice to the owner or operator of the facility and a reasonable opportunity for the owner or operator to respond to the proposed sanctions and appropriate procedures for appealing determinations relating to the imposition of sanctions.

(i) SUSPENSION AND REVOCATION.—

(1) IN GENERAL.—The certificate of a facility issued under subsection (c) may be suspended or revoked if the Secretary finds, after providing, except as provided in paragraph (2), reasonable notice and an opportunity for a hearing to the owner or operator of the facility, that the owner, operator, or any employee of the facility—

(A) has been guilty of misrepresentation in obtaining the certificate;

(B) has failed to comply with the requirements of subsection (d)(1)(B)(ii)(III) or the standards established by the Secretary under subsection (f);

(C) has failed to comply with reasonable requests of the Secretary (or of an accreditation body approved pursuant to subsection (e)) for any record, information, report, or material that the Secretary (or such accreditation body or State carrying out certification program requirements pursuant to subsection (q)) concludes is necessary to determine the continued eligibility of the facility for a certificate

or continued compliance with the standards established under subsection (f);

(D) has refused a reasonable request of the Secretary, any Federal officer or employee duly designated by the Secretary, or any State or local officer or employee duly designated by the State or local agency, for permission to inspect the facility or the operations and pertinent records of the facility in accordance with subsection (g);

(E) has violated or aided and abetted in the violation of any provision of, or regulation promulgated under, this section; or

(F) has failed to comply with a sanction imposed under subsection (h).

(2) ACTION BEFORE A HEARING.—

(A) IN GENERAL.—The Secretary may suspend the certificate of the facility before holding a hearing required by paragraph (1) if the Secretary has reason to believe that the circumstance of the case will support one or more of the findings described in paragraph (1) and that—

(i) the failure or violation was intentional; or

(ii) the failure or violation presents a serious risk to human health.

(B) HEARING.—If the Secretary suspends a certificate under subparagraph (A), the Secretary shall provide an opportunity for a hearing to the owner or operator of the facility not later than 60 days from the effective date of the suspension. The suspension shall remain in effect until the decision of the Secretary made after the hearing.

(3) INELIGIBILITY TO OWN OR OPERATE FACILITIES AFTER REVOCATION.—If the Secretary revokes the certificate of a facility on the basis of an act described in paragraph (1), no person who owned or operated the facility at the time of the act may, within 2 years of the revocation of the certificate, own or operate a facility that requires a certificate under this section.

(j) INJUNCTIONS.—If the Secretary determines that—

(1) continuation of any activity related to the provision of mammography by a facility would constitute a serious risk to human health, the Secretary may bring suit in the district court of the United States for the district in which the facility is situated to enjoin continuation of the activity; and

(2) a facility is operating without a certificate as required by subsection (b), the Secretary may bring suit in the district court of the United States for the district in which the facility is situated to enjoin the operation of the facility.

Upon a proper showing, the district court shall grant a temporary injunction or restraining order against continuation of the activity or against operation of a facility, as the case may be, without requiring the Secretary to post a bond, pending issuance of a final order under this subsection.

(k) JUDICIAL REVIEW.—

(1) PETITION.—If the Secretary imposes a sanction on a facility under subsection (h) or suspends or revokes the certificate of a facility under subsection (i), the owner or operator of the facility may, not later than 60 days after the date the ac-

tion of the Secretary becomes final, file a petition with the United States court of appeals for the circuit in which the facility is situated for judicial review of the action. As soon as practicable after receipt of the petition, the clerk of the court shall transmit a copy of the petition to the Secretary or other officer designated by the Secretary. As soon as practicable after receipt of the copy, the Secretary shall file in the court the record on which the action of the Secretary is based, as provided in section 2112 of title 28, United States Code.

(2) ADDITIONAL EVIDENCE.—If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that the additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Secretary, the court may order the additional evidence (and evidence in rebuttal of the additional evidence) to be taken before the Secretary, and to be adduced upon the hearing in such manner and upon such terms and conditions as the court may determine to be proper. The Secretary may modify the findings of the Secretary as to the facts, or make new findings, by reason of the additional evidence so taken, and the Secretary shall file the modified or new findings, and the recommendations of the Secretary, if any, for the modification or setting aside of the original action of the Secretary with the return of the additional evidence.

(3) JUDGMENT OF COURT.—Upon the filing of the petition referred to in paragraph (1), the court shall have jurisdiction to affirm the action, or to set the action aside in whole or in part, temporarily or permanently. The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive.

(4) FINALITY OF JUDGMENT.—The judgment of the court affirming or setting aside, in whole or in part, any action of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification, as provided in section 1254 of title 28, United States Code.

(l) INFORMATION.—

(1) IN GENERAL.—Not later than October 1, 1996, and annually thereafter, the Secretary shall compile and make available to physicians and the general public information that the Secretary determines is useful in evaluating the performance of facilities, including a list of facilities—

(A) that have been convicted under Federal or State laws relating to fraud and abuse, false billings, or kickbacks;

(B) that have been subject to sanctions under subsection (h), together with a statement of the reasons for the sanctions;

(C) that have had certificates revoked or suspended under subsection (i), together with a statement of the reasons for the revocation or suspension;

(D) against which the Secretary has taken action under subsection (j), together with a statement of the reasons for the action;

(E) whose accreditation has been revoked, together with a statement of the reasons of the revocation;

(F) against which a State has taken adverse action; and

(G) that meets such other measures of performance as the Secretary may develop.

(2) DATE.—The information to be compiled under paragraph (1) shall be information for the calendar year preceding the date the information is to be made available to the public.

(3) EXPLANATORY INFORMATION.—The information to be compiled under paragraph (1) shall be accompanied by such explanatory information as may be appropriate to assist in the interpretation of the information compiled under such paragraph.

(m) STATE LAWS.—Nothing in this section shall be construed to limit the authority of any State to enact and enforce laws relating to the matters covered by this section that are at least as stringent as this section or the regulations issued under this section.

(n) NATIONAL ADVISORY COMMITTEE.—

(1) ESTABLISHMENT.—In carrying out this section, the Secretary shall establish an advisory committee to be known as the National Mammography Quality Assurance Advisory Committee (hereafter in this subsection referred to as the "Advisory Committee").

(2) COMPOSITION.—The Advisory Committee shall be composed of not fewer than 13, nor more than 19 individuals, who are not officers or employees of the Federal Government. The Secretary shall make appointments to the Advisory Committee from among—

(A) physicians,

(B) practitioners, and

(C) other health professionals,

whose clinical practice, research specialization, or professional expertise include a significant focus on mammography. The Secretary shall appoint at least 4 individuals from among national breast cancer or consumer health organizations with expertise in mammography, at least 2 industry representatives with expertise in mammography equipment, and at least 2 practicing physicians who provide mammography services.

(3) FUNCTIONS AND DUTIES.—The Advisory Committee shall—

(A) advise the Secretary on appropriate quality standards and regulations for mammography facilities;

(B) advise the Secretary on appropriate standards and regulations for accreditation bodies;

(C) advise the Secretary in the development of regulations with respect to sanctions;

(D) assist in developing procedures for monitoring compliance with standards under subsection (f);

(E) make recommendations and assist in the establishment of a mechanism to investigate consumer complaints;

(F) report on new developments concerning breast imaging that should be considered in the oversight of mammography facilities;

(G) determine whether there exists a shortage of mammography facilities in rural and health professional shortage areas and determine the effects of personnel or other requirements of subsection (f) on access to the services of such facilities in such areas;

(H) determine whether there will exist a sufficient number of medical physicists after October 1, 1999, to assure compliance with the requirements of subsection (f)(1)(E);

(I) determine the costs and benefits of compliance with the requirements of this section (including the requirements of regulations promulgated under this section); and

(J) perform other activities that the Secretary may require.

The Advisory Committee shall report the findings made under subparagraphs (G) and (I) to the Secretary and the Congress no later than October 1, 1993.

(4) MEETINGS.—The Advisory Committee shall meet not less than quarterly for the first 3 years of the program and thereafter, at least annually.

(5) CHAIRPERSON.—The Secretary shall appoint a chairperson of the Advisory Committee.

(o) CONSULTATIONS.—In carrying out this section, the Secretary shall consult with appropriate Federal agencies within the Department of Health and Human Services for the purposes of developing standards, regulations, evaluations, and procedures for compliance and oversight.

(p) BREAST CANCER SCREENING SURVEILLANCE RESEARCH GRANTS.—

(1) RESEARCH.—

(A) GRANTS.—The Secretary shall award grants to such entities as the Secretary may determine to be appropriate to establish surveillance systems in selected geographic areas to provide data to evaluate the functioning and effectiveness of breast cancer screening programs in the United States, including assessments of participation rates in screening mammography, diagnostic procedures, incidence of breast cancer, mode of detection (mammography screening or other methods), outcome and follow up information, and such related epidemiologic analyses that may improve early cancer detection and contribute to reduction in breast cancer mortality. Grants may be awarded for further research on breast cancer surveillance systems upon the Secretary's review of the evaluation of the program.

(B) USE OF FUNDS.—Grants awarded under subparagraph (A) may be used—

(i) to study—

(I) methods to link mammography and clinical breast examination records with population-based cancer registry data;

(II) methods to provide diagnostic outcome data, or facilitate the communication of diagnostic outcome data, to radiology facilities for purposes

of evaluating patterns of mammography interpretation; and

(III) mechanisms for limiting access and maintaining confidentiality of all stored data; and

(ii) to conduct pilot testing of the methods and mechanisms described in subclauses (I), (II), and (III) of clause (i) on a limited basis.

(C) GRANT APPLICATION.—To be eligible to receive funds under this paragraph, an entity shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require.

(D) REPORT.—A recipient of a grant under this paragraph shall submit a report to the Secretary containing the results of the study and testing conducted under clauses (i) and (ii) of subparagraph (B), along with recommendations for methods of establishing a breast cancer screening surveillance system.

(2) ESTABLISHMENT.—The Secretary shall establish a breast cancer screening surveillance system based on the recommendations contained in the report described in paragraph (1)(D).

(3) STANDARDS AND PROCEDURES.—The Secretary shall establish standards and procedures for the operation of the breast cancer screening surveillance system, including procedures to maintain confidentiality of patient records.

(4) INFORMATION.—The Secretary shall recruit facilities to provide to the breast cancer screening surveillance system relevant data that could help in the research of the causes, characteristics, and prevalence of, and potential treatments for, breast cancer and benign breast conditions, if the information may be disclosed under section 552 of title 5, United States Code.

(q) STATE PROGRAM.—

(1) IN GENERAL.—The Secretary may, upon application, authorize a State—

(A) to carry out, subject to paragraph (2), the certification program requirements under subsections (b), (c), (d), (g)(1), (h), (i), and (j) (including the requirements under regulations promulgated pursuant to such subsections), and

(B) to implement the standards established by the Secretary under subsection (f),

with respect to mammography facilities operating within the State.

(2) APPROVAL.—The Secretary may approve an application under paragraph (1) if the Secretary determines that—

(A) the State has enacted laws and issued regulations relating to mammography facilities which are the requirements of this section (including the requirements under regulations promulgated pursuant to such subsections), and

(B) the State has provided satisfactory assurances that the State—

(i) has the legal authority and qualified personnel necessary to enforce the requirements of and the regulations promulgated pursuant to this section (including the requirements under regulations promulgated pursuant to such subsections),

(ii) will devote adequate funds to the administration and enforcement of such requirements, and

(iii) will provide the Secretary with such information and reports as the Secretary may require.

(3) AUTHORITY OF SECRETARY.—In a State with an approved application—

(A) the Secretary shall carry out the Secretary's functions under subsections (e) and (f);

(B) the Secretary may take action under subsections (h), (i), and (j); and

(C) the Secretary shall conduct oversight functions under subsections (g)(2) and (g)(3).

(4) WITHDRAWAL OF APPROVAL.—

(A) IN GENERAL.—The Secretary may, after providing notice and opportunity for corrective action, withdraw the approval of a State's authority under paragraph (1) if the Secretary determines that the State does not meet the requirements of such paragraph. The Secretary shall promulgate regulations for the implementation of this subparagraph.

(B) EFFECT OF WITHDRAWAL.—If the Secretary withdraws the approval of a State under subparagraph (A), the certificate of any facility certified by the State shall continue in effect until the expiration of a reasonable period, as determined by the Secretary, for such facility to obtain certification by the Secretary.

(r) FUNDING.—

(1) FEES.—

(A) IN GENERAL.—The Secretary shall, in accordance with this paragraph assess and collect fees from persons described in subsection (d)(1)(A) (other than persons who are governmental entities, as determined by the Secretary) to cover the costs of inspections conducted under subsection (g)(1) by the Secretary or a State acting under a delegation under subparagraph (A) of such subsection. Fees may be assessed and collected under this paragraph only in such manner as would result in an aggregate amount of fees collected during any fiscal year which equals the aggregate amount of costs for such fiscal year for inspections of facilities of such persons under subsection (g)(1). A person's liability for fees shall be reasonably based on the proportion of the inspection costs which relate to such person.

(B) DEPOSIT AND APPROPRIATIONS.—

(i) DEPOSIT AND AVAILABILITY.—Fees collected under subparagraph (A) shall be deposited as an offsetting collection to the appropriations for the Department of Health and Human Services as provided in

appropriation Acts and shall remain available without fiscal year limitation.

(ii) APPROPRIATIONS.—Fees collected under subparagraph (A) shall be collected and available only to the extent provided in advance in appropriation Acts.

(2) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section—

(A) to award research grants under subsection (p), such sums as may be necessary for each of the fiscal years 1993 through 2007; and

(B) for the Secretary to carry out other activities which are not supported by fees authorized and collected under paragraph (1), such sums as may be necessary for fiscal years 1993 through 2007.

PART G—QUARANTINE AND INSPECTION

CONTROL OF COMMUNICABLE DISEASES.

SEC. 361.[264] (a) The Surgeon General, with the approval of the Secretary is authorized to make and enforce such regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession. For purposes of carrying out and enforcing such regulations, the Surgeon General may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, as in his judgment may be necessary.

(b) Regulations prescribed under this section shall not provide for the apprehension, detention, or conditional release of individuals except for the purpose of preventing the introduction, transmission, or spread of such communicable diseases as may be specified from time to time in Executive orders of the President upon the recommendation of the Secretary, in consultation with the Surgeon General,[75].

(c) Except as provided in subsection (d), regulations prescribed under this section, insofar as they provide for the apprehension, detention, examination, or conditional release of individuals, shall be applicable only to individuals coming into a State or possession from a foreign country or a possession.

(d)(1) Regulations prescribed under this section may provide for the apprehension and examination of any individual reasonably believed to be infected with a communicable disease in a qualifying stage and (A) to be moving or about to move from a State to another State; or (B) to be a probable source of infection to individuals who, while infected with such disease in a qualifying stage, will be moving from a State to another State. Such regulations may provide that if upon examination any such individual is found to be infected, he may be detained for such time and in such manner as may be reasonably necessary. For purposes of this subsection,

[75] The comma is so in law. See the amendment made by section 142(a)(1) of Public Law 107–188 (116 Stat. 626).

the term "State" includes, in addition to the several States, only the District of Columbia.

(2) For purposes of this subsection, the term "qualifying stage", with respect to a communicable disease, means that such disease—

(A) is in a communicable stage; or

(B) is in a precommunicable stage, if the disease would be likely to cause a public health emergency if transmitted to other individuals.

(e) Nothing in this section or section 363, or the regulations promulgated under such sections, may be construed as superseding any provision under State law (including regulations and including provisions established by political subdivisions of States), except to the extent that such a provision conflicts with an exercise of Federal authority under this section or section 363.

SUSPENSION OF ENTRIES AND IMPORTS FROM DESIGNATED PLACES.

SEC. 362.[265] Whenever the Surgeon General determines that by reason of the existence of any communicable disease in a foreign country there is serious danger of the introduction of such disease into the United States, and that this danger is so increased by the introduction of persons or property from such country that a suspension of the right to introduce such persons and property is required in the interest of the public health, the Surgeon General, in accordance with regulations approved by the President, shall have the power to prohibit, in whole or in part, the introduction of persons and property from such countries or places as he shall designate in order to avert such danger, and for such period of time as he may deem necessary for such purpose.

SPECIAL POWERS IN TIME OF WAR.

SEC. 363.[76][266] To protect the military and naval forces and war workers of the United States, in time of war, against any communicable disease specified in Executive orders as provided in subsection (b) of section 361, the Secretary, in consultation with the Surgeon General, is authorized to provide by regulations for the apprehension and examination, in time of war, of any individual reasonably believed (1) to be infected with such disease and (2) to be a probable source of infection to members of the armed forces of the United States or to individuals engaged in the production or transportation of arms, munitions, ships, food, clothing, or other supplies for the armed forces. Such regulations may provide that if upon examination any such individual is found to be so infected, he may be detained for such time and in such manner as may be reasonably necessary.

QUARANTINE STATIONS.

SEC. 364.[267] (a) Except as provided in title II of the Act of June 15, 1917, as amended (U.S.C., 1940 edition, title 50, secs. 191–194),[77] the Surgeon General shall control, direct, and manage

[76] Under section 3 of Public Law 239, 80th Congress, the date of July 25, 1947, is deemed, for purposes of this section, to be the date of termination of "any state of war heretofore declared by the Congress".

[77] Now codified to sections 191, 192, 194, and 195 of title 50, United States Code.

all United States quarantine stations, grounds, and anchorages, designate their boundaries, and designate the quarantine officers to be in charge thereof. With the approval of the President he shall from time to time select suitable sites for and establish such additional stations, grounds, and anchorages in the States and possessions of the United States as in his judgment are necessary to prevent the introduction of communicable diseases into the States and possessions of the United States.

(b) The Surgeon General shall establish the hours during which quarantine service shall be performed at each quarantine station, and, upon application by any interested party, may establish quarantine inspection during the twenty-four hours of the day, or any fraction thereof, at such quarantine stations as, in his opinion, require such extended service. He may restrict the performance of quarantine inspection to hours of daylight for such arriving vessels as cannot, in his opinion, be satisfactorily inspected during hours of darkness. No vessel shall be required to undergo quarantine inspection during the hours of darkness, unless the quarantine officer at such quarantine station shall deem an immediate inspection necessary to protect the public health. Uniformity shall not be required in the hours during which quarantine inspection may be obtained at the various ports of the United States.

(c) The Surgeon General shall fix a reasonable rate of extra compensation for overtime services of employees of the United States Public Health Service, Foreign Quarantine Division, performing overtime duties including the operation of vessels, in connection with the inspection or quarantine treatment of persons (passengers and crews), conveyances, or goods arriving by land, water, or air in the United States or any place subject to the jurisdiction thereof, hereinafter referred to as "employees of the Public Health Service", when required to be on duty between the hours of 6 o'clock postmeridian and 6 o'clock antemeridian (or between the hours of 7 o'clock postmeridian and 7 o'clock antemeridian at stations which have a declared workday of from 7 o'clock antemeridian to 7 o'clock postmeridian), or on Sundays or holidays, such rate, in lieu of compensation under any other provision of law, to be fixed at two times the basic hourly rate for each hour that the overtime extends beyond 6 o'clock (or 7 o'clock as the case may be) postmeridian, and two times the basic hourly rate for each overtime hour worked on Sundays or holidays. As used in this subsection, the term "basic hourly rate" shall mean the regular basic rate of pay which is applicable to such employees for work performed within their regular scheduled tour of duty.

(d)(1) The said extra compensation shall be paid to the United States by the owner, agent, consignee, operator, or master or other person in charge of any conveyance, for whom, at his request, services as described in this subsection (hereinafter referred to as overtime service) are performed. If such employees have been ordered to report for duty and have so reported, and the requested services are not performed by reason of circumstances beyond the control of the employees concerned, such extra compensation shall be paid on the same basis as though the overtime services had actually been performed during the period between the time the employees were ordered to report for duty and did so report, and the time they

were notified that their services would not be required, and in any case as though their services had continued for not less than one hour. The Surgeon General with the approval of the Secretary of Health, Education, and Welfare may prescribe regulations requiring the owner, agent, consignee, operator, or master or other person for whom the overtime services are performed to file a bond in such amounts and containing such conditions and with such sureties, or in lieu of a bond, to deposit money or obligations of the United States in such amount, as will assure the payment of charges under this subsection, which bond or deposit may cover one or more transactions or all transactions during a specified period: *Provided,* That no charges shall be made for services performed in connection with the inspection of (1) persons arriving by international highways, ferries, bridges, or tunnels, or the conveyances in which they arrive, or (2) persons arriving by aircraft or railroad trains, the operations of which are covered by published schedules, or the aircraft or trains in which they arrive, or (3) persons arriving by vessels operated between Canadian ports and ports on Puget Sound or operated on the Great Lakes and connecting waterways, the operations of which are covered by published schedules, or the vessels in which they arrive.

(2) Moneys collected under this subsection shall be deposited in the Treasury of the United States to the credit of the appropriation charged with the expense of the services, and the appropriations so credited shall be available for the payment of such compensation to the said employees for services so rendered.

CERTAIN DUTIES OF CONSULAR AND OTHER OFFICERS.

SEC. 365.[268] (a) Any consular or medical officer of the United States, designated for such purpose by the Secretary, shall make reports to the Surgeon General, on such forms and at such intervals as the Surgeon General may prescribe, of the health conditions at the port or place at which such officer is stationed.

(b) It shall be the duty of the customs officers and of Coast Guard officers to aid in the enforcement of quarantine rules and regulations; but no additional compensation, except actual and necessary traveling expenses, shall be allowed any such officer by reason of such services.

BILLS OF HEALTH.

SEC. 366.[269] (a) Except as otherwise prescribed in regulations, any vessel at any foreign port or place clearing or departing for any port or place in a State or possession shall be required to obtain from the consular officer of the United States or from the Public Health Service officer, or other medical officer of the United States designated by the Surgeon General, at the port or place of departure, a bill of health in duplicate, in the form prescribed by the Surgeon General. The President, from time to time, shall specify the ports at which a medical officer shall be stationed for this purpose. Such bill of health shall set forth the sanitary history and condition of said vessel, and shall state that it has in all respects complied with the regulations prescribed pursuant to subsection (c). Before granting such duplicate bill of health, such consular or med-

ical officer shall be satisfied that the matters and things therein stated are true. The consular officer shall be entitled to demand and receive the fees for bills of health and such fees shall be established by regulation.

(b) Original bills of health shall be delivered to the collectors of customs at the port of entry. Duplicate copies of such bills of health shall be delivered at the time of inspection to quarantine officers at such port. The bills of health herein prescribed shall be considered as part of the ship's papers, and when duly certified to by the proper consular or other officer of the United States, over his official signature and seal, shall be accepted as evidence of the statements therein contained in any court of the United States.

(c) The Surgeon General shall from time to time prescribe regulations, applicable to vessels referred to in subsection (a) of this section for the purpose of preventing the introduction into the States or possessions of the United States of any communicable disease by securing the best sanitary condition of such vessels, their cargoes, passengers, and crews. Such regulations shall be observed by such vessels prior to departure, during the course of the voyage, and also during inspection, disinfection, or other quarantine procedure upon arrival at any United States quarantine station.

(d) The provisions of subsections (a) and (b) of this section shall not apply to vessels plying between such foreign ports on or near the frontiers of the United States and ports of the United States as are designated by treaty.

(e) It shall be unlawful for any vessel to enter any port in any State or possession of the United States to discharge its cargo, or land its passengers, except upon a certificate of the quarantine officer that regulations prescribed under subsection (c) have in all respects been complied with by such officer, the vessel, and its master. The master of every such vessel shall deliver such certificate to the collector of customs at the port of entry, together with the original bill of health and other papers of the vessel. The certificate required by this subsection shall be procurable from the quarantine officer, upon arrival of the vessel at the quarantine station and satisfactory inspection thereof, at any time within which quarantine services are performed at such station.

CIVIL AIR NAVIGATION AND CIVIL AIRCRAFT.

SEC. 367.[270] The Surgeon General is authorized to provide by regulations for the application to air navigation and aircraft of any of the provisions of sections 364, 365, and 366 and regulations prescribed thereunder (including penalties and forfeitures for violations of such sections and regulations), to such extent and upon such conditions as he deems necessary for the safeguarding of the public health.

PENALTIES.

SEC. 368.[271] (a) Any person who violates any regulation prescribed under section 361, 362, or 363, or any provision of section 366 or any regulation prescribed thereunder, or who enters or departs from the limits of any quarantine station, ground, or anchorage in disregard of quarantine rules and regulations or without

permission of the quarantine officer in charge, shall be punished by a fine of not more than $1,000 or by imprisonment for not more than one year, or both.

(b) Any vessel which violates section 366, or any regulations thereunder or under section 364, or which enters within or departs from the limits of any quarantine station, ground, or anchorage in disregard of the quarantine rules and regulations or without permission of the officer in charge, shall forfeit to the United States not more than $5,000, the amount to be determined by the court, which shall be a lien on such vessel, to be recovered by proceedings in the proper district court of the United States. In all such proceedings the United States attorney shall appear on behalf of the United States; and all such proceedings shall be conducted in accordance with the rules and laws governing cases of seizure of vessels for violation of the revenue laws of the United States.

(c) With the approval of the Secretary, the Surgeon General may, upon application therefor, remit or mitigate any forfeiture provided for under subsection (b) of this section, and he shall have authority to ascertain the facts upon all such applications.

ADMINISTRATION OF OATHS.

SEC. 369.[272] Medical officers of the United States, when performing duties as quarantine officers at any port or place within the United States, are authorized to take declarations and administer oaths in matters pertaining to the administration of the quarantine laws and regulations of the United States.

PART H—ORGAN TRANSPLANTS [78]

ORGAN PROCUREMENT ORGANIZATIONS.

SEC. 371.[273] (a)(1) The Secretary may make grants for the planning of qualified organ procurement organizations described in subsection (b).

(2) The Secretary may make grants for the establishment, initial operation, consolidation, and expansion of qualified organ procurement organizations described in subsection (b).

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[78] Section 301 of the National Organ Transplant Act (Public Law 98–507; 42 U.S.C. 274e) provides:

SEC. 301. (a) It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantaion if the transfer affects interstate commerce.

(b) Any person who violates subsection (a) shall be fined not more than $50,000 or imprisoned not more than five years, or both.

(c) For purposes of subsection (a):

(1) The term "human organ" means the human (including fetal) kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin or any subpart thereof and any other human organ (or any subpart thereof, including that derived from a fetus) specified by the Secretary of Health and Human Services by regulation.

(2) The term "valuable consideration" does not include the reasonable payments associated with the removal, transportation, implantation, processing, preservation, quality control, and storage of a human organ or the expenses of travel, housing, and lost wages incurred by the donor of a human organ in connection with the donation of the organ.

(3) The term "interstate commerce" has the meaning prescribed for it by section 201(b) of the Federal Food, Drug and Cosmetic Act.

(b)(1)[79] A qualified organ procurement organization for which grants may be made under subsection (a) is an organization which, as determined by the Secretary, will carry out the functions described in paragraph (2)[80] and—

(A) is a nonprofit entity,

(B) has accounting and other fiscal procedures (as specified by the Secretary) necessary to assure the fiscal stability of the organization,

(C) has an agreement with the Secretary to be reimbursed under title XVIII of the Social Security Act for the procurement of kidneys,

(D) notwithstanding any other provision of law, has met the other requirements of this section and has been certified or recertified by the Secretary within the previous 4-year period as meeting the performance standards to be a qualified organ procurement organization through a process that either—

(i) granted certification or recertification within such 4-year period with such certification or recertification in effect as of January 1, 2000, and remaining in effect through the earlier of—

(I) January 1, 2002; or

(II) the completion of recertification under the requirements of clause (ii); or

(ii) is defined through regulations that are promulgated by the Secretary by not later than January 1, 2002, that—

(I) require recertifications of qualified organ procurement organizations not more frequently than once every 4 years;

(II) rely on outcome and process performance measures that are based on empirical evidence, obtained through reasonable efforts, of organ donor potential and other related factors in each service area of qualified organ procurement organizations;

(III) use multiple outcome measures as part of the certification process; and

(IV) provide for a qualified organ procurement organization to appeal a decertification to the Secretary on substantive and procedural grounds;

(E) notwithstanding any other provision of law, has met the other requirements of this section and has been certified or recertified by the Secretary within the previous 4-year period as meeting the performance standards to be a qualified organ procurement organization through a process that either—

[79] So in law. Subparagraphs (D) and (E) have the same text, and there are two subparagraphs (H). This results from the same set of amendments to section 371(b)(1) being enacted twice. The first set of amendments was made by section 701(c) of Public Law 106–505 (114 Stat. 2347). These amendments redesignated subparagraphs (D) through (G) as subparagraphs (E) through (H), respectively, and then added a new subparagraph (D). The second set was made by section 219(b) of the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2001 (as enacted into law by section 1(a)(1) of Public Law 106–554; 114 Stat. 2763A–29). Per the second set of amendments, the subparagraph (D) added by the first set was redesignated as (E), and the same text was again added as a subparagraph (D). Per the second set, subparagraphs (F) and (G), as redesignated by the first set, were redesignated as (G) and (H), which resulted in there being two subparagraphs (H).

[80] So in law. Probably should be "paragraph (3)".

(i) granted certification or recertification within such 4-year period with such certification or recertification in effect as of January 1, 2000, and remaining in effect through the earlier of—

(I) January 1, 2002; or

(II) the completion of recertification under the requirements of clause (ii); or

(ii) is defined through regulations that are promulgated by the Secretary by not later than January 1, 2002, that—

(I) require recertifications of qualified organ procurement organizations not more frequently than once every 4 years;

(II) rely on outcome and process performance measures that are based on empirical evidence, obtained through reasonable efforts, of organ donor potential and other related factors in each service area of qualified organ procurement organizations;

(III) use multiple outcome measures as part of the certification process; and

(IV) provide for a qualified organ procurement organization to appeal a decertification to the Secretary on substantive and procedural grounds;[81]

(F) has procedures to obtain payment for non-renal organs provided to transplant centers,

(G) has a defined service area that is of sufficient size to assure maximum effectiveness in the procurement and equitable distribution of organs, and that either includes an entire metropolitan statistical area (as specified by the Director of the Office of Management and Budget) or does not include any part of the area,

(H) has a director and such other staff, including the organ donation coordinators and organ procurement specialists necessary to effectively obtain organs from donors in its service area, and

(H) has a board of directors or an advisory board which—

(i) is composed of—

(I) members who represent hospital administrators, intensive care or emergency room personnel, tissue banks, and voluntary health associations in its service area,

(II) members who represent the public residing in such area,

(III) a physician with knowledge, experience, or skill in the field of histocompatability[82] or an individual with a doctorate degree in a biological science with knowledge, experience, or skill in the field of histocompatibility,

(IV) a physician with knowledge or skill in the field of neurology, and

[81] So in law. Subparagraphs (D) and (E) have semicolons at the end of organizational units, rather than commas.

[82] So in law. Probably should be "histocompatibility".

(V) from each transplant center in its service area which has arrangements described in paragraph (2)[83](G) with the organization, a member who is a surgeon who has practicing privileges in such center and who performs organ transplant surgery,

(ii) has the authority to recommend policies for the procurement of organs and the other functions described in paragraph (2), and

(iii) has no authority over any other activity of the organization.

(2)(A) Not later than 90 days after the date of the enactment of this paragraph,[84] the Secretary shall publish in the Federal Register a notice of proposed rulemaking to establish criteria for determining whether an entity meets the requirement established in paragraph (1)(E).

(B) Not later than 1 year after the date of enactment of this paragraph, the Secretary shall publish in the Federal Register a final rule to establish the criteria described in subparagraph (A).

(3) An organ procurement organization shall—

(A) have effective agreements, to identify potential organ donors, with a substantial majority of the hospitals and other health care entities in its service area which have facilities for organ donations,

(B) conduct and participate in systematic efforts, including professional education, to acquire all usable organs from potential donors,

(C) arrange for the acquisition and preservation of donated organs and provide quality standards for the acquisition of organs which are consistent with the standards adopted by the Organ Procurement and Transplantation Network under section 372(b)(2)(E), including arranging for testing with respect to preventing the acquisition of organs that are infected with the etiologic agent for acquired immune deficiency syndrome,

(D) arrange for the appropriate tissue typing of donated organs,

(E) have a system to allocate donated organs equitably among transplant patients according to established medical criteria,

(F) provide or arrange for the transportation of donated organs to transplant centers,

(G) have arrangements to coordinate its activities with transplant centers in its service area,

(H) participate in the Organ Procurement Transplantation Network established under section 372,

(I) have arrangements to cooperate with tissue banks for the retrieval, processing, preservation, storage, and distribution of tissues as may be appropriate to assure that all usable tissues are obtained from potential donors,

(J) evaluate annually the effectiveness of the organization in acquiring potentially available organs, and

[83] So in law. Probably should be paragraph (3).
[84] Enacted November 16, 1990. See section 201(d) of Public Law 101–616.

(K) assist hospitals in establishing and implementing protocols for making routine inquiries about organ donations by potential donors.

(c) Pancreata procured by an organ procurement organization and used for islet cell transplantation or research shall be counted for purposes of certification or recertification under subsection (b).

SEC. 371A.[273a] NATIONAL LIVING DONOR MECHANISMS.

The Secretary may establish and maintain mechanisms to evaluate the long-term effects associated with living organ donations by individuals who have served as living donors.

ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK.

SEC. 372.[274] (a) The Secretary shall by contract provide for the establishment and operation of an Organ Procurement and Transplantation Network which meets the requirements of subsection (b). The amount provided under such contract in any fiscal year may not exceed $7,000,000. Funds for such contracts shall be made available from funds available to the Public Health Service from appropriations for fiscal years beginning after fiscal year 1984.

(b)(1) The Organ Procurement and Transplantation Network shall carry out the functions described in paragraph (2) and shall—

(A) be a private nonprofit entity that has an expertise in organ procurement and transplantation, and

(B) have a board of directors—

(i) that includes representatives of organ procurement organizations (including organizations that have received grants under section 371), transplant centers, voluntary health associations, and the general public; and

(ii) that shall establish an executive committee and other committees, whose chairpersons shall be selected to ensure continuity of leadership for the board.

(2) The Organ Procurement and Transplantation Network shall—

(A) establish in one location or through regional centers—

(i) a national list of individuals who need organs, and

(ii) a national system, through the use of computers and in accordance with established medical criteria, to match organs and individuals included in the list, especially individuals whose immune system makes it difficult for them to receive organs,

(B) establish membership criteria and medical criteria for allocating organs and provide to members of the public an opportunity to comment with respect to such criteria,

(C) maintain a twenty-four-hour telephone service to facilitate matching organs with individuals included in the list,

(D) assist organ procurement organizations in the nationwide distribution of organs equitably among transplant patients,

(E) adopt and use standards of quality for the acquisition and transportation of donated organs, including standards for preventing the acquisition of organs that are infected with the etiologic agent for acquired immune deficiency syndrome,

(F) prepare and distribute, on a regionalized basis (and, to the extent practicable, among regions or on a national basis), samples of blood sera from individuals who are included on the list and whose immune system makes it difficult for them to receive organs, in order to facilitate matching the compatibility of such individuals with organ donors,

(G) coordinate, as appropriate, the transportation of organs from organ procurement organizations to transplant centers,

(H) provide information to physicians and other health professionals regarding organ donation,

(I) collect, analyze, and publish data concerning organ donation and transplants,

(J) carry out studies and demonstration projects for the purpose of improving procedures for organ procurement and allocation,

(K) work actively to increase the supply of donated organs,

(L) submit to the Secretary an annual report containing information on the comparative costs and patient outcomes at each transplant center affiliated with the organ procurement and transplantation network,

(M)[85] recognize the differences in health and in organ transplantation issues between children and adults throughout the system and adopt criteria, polices, and procedures that address the unique health care needs of children,

(N) carry out studies and demonstration projects for the purpose of improving procedures for organ donation procurement and allocation, including but not limited to projects to examine and attempt to increase transplantation among populations with special needs, including children and individuals who are members of racial or ethnic minority groups, and among populations with limited access to transportation, and

(O) provide that for purposes of this paragraph, the term "children" refers to individuals who are under the age of 18.

(c) The Secretary shall establish procedures for—

(1) receiving from interested persons critical comments relating to the manner in which the Organ Procurement and Transplantation Network is carrying out the duties of the Network under subsection (b); and

(2) the consideration by the Secretary of such critical comments.

SCIENTIFIC REGISTRY.

SEC. 373.[274a] The Secretary shall, by grant or contract, develop and maintain a scientific registry of the recipients of organ transplants. The registry shall include such information respecting patients and transplant procedures as the Secretary deems necessary to an ongoing evaluation of the scientific and clinical status of organ transplantation. The Secretary shall prepare for inclusion

[85] Indentation is so in law. See section 2101(a)(3) of Public Law 106–310 (114 Stat. 1156).

in the report under section 376 an analysis of information derived from the registry.

GENERAL PROVISIONS RESPECTING GRANTS AND CONTRACTS.

SEC. 374.[274b] (a) No grant may be made under this part or contract entered into under section 372 or 373 unless an application therefor has been submitted to, and approved by, the Secretary. Such an application shall be in such form and shall be submitted in such manner as the Secretary shall by regulation prescribe.

(b)(1) A grant for planning under section 371(a)(1) may be made for one year with respect to any organ procurement organization and may not exceed $100,000.

(2) Grants under section 371(a)(2) may be made for two years. No such grant may exceed $500,000 for any year and no organ procurement organization may receive more than $800,000 for initial operation or expansion.

(3) Grants or contracts under section 371(a)(3) may be made for not more than 3 years.

(c)(1) The Secretary shall determine the amount of a grant or contract made under section 371 or 373. Payments under such grants and contracts may be made in advance on the basis of estimates or by the way of reimbursement, with necessary adjustments on account of underpayments or overpayments, and in such installments and on such terms and conditions as the Secretary finds necessary to carry out the purposes of such grants and contracts.

(2)(A) Each recipient of a grant or contract under section 371 or 373 shall keep such records as the Secretary shall prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of such grant or contract, the total cost of the undertaking in connection with which such grant or contract was made, and the amount of that portion of the cost of the undertaking supplied by other sources, and such other records as will facilitate an effective audit.

(B) The Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of the recipient of a grant or contract under section 371 or 373 that are pertinent to such grant or contract.

(d) For purposes of this part:

(1) The term "transplant center" means a health care facility in which transplants of organs are performed.

(2) The term "organ" means the human kidney, liver, heart, lung, pancreas, and any other human organ (other than corneas and eyes) specified by the Secretary by regulation and for purposes of section 373, such term includes bone marrow.

ADMINISTRATION.

SEC. 375.[274c] The Secretary shall designate and maintain an identifiable administrative unit in the Public Health Service to—

(1) administer this part and coordinate with the organ procurement activities under title XVIII of the Social Security Act,

(2) conduct a program of public information to inform the public of the need for organ donations,

(3) provide technical assistance to organ procurement organizations, the Organ Procurement and Transplantation Network established under section 372, and other entities in the health care system involved in organ donations, procurement, and transplants, and

(4) provide information—

(i)[86] to patients, their families, and their physicians about transplantation; and

(ii) to patients and their families about the resources available nationally and in each State, and the comparative costs and patient outcomes at each transplant center affiliated with the organ procurement and transplantation network, in order to assist the patients and families with the costs associated with transplantation.

REPORT.

SEC. 376.[274d] Not later than February 10 of 1991 and of each second year thereafter, the Secretary shall publish, and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate.[87] a report on the scientific and clinical status of organ transplantation. The Secretary shall consult with the Director of the National Institutes of Health and the Commissioner of the Food and Drug Administration in the preparation of the report.

SEC. 377.[274f] REIMBURSEMENT OF TRAVEL AND SUBSISTENCE EXPENSES INCURRED TOWARD LIVING ORGAN DONATION.

(a) IN GENERAL.—The Secretary may award grants to States, transplant centers, qualified organ procurement organizations under section 371, or other public or private entities for the purpose of—

(1) providing for the reimbursement of travel and subsistence expenses incurred by individuals toward making living donations of their organs (in this section referred to as "donating individuals"); and

(2) providing for the reimbursement of such incidental nonmedical expenses that are so incurred as the Secretary determines by regulation to be appropriate.

(b) PREFERENCE.—The Secretary shall, in carrying out subsection (a), give preference to those individuals that the Secretary determines are more likely to be otherwise unable to meet such expenses.

(c) CERTAIN CIRCUMSTANCES.—The Secretary may, in carrying out subsection (a), consider—

[86] Clauses (i) and (ii) probably should be redesignated as subparagraphs (A) and (B). See section 204(b)(2) of Public Law 101–616 (104 Stat. 3285).

[87] So in law. There probably should be a comma after "Senate" rather than a period. See section 205 of Public Law 101–616.

(1) the term "donating individuals" as including individuals who in good faith incur qualifying expenses toward the intended donation of an organ but with respect to whom, for such reasons as the Secretary determines to be appropriate, no donation of the organ occurs; and

(2) the term "qualifying expenses" as including the expenses of having relatives or other individuals, not to exceed 2, accompany or assist the donating individual for purposes of subsection (a) (subject to making payment for only those types of expenses that are paid for a donating individual).

(d) RELATIONSHIP TO PAYMENTS UNDER OTHER PROGRAMS.—An award may be made under subsection (a) only if the applicant involved agrees that the award will not be expended to pay the qualifying expenses of a donating individual to the extent that payment has been made, or can reasonably be expected to be made, with respect to such expenses—

(1) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program;

(2) by an entity that provides health services on a prepaid basis; or

(3) by the recipient of the organ.

(e) DEFINITIONS.—For purposes of this section:

(1) The term "donating individuals" has the meaning indicated for such term in subsection (a)(1), subject to subsection (c)(1).

(2) The term "qualifying expenses" means the expenses authorized for purposes of subsection (a), subject to subsection (c)(2).

(f) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there is authorized to be appropriated $5,000,000 for each of the fiscal years 2005 through 2009.

SEC. 377A.[274f–1] PUBLIC AWARENESS; STUDIES AND DEMONSTRATIONS.

(a) ORGAN DONATION PUBLIC AWARENESS PROGRAM.—The Secretary shall, directly or through grants or contracts, establish a public education program in cooperation with existing national public awareness campaigns to increase awareness about organ donation and the need to provide for an adequate rate of such donations.

(b) STUDIES AND DEMONSTRATIONS.—The Secretary may make peer-reviewed grants to, or enter into peer-reviewed contracts with, public and nonprofit private entities for the purpose of carrying out studies and demonstration projects to increase organ donation and recovery rates, including living donation.

(c) GRANTS TO STATES.—

(1) IN GENERAL.—The Secretary may make grants to States for the purpose of assisting States in carrying out organ donor awareness, public education, and outreach activities and programs designed to increase the number of organ donors within the State, including living donors.

(2) ELIGIBILITY.—To be eligible to receive a grant under this subsection, a State shall—

(A) submit an application to the Department in the form prescribed;

(B) establish yearly benchmarks for improvement in organ donation rates in the State; and

(C) report to the Secretary on an annual basis a description and assessment of the State's use of funds received under this subsection, accompanied by an assessment of initiatives for potential replication in other States.

(3) USE OF FUNDS.—Funds received under this subsection may be used by the State, or in partnership with other public agencies or private sector institutions, for education and awareness efforts, information dissemination, activities pertaining to the State donor registry, and other innovative donation specific initiatives, including living donation.

(d) EDUCATIONAL ACTIVITIES.—The Secretary, in coordination with the Organ Procurement and Transplantation Network and other appropriate organizations, shall support the development and dissemination of educational materials to inform health care professionals and other appropriate professionals in issues surrounding organ, tissue, and eye donation including evidence-based proven methods to approach patients and their families, cultural sensitivities, and other relevant issues.

(e) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $15,000,000 for fiscal year 2005, and such sums as may be necessary for each of the fiscal years 2006 through 2009. Such authorization of appropriations is in addition to any other authorizations of appropriations that are available for such purpose.

SEC. 377B.[274f–2] GRANTS REGARDING HOSPITAL ORGAN DONATION COORDINATORS.

(a) AUTHORITY.—

(1) IN GENERAL.—The Secretary may award grants to qualified organ procurement organizations and hospitals under section 371 to establish programs coordinating organ donation activities of eligible hospitals and qualified organ procurement organizations under section 371. Such activities shall be coordinated to increase the rate of organ donations for such hospitals.

(2) ELIGIBLE HOSPITAL.—For purposes of this section, the term "eligible hospital" means a hospital that performs significant trauma care, or a hospital or consortium of hospitals that serves a population base of not fewer than 200,000 individuals.

(b) ADMINISTRATION OF COORDINATION PROGRAM.—A condition for the receipt of a grant under subsection (a) is that the applicant involved agree that the program under such subsection will be carried out jointly—

(1) by representatives from the eligible hospital and the qualified organ procurement organization with respect to which the grant is made; and

(2) by such other entities as the representatives referred to in paragraph (1) may designate.

(c) REQUIREMENTS.—Each entity receiving a grant under subsection (a) shall—

(1) establish joint organ procurement organization and hospital designated leadership responsibility and accountability for the project;

(2) develop mutually agreed upon overall project performance goals and outcome measures, including interim outcome targets; and

(3) collaboratively design and implement an appropriate data collection process to provide ongoing feedback to hospital and organ procurement organization leadership on project progress and results.

(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to interfere with regulations in force on the date of enactment of the Organ Donation and Recovery Improvement Act.

(e) EVALUATIONS.—Within 3 years after the award of grants under this section, the Secretary shall ensure an evaluation of programs carried out pursuant to subsection (a) in order to determine the extent to which the programs have increased the rate of organ donation for the eligible hospitals involved.

(f) MATCHING REQUIREMENT.—The Secretary may not award a grant to a qualifying organ donation entity under this section unless such entity agrees that, with respect to costs to be incurred by the entity in carrying out activities for which the grant was awarded, the entity shall contribute (directly or through donations from public or private entities) non-Federal contributions in cash or in kind, in an amount equal to not less than 30 percent of the amount of the grant awarded to such entity.

(g) FUNDING.—For the purpose of carrying out this section, there are authorized to be appropriated $3,000,000 for fiscal year 2005, and such sums as may be necessary for each of fiscal years 2006 through 2009.

SEC. 377C.[274f–3] STUDIES RELATING TO ORGAN DONATION AND THE RECOVERY, PRESERVATION, AND TRANSPORTATION OF ORGANS.

(a) DEVELOPMENT OF SUPPORTIVE INFORMATION.—The Secretary, acting through the Director of the Agency for Healthcare Research and Quality, shall develop scientific evidence in support of efforts to increase organ donation and improve the recovery, preservation, and transportation of organs.

(b) ACTIVITIES.—In carrying out subsection (a), the Secretary shall—

(1) conduct or support evaluation research to determine whether interventions, technologies, or other activities improve the effectiveness, efficiency, or quality of existing organ donation practice;

(2) undertake or support periodic reviews of the scientific literature to assist efforts of professional societies to ensure that the clinical practice guidelines that they develop reflect the latest scientific findings;

(3) ensure that scientific evidence of the research and other activities undertaken under this section is readily accessible by the organ procurement workforce; and

(4) work in coordination with the appropriate professional societies as well as the Organ Procurement and Transplantation Network and other organ procurement and transplan-

tation organizations to develop evidence and promote the adoption of such proven practices.

(c) RESEARCH AND DISSEMINATION.—The Secretary, acting through the Director of the Agency for Healthcare Research and Quality, as appropriate, shall provide support for research and dissemination of findings, to—

(1) develop a uniform clinical vocabulary for organ recovery;

(2) apply information technology and telecommunications to support the clinical operations of organ procurement organizations;

(3) enhance the skill levels of the organ procurement workforce in undertaking quality improvement activities; and

(4) assess specific organ recovery, preservation, and transportation technologies.

(d) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $2,000,000 for fiscal year 2005, and such sums as may be necessary for each of fiscal years 2006 through 2009.

SEC. 377D.[274f–4] REPORT RELATING TO ORGAN DONATION AND THE RECOVERY, PRESERVATION, AND TRANSPORTATION OF ORGANS.

(a) IN GENERAL.—Not later than December 31, 2005, and every 2 years thereafter, the Secretary shall report to the appropriate committees of Congress on the activities of the Department carried out pursuant to this part, including an evaluation describing the extent to which the activities have affected the rate of organ donation and recovery.

(b) REQUIREMENTS.—To the extent practicable, each report submitted under subsection (a) shall—

(1) evaluate the effectiveness of activities, identify effective activities, and disseminate such findings with respect to organ donation and recovery;

(2) assess organ donation and recovery activities that are recently completed, ongoing, or planned; and

(3) evaluate progress on the implementation of the plan required under subsection (c)(5).

(c) INITIAL REPORT REQUIREMENTS.—The initial report under subsection (a) shall include the following:

(1) An evaluation of the organ donation practices of organ procurement organizations, States, other countries, and other appropriate organizations including an examination across all populations, including those with low organ donation rates, of—

(A) existing barriers to organ donation; and

(B) the most effective donation and recovery practices.

(2) An evaluation of living donation practices and procedures. Such evaluation shall include an assessment of issues relating to informed consent and the health risks associated with living donation (including possible reduction of long-term effects).

(3) An evaluation of—

(A) federally supported or conducted organ donation efforts and policies, as well as federally supported or con-

ducted basic, clinical, and health services research (including research on preservation techniques and organ rejection and compatibility); and

(B) the coordination of such efforts across relevant agencies within the Department and throughout the Federal Government.

(4) An evaluation of the costs and benefits of State donor registries, including the status of existing State donor registries, the effect of State donor registries on organ donation rates, issues relating to consent, and recommendations regarding improving the effectiveness of State donor registries in increasing overall organ donation rates.

(5) A plan to improve federally supported or conducted organ donation and recovery activities, including, when appropriate, the establishment of baselines and benchmarks to measure overall outcomes of these programs. Such plan shall provide for the ongoing coordination of federally supported or conducted organ donation and research activities.

SEC. 378.[274g] AUTHORIZATION OF APPROPRIATIONS.

For the purpose of carrying out this part, there are authorized to be appropriated $8,000,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 and 1993.

PART I—C.W. BILL YOUNG CELL TRANSPLANTATION PROGRAM

SEC. 379.[274k] NATIONAL PROGRAM.

(a) ESTABLISHMENT.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall by one or more contracts establish and maintain a C.W. Bill Young Cell Transplantation Program (referred to in this section as the "Program"), successor to the National Bone Marrow Donor Registry, that has the purpose of increasing the number of transplants for recipients suitably matched to biologically unrelated donors of bone marrow and cord blood, and that meets the requirements of this section. The Secretary may award a separate contract to perform each of the major functions of the Program described in paragraphs (1) and (2) of subsection (d) if deemed necessary by the Secretary to operate an effective and efficient system that is in the best interest of patients. The Secretary shall conduct a separate competition for the initial establishment of the cord blood functions of the Program. The Program shall be under the general supervision of the Secretary. The Secretary shall establish an Advisory Council to advise, assist, consult with, and make recommendations to the Secretary on matters related to the activities carried out by the Program. The members of the Advisory Council shall be appointed in accordance with the following:

(1) Each member of the Advisory Council shall serve for a term of 2 years, and each such member may serve as many as 3 consecutive 2-year terms, except that—

(A) such limitations shall not apply to the Chair of the Advisory Council (or the Chair-elect) or to the member of

the Advisory Council who most recently served as the Chair; and

(B) one additional consecutive 2-year term may be served by any member of the Advisory Council who has no employment, governance, or financial affiliation with any donor center, recruitment organization, transplant center, or cord blood bank.

(2) A member of the Advisory Council may continue to serve after the expiration of the term of such member until a successor is appointed.

(3) In order to ensure the continuity of the Advisory Council, the Advisory Council shall be appointed so that each year the terms of approximately one-third of the members of the Advisory Council expire.

(4) The membership of the Advisory Council—

(A) shall include as voting members a balanced number of representatives including representatives of marrow donor centers and marrow transplant centers, representatives of cord blood banks and participating birthing hospitals, recipients of a bone marrow transplant, recipients of a cord blood transplant, persons who require such transplants, family members of such a recipient or family members of a patient who has requested the assistance of the Program in searching for an unrelated donor of bone marrow or cord blood, persons with expertise in bone marrow and cord blood transplantation, persons with expertise in typing, matching, and transplant outcome data analysis, persons with expertise in the social sciences, basic scientists with expertise in the biology of adult stem cells, and members of the general public; and

(B) shall include as nonvoting members representatives from the Department of Defense Marrow Donor Recruitment and Research Program operated by the Department of the Navy, the Division of Transplantation of the Health Resources and Services Administration, the Food and Drug Administration, and the National Institutes of Health.

(5) Members of the Advisory Council shall be chosen so as to ensure objectivity and balance and reduce the potential for conflicts of interest. The Secretary shall establish bylaws and procedures—

(A) to prohibit any member of the Advisory Council who has an employment, governance, or financial affiliation with a donor center, recruitment organization, transplant center, or cord blood bank from participating in any decision that materially affects the center, recruitment organization, transplant center, or cord blood bank; and

(B) to limit the number of members of the Advisory Council with any such affiliation.

(6) The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall submit to Congress an annual report on the activities carried out under this section.

(b) ACCREDITATION.—The Secretary shall, through a public process, recognize one or more accreditation entities for the accreditation of cord blood banks.

(c) INFORMED CONSENT.—The Secretary shall, through a public process, examine issues of informed consent, including—

(1) the appropriate timing of such consent; and

(2) the information provided to the maternal donor regarding all of her medically appropriate cord blood options.

Based on such examination, the Secretary shall require that the standards used by the accreditation entities recognized under subsection (b) ensure that a cord blood unit is acquired with the informed consent of the maternal donor.

(d) FUNCTIONS.—[88]

(1) BONE MARROW FUNCTIONS.—With respect to bone marrow, the Program shall—

(A) operate a system for identifying, matching, and facilitating the distribution of bone marrow that is suitably matched to candidate patients;

(B) consistent with paragraph (3), permit transplant physicians, other appropriate health care professionals, and patients to search by means of electronic access all available bone marrow donors listed in the Program;

(C) carry out a program for the recruitment of bone marrow donors in accordance with subsection (e), including with respect to increasing the representation of racial and ethnic minority groups (including persons of mixed ancestry) in the enrollment of the Program;

(D) maintain and expand medical contingency response capabilities, in coordination with Federal programs, to prepare for and respond effectively to biological, chemical, or radiological attacks, and other public health emergencies that can damage marrow, so that the capability of

[88] Section 5 of Public Law 105–196 (112 Stat. 636) provides as follows:

"SEC. 5. STUDY BY GENERAL ACCOUNTING OFFICE.

"(a) IN GENERAL.—During the period indicated pursuant to subsection (b), the Comptroller General of the United States shall conduct a study of the National Bone Marrow Donor Registry under section 379 of the Public Health Service Act for purposes of making determinations of the following:

"(1) The extent to which, relative to the effective date of this Act, such Registry has increased the representation of racial and ethnic minority groups (including persons of mixed ancestry) among potential donors of bone marrow who are enrolled with the Registry, and whether the extent of increase results in a level of representation that meets the standard established in subsection (c)(1)(A) of such section 379 (as added by section 2(c) of this Act).

"(2) The extent to which patients in need of a transplant of bone marrow from a biologically unrelated donor, and the physicians of such patients, have been utilizing the Registry in the search for such a donor.

"(3) The number of such patients for whom the Registry began a preliminary search but for whom the full search process was not completed, and the reasons underlying such circumstances.

"(4) The extent to which the plan required in section 2(b)(2) of this Act (relating to the relationship between the Registry and donor centers) has been implemented.

"(5) The extent to which the Registry, donor centers, donor registries, collection centers, transplant centers, and other appropriate entities have been complying with the standards, criteria, and procedures under subsection (e) of such section 379 (as redesignated by section 2(c) of this Act).

"(b) REPORT.—A report describing the findings of the study under subsection (a) shall be submitted to the Congress not later than October 1, 2001. The report may not be submitted before January 1, 2001.".

supporting patients with marrow damage from disease can be used to support casualties with marrow damage;

(E) carry out informational and educational activities in accordance with subsection (e);

(F) at least annually update information to account for changes in the status of individuals as potential donors of bone marrow;

(G) provide for a system of patient advocacy through the office established under subsection (h);

(H) provide case management services for any potential donor of bone marrow to whom the Program has provided a notice that the potential donor may be suitably matched to a particular patient through the office established under subsection (h);

(I) with respect to searches for unrelated donors of bone marrow that are conducted through the system under subparagraph (A), collect, analyze, and publish data in a standardized electronic format on the number and percentage of patients at each of the various stages of the search process, including data regarding the furthest stage reached, the number and percentage of patients who are unable to complete the search process, and the reasons underlying such circumstances;

(J) support studies and demonstration and outreach projects for the purpose of increasing the number of individuals who are willing to be marrow donors to ensure a genetically diverse donor pool; and

(K) facilitate research with the appropriate Federal agencies to improve the availability, efficiency, safety, and cost of transplants from unrelated donors and the effectiveness of Program operations.

(2) CORD BLOOD FUNCTIONS.—

(A) IN GENERAL.—With respect to cord blood, the Program shall—

(i)[89] operate a system for identifying, matching, and facilitating the distribution of donated cord blood units that are suitably matched to candidate patients and meet all applicable Federal and State regulations (including informed consent and Food and Drug Administration regulations) from a qualified cord blood bank;

(ii) consistent with paragraph (3), allow transplant physicians, other appropriate health care professionals, and patients to search by means of electronic access all available cord blood units made available through the Program;

(iii) allow transplant physicians and other appropriate health care professionals to reserve, as defined by the Secretary, a cord blood unit for transplantation;

[89] Margin so in law. The amendment by section 2(b)(2)(A)(ii) of Public Law 111–264 redesignates subpargraphs (A)–(H) as clauses (i)–(viii); however, the amendment did not move the margins of such clauses to the right so that it appears indented 6 ems from the left margin (except for clause (iv) which was amended in its entirety by section 2(b)(2)(A)(iii) of such Public Law and as rewritten appears on the correct margin).

(iv) support and expand new and existing studies and demonstration and outreach projects for the purpose of increasing cord blood unit donation and collection from a genetically diverse population and expanding the number of cord blood unit collection sites partnering with cord blood banks receiving a contract under the National Cord Blood Inventory program under section 2 of the Stem Cell Therapeutic and Research Act of 2005, including such studies and projects that focus on—

(I) remote collection of cord blood units, consistent with the requirements under the Program and the National Cord Blood Inventory program goal described in section 2(a) of the Stem Cell Therapeutic and Research Act of 2005; and

(II) exploring novel approaches or incentives to encourage innovative technological advances that could be used to collect cord blood units, consistent with the requirements under the Program and such National Cord Blood Inventory program goal;

(v) provide for a system of patient advocacy through the office established under subsection (h);

(vi) coordinate with the qualified cord blood banks to support informational and educational activities in accordance with subsection (g);

(vii) maintain and expand medical contingency response capabilities, in coordination with Federal programs, to prepare for and respond effectively to biological, chemical, or radiological attacks, and other public health emergencies that can damage marrow, so that the capability of supporting patients with marrow damage from disease can be used to support casualties with marrow damage; and

(viii) with respect to the system under subparagraph (A), collect, analyze, and publish data in a standardized electronic format, as required by the Secretary, on the number and percentage of patients at each of the various stages of the search process, including data regarding the furthest stage reached, the number and percentage of patients who are unable to complete the search process, and the reasons underlying such circumstances.

(B) EFFORTS TO INCREASE COLLECTION OF HIGH QUALITY CORD BLOOD UNITS.—In carrying out subparagraph (A)(iv), not later than 1 year after the date of enactment of the Stem Cell Therapeutic and Research Reauthorization Act of 2010 and annually thereafter, the Secretary shall set an annual goal of increasing collections of high quality cord blood units, consistent with the inventory goal described in section 2(a) of the Stem Cell Therapeutic and Research Act of 2005 (referred to in this subparagraph as the "inventory goal"), and shall identify at least one project under subparagraph (A)(iv) to replicate and expand nationwide, as appropriate. If the Secretary cannot identify a project as described in the preceding sentence, the Sec-

retary shall submit a plan, not later than 180 days after the date on which the Secretary was required to identify such a project, to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives for expanding remote collection of high quality cord blood units, consistent with the requirements under the National Cord Blood Inventory program under section 2 of the Stem Cell Therapeutic and Research Act of 2005 and the inventory goal. Each such plan shall be made available to the public.

(C) DEFINITION.—In this paragraph, the term "remote collection" means the collection of cord blood units at locations that do not have written contracts with cord blood banks for collection support.

(3) SINGLE POINT OF ACCESS; STANDARD DATA.—

(A) SINGLE POINT OF ACCESS.—The Secretary shall ensure that health care professionals and patients are able to search electronically for and facilitate access to, in the manner and to the extent defined by the Secretary and consistent with the functions described in paragraphs (1)(A) and (2)(A)(i), cells from bone marrow donors and cord blood units through a single point of access.

(B) STANDARD DATA.—The Secretary shall require all recipients of contracts under this section to make available a standard dataset for purposes of subparagraph (A) in a standardized electronic format that enables transplant physicians to compare among and between bone marrow donors and cord blood units to ensure the best possible match for the patient.

(4) DEFINITION.—The term "qualified cord blood bank" means a cord blood bank that—

(A) has obtained all applicable Federal and State licenses, certifications, registrations (including pursuant to the regulations of the Food and Drug Administration), and other authorizations required to operate and maintain a cord blood bank;

(B) has implemented donor screening, cord blood collection practices, and processing methods intended to protect the health and safety of donors and transplant recipients to improve transplant outcomes, including with respect to the transmission of potentially harmful infections and other diseases;

(C) is accredited by an accreditation entity recognized by the Secretary under subsection (b);

(D) has established a system of strict confidentiality to protect the identity and privacy of patients and donors in accordance with existing Federal and State law;

(E) has established a system for encouraging donation by a genetically diverse group of donors; and

(F) has established a system to confidentially maintain linkage between a cord blood unit and a maternal donor.

(e) BONE MARROW RECRUITMENT; PRIORITIES; INFORMATION AND EDUCATION.—

(1) RECRUITMENT; PRIORITIES.—The Program shall carry out activities for the recruitment of bone marrow donors. Such recruitment program shall identify populations that are underrepresented among potential donors enrolled with the Program. In the case of populations that are identified under the preceding sentence:

(A) The Program shall give priority to carrying out activities under this part to increase representation for such populations in order to enable a member of such a population, to the extent practicable, to have a probability of finding a suitable unrelated donor that is comparable to the probability that an individual who is not a member of an underrepresented population would have.

(B) The Program shall consider racial and ethnic minority groups (including persons of mixed ancestry) to be populations that have been identified for purposes of this paragraph, and shall carry out subparagraph (A) with respect to such populations.

(2) INFORMATION AND EDUCATION REGARDING RECRUITMENT; TESTING AND ENROLLMENT.—

(A) IN GENERAL.—The Program shall carry out informational and educational activities, in coordination with organ donation public awareness campaigns operated through the Department of Health and Human Services, for purposes of recruiting individuals to serve as donors of bone marrow, and shall test and enroll with the Program potential bone marrow donors. Such information and educational activities shall include the following:

(i) Making information available to the general public, including information describing the needs of patients with respect to donors of bone marrow.

(ii) Educating and providing information to individuals who are willing to serve as potential bone marrow donors.

(iii) Training individuals in requesting individuals to serve as potential bone marrow donors.

(B) PRIORITIES.—In carrying out informational and educational activities under subparagraph (A), the Program shall give priority to recruiting individuals to serve as donors of bone marrow for populations that are identified under paragraph (1).

(3) TRANSPLANTATION AS TREATMENT OPTION.—In addition to activities regarding recruitment, the recruitment program under paragraph (1) shall provide information to physicians, other health care professionals, and the public regarding bone marrow transplants from unrelated donors as a treatment option.

(4) IMPLEMENTATION OF SUBSECTION.—The requirements of this subsection shall be carried out by the entity that has been awarded a contract by the Secretary under subsection (a) to carry out the functions described in subsection (d)(1).

(f) BONE MARROW CRITERIA, STANDARDS, AND PROCEDURES.—The Secretary shall enforce, for participating entities, including the

Program, individual marrow donor centers, marrow donor registries, marrow collection centers, and marrow transplant centers—

(1) quality standards and standards for tissue typing, obtaining the informed consent of donors, and providing patient advocacy;

(2) donor selection criteria, based on established medical criteria, to protect both the donor and the recipient and to prevent the transmission of potentially harmful infectious diseases such as the viruses that cause hepatitis and the etiologic agent for Acquired Immune Deficiency Syndrome;

(3) procedures to ensure the proper collection and transportation of the marrow;

(4) standards for the system for patient advocacy operated under subsection (h), including standards requiring the provision of appropriate information (at the start of the search process and throughout the process) to patients and their families and physicians;

(5) standards that—

(A) require the establishment of a system of strict confidentiality to protect the identity and privacy of patients and donors in accordance with Federal and State law; and

(B) prescribe the purposes for which the records described in subparagraph (A) may be disclosed, and the circumstances and extent of the disclosure; and

(6) in the case of a marrow donor center or marrow donor registry participating in the program, procedures to ensure the establishment of a method for integrating donor files, searches, and general procedures of the center or registry with the Program.

(g) CORD BLOOD RECRUITMENT; PRIORITIES; INFORMATION AND EDUCATION.—

(1) RECRUITMENT; PRIORITIES.—The Program shall support activities, in cooperation with qualified cord blood banks, for the recruitment of cord blood donors. Such recruitment program shall identify populations that are underrepresented among cord blood donors. In the case of populations that are identified under the preceding sentence:

(A) The Program shall give priority to supporting activities under this part to increase representation for such populations in order to enable a member of such a population, to the extent practicable, to have a probability of finding a suitable cord blood unit that is comparable to the probability that an individual who is not a member of an underrepresented population would have.

(B) The Program shall consider racial and ethnic minority groups (including persons of mixed ancestry) to be populations that have been identified for purposes of this paragraph, and shall support activities under subparagraph (A) with respect to such populations.

(2) INFORMATION AND EDUCATION REGARDING RECRUITMENT; TESTING AND DONATION.—

(A) IN GENERAL.—In carrying out the recruitment program under paragraph (1), the Program shall support informational and educational activities in coordination with

qualified cord blood banks and organ donation public awareness campaigns operated through the Department of Health and Human Services, for purposes of recruiting pregnant women to serve as donors of cord blood. Such information and educational activities shall include the following:

(i) Making information available to the general public, including information describing the needs of patients with respect to cord blood units.

(ii) Educating and providing information to pregnant women who are willing to donate cord blood units.

(iii) Training individuals in requesting pregnant women to serve as cord blood donors.

(B) PRIORITIES.—In carrying out informational and educational activities under subparagraph (A), the Program shall give priority to supporting the recruitment of pregnant women to serve as donors of cord blood for populations that are identified under paragraph (1).

(3) TRANSPLANTATION AS TREATMENT OPTION.—In addition to activities regarding recruitment, the recruitment program under paragraph (1) shall provide information to physicians, other health care professionals, and the public regarding cord blood transplants from donors as a treatment option.

(4) IMPLEMENTATION OF SUBSECTION.—The requirements of this subsection shall be carried out by the entity that has been awarded a contract by the Secretary under subsection (a) to carry out the functions described in subsection (d)(2).

(h) PATIENT ADVOCACY AND CASE MANAGEMENT FOR BONE MARROW AND CORD BLOOD.—

(1) IN GENERAL.—The Secretary shall establish and maintain, through a contract or other means determined appropriate by the Secretary, an office of patient advocacy (in this subsection referred to as the "Office").

(2) GENERAL FUNCTIONS.—The Office shall meet the following requirements:

(A) The Office shall be headed by a director.

(B) The Office shall be staffed by individuals with expertise in bone marrow and cord blood therapy covered under the Program.

(C) The Office shall operate a system for patient advocacy, which shall be separate from mechanisms for donor advocacy, and which shall serve patients for whom the Program is conducting, or has been requested to conduct, a search for a bone marrow donor or cord blood unit.

(D) In the case of such a patient, the Office shall serve as an advocate for the patient by directly providing to the patient (or family members, physicians, or other individuals acting on behalf of the patient) individualized services with respect to efficiently utilizing the system under paragraphs (1) and (2) of subsection (d) to conduct an ongoing search for a bone marrow donor or cord blood unit and assist with information regarding third party payor matters.

(E) In carrying out subparagraph (D), the Office shall monitor the system under paragraphs (1) and (2) of subsection (d) to determine whether the search needs of the patient involved are being met, including with respect to the following:

(i) Periodically providing to the patient (or an individual acting on behalf of the patient) information regarding bone marrow donors or cord blood units that are suitably matched to the patient, and other information regarding the progress being made in the search.

(ii) Informing the patient (or such other individual) if the search has been interrupted or discontinued.

(iii) Identifying and resolving problems in the search, to the extent practicable.

(F) The Office shall ensure that the following data are made available to patients:

(i) The resources available through the Program.

(ii) A comparison of transplant centers regarding search and other costs that prior to transplantation are charged to patients by transplant centers.

(iii) The post-transplant outcomes for individual transplant centers.

(iv) Information concerning issues that patients may face after a transplant.

(v) Such other information as the Program determines to be appropriate.

(G) The Office shall conduct surveys of patients (or family members, physicians, or other individuals acting on behalf of patients) to determine the extent of satisfaction with the system for patient advocacy under this subsection, and to identify ways in which the system can be improved to best meet the needs of patients.

(3) CASE MANAGEMENT.—

(A) IN GENERAL.—In serving as an advocate for a patient under paragraph (2), the Office shall provide individualized case management services directly to the patient (or family members, physicians, or other individuals acting on behalf of the patient), including—

(i) individualized case assessment; and

(ii) the functions described in paragraph (2)(D) (relating to progress in the search process).

(B) POSTSEARCH FUNCTIONS.—In addition to the case management services described in paragraph (1) for patients, the Office shall, on behalf of patients who have completed the search for a bone marrow donor or cord blood unit, provide information and education on the process of receiving a transplant, including the post-transplant process.

(i) COMMENT PROCEDURES.—The Secretary shall establish and provide information to the public on procedures under which the Secretary shall receive and consider comments from interested persons relating to the manner in which the Program is carrying out

the duties of the Program. The Secretary may promulgate regulations under this section.

(j) CONSULTATION.—In developing policies affecting the Program, the Secretary shall consult with the Advisory Council, the Department of Defense Marrow Donor Recruitment and Research Program operated by the Department of the Navy, and the board of directors of each entity awarded a contract under this section.

(k) CONTRACTS.—

(1) APPLICATION.—To be eligible to enter into a contract under this section, an entity shall submit to the Secretary and obtain approval of an application at such time, in such manner, and containing such information as the Secretary shall by regulation prescribe.

(2) CONSIDERATIONS.—In awarding contracts under this section, the Secretary shall give consideration to the continued safety of donors and patients and other factors deemed appropriate by the Secretary.

(l) ELIGIBILITY.—Entities eligible to receive a contract under this section shall include private nonprofit entities.

(m) RECORDS.—

(1) RECORDKEEPING.—Each recipient of a contract or subcontract under subsection (a) shall keep such records as the Secretary shall prescribe, including records that fully disclose the amount and disposition by the recipient of the proceeds of the contract, the total cost of the undertaking in connection with which the contract was made, and the amount of the portion of the cost of the undertaking supplied by other sources, and such other records as will facilitate an effective audit.

(2) EXAMINATION OF RECORDS.—The Secretary and the Comptroller General of the United States shall have access to any books, documents, papers, and records of the recipient of a contract or subcontract entered into under this section that are pertinent to the contract, for the purpose of conducting audits and examinations.

(n) PENALTIES FOR DISCLOSURE.—Any person who discloses the content of any record referred to in subsection (d)(4)(D) or (f)(5)(A) without the prior written consent of the donor or potential donor with respect to whom the record is maintained, or in violation of the standards described in subsection (f)(5)(B), shall be imprisoned for not more than 2 years or fined in accordance with title 18, United States Code, or both.

SEC. 379A.[274l] STEM CELL THERAPEUTIC OUTCOMES DATABASE.

(a) ESTABLISHMENT.—The Secretary shall by contract establish and maintain a scientific database of information relating to patients who have been recipients of a stem cell therapeutics product (including bone marrow, cord blood, or other such product) from a donor.

(b) INFORMATION.—The outcomes database shall include information in a standardized electronic format with respect to patients described in subsection (a), diagnosis, transplant procedures, results, long-term follow-up, and such other information as the Secretary determines to be appropriate, to conduct an ongoing evalua-

tion of the scientific and clinical status of transplantation involving recipients of a stem cell therapeutics product from a donor.

(c) ANNUAL REPORT ON PATIENT OUTCOMES.—The Secretary shall require the entity awarded a contract under this section to submit to the Secretary an annual report concerning patient outcomes with respect to each transplant center, based on data collected and maintained by the entity pursuant to this section.

(d) PUBLICLY AVAILABLE DATA.—The outcomes database shall make relevant scientific information not containing individually identifiable information available to the public in the form of summaries and data sets to encourage medical research and to provide information to transplant programs, physicians, patients, entities awarded a contract under section 379 donor registries, and cord blood banks.

SEC. 379A–1.[274l–1] DEFINITIONS.

In this part:

(1) The term "Advisory Council" means the advisory council established by the Secretary under section 379(a)(1).

(2) The term "bone marrow" means the cells found in adult bone marrow and peripheral blood.

(3) The term "outcomes database" means the database established by the Secretary under section 379A.

(4) The term "Program" means the C.W. Bill Young Cell Transplantation Program established under section 379.

SEC. 379B.[274m] AUTHORIZATION OF APPROPRIATIONS.

For the purpose of carrying out this part, there are authorized to be appropriated $30,000,000 for each of fiscal years 2011 through 2014 and $33,000,000 for fiscal year 2015.

PART J—PREVENTION AND CONTROL OF INJURIES

RESEARCH.

SEC. 391.[280b] (a) The Secretary, through the Director of the Centers for Disease Control and Prevention, shall—

(1) conduct, and give assistance to public and nonprofit private entities, scientific institutions, and individuals engaged in the conduct of, research relating to the causes, mechanisms, prevention, diagnosis, treatment of injuries, and rehabilitation from injuries;

(2) make grants to, or enter into cooperative agreements or contracts with, public and nonprofit private entities (including academic institutions, hospitals, and laboratories) and individuals for the conduct of such research; and

(3) make grants to, or enter into cooperative agreements or contracts with, academic institutions for the purpose of providing training on the causes, mechanisms, prevention, diagnosis, treatment of injuries, and rehabilitation from injuries.

(b) The Secretary, through the Director of the Centers for Disease Control and Prevention, shall collect and disseminate, through publications and other appropriate means, information concerning the practical applications of research conducted or assisted under subsection (a). In carrying out the preceding sentence, the Sec-

retary shall disseminate such information to the public, including through elementary and secondary schools.

PREVENTION AND CONTROL ACTIVITIES.

SEC. 392.[280b–1] (a) The Secretary, through the Director of the Centers for Disease Control and Prevention, shall—

(1) assist States and political subdivisions of States in activities for the prevention and control of injuries; and

(2) encourage regional activities between States designed to reduce injury rates.

(b) The Secretary, through the Director of the Centers for Disease Control and Prevention, may—

(1) enter into agreements between the Service and public and private community health agencies which provide for cooperative planning of activities to deal with problems relating to the prevention and control of injuries;

(2) work in cooperation with other Federal agencies, and with public and nonprofit private entities, to promote activities regarding the prevention and control of injuries; and

(3) make grants to States and, after consultation with State health agencies, to other public or nonprofit private entities for the purpose of carrying out demonstration projects for the prevention and control of injuries at sites that are not subject to the Occupational Safety and Health Act of 1970, including homes, elementary and secondary schools, and public buildings.

INTERPERSONAL VIOLENCE WITHIN FAMILIES AND AMONG ACQUAINTANCES.

SEC. 393.[280b–1a] (a) With respect to activities that are authorized in sections 391 and 392, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall carry out such activities with respect to interpersonal violence within families and among acquaintances. Activities authorized in the preceding sentence include the following:

(1) Collecting data relating to the incidence of such violence.

(2) Making grants to public and nonprofit private entities for the evaluation of programs whose purpose is to prevent such violence, including the evaluation of demonstration projects under paragraph (6).

(3) Making grants to public and nonprofit private entities for the conduct of research on identifying effective strategies for preventing such violence.

(4) Providing to the public information and education on such violence, including information and education to increase awareness of the public health consequences of such violence.

(5) Training health care providers as follows:

(A) To identify individuals whose medical conditions or statements indicate that the individuals are victims of such violence.

(B) To routinely determine, in examining patients, whether the medical conditions or statements of the patients so indicate.

(C) To refer individuals so identified to entities that provide services regarding such violence, including referrals for counseling, housing, legal services, and services of community organizations.

(6) Making grants to public and nonprofit private entities for demonstration projects with respect to such violence, including with respect to prevention.

(b) For purposes of this part, the term "interpersonal violence within families and among acquaintances" includes behavior commonly referred to as domestic violence, sexual assault, spousal abuse, woman battering, partner abuse, elder abuse, and acquaintance rape.

SEC. 393A.[280b–1b] USE OF ALLOTMENTS FOR RAPE PREVENTION EDUCATION.

(a) PERMITTED USE.—The Secretary, acting through the National Center for Injury Prevention and Control at the Centers for Disease Control and Prevention, shall award targeted grants to States to be used for rape prevention and education programs conducted by rape crisis centers, State, territorial or tribal sexual assault coalitions, and other public and private nonprofit entities for—

(1) educational seminars;

(2) the operation of hotlines;

(3) training programs for professionals;

(4) the preparation of informational material;

(5) education and training programs for students and campus personnel designed to reduce the incidence of sexual assault at colleges and universities;

(6) education to increase awareness about drugs and alcohol used to facilitate rapes or sexual assaults; and

(7) other efforts to increase awareness of the facts about, or to help prevent, sexual assault, including efforts to increase awareness in underserved communities and awareness among individuals with disabilities (as defined in section 3 of the Americans with Disabilities Act of 1990 (42 U.S.C. 12102)).

(b) COLLECTION AND DISSEMINATION OF INFORMATION ON SEXUAL ASSAULT.—The Secretary shall, through the National Resource Center on Sexual Assault established under the National Center for Injury Prevention and Control at the Centers for Disease Control and Prevention, provide resource information, policy, training, and technical assistance to Federal, State, local, and Indian tribal agencies, as well as to State sexual assault coalitions and local sexual assault programs and to other professionals and interested parties on issues relating to sexual assault, including maintenance of a central resource library in order to collect, prepare, analyze, and disseminate information and statistics and analyses thereof relating to the incidence and prevention of sexual assault.

(c) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—There is authorized to be appropriated to carry out this section $50,000,000 for each of fiscal years 2014 through 2018.

(2) NATIONAL SEXUAL VIOLENCE RESOURCE CENTER ALLOTMENT.—Of the total amount made available under this subsection in each fiscal year, not less than $1,500,000 shall be available for allotment under subsection (b).

(3) BASELINE FUNDING FOR STATES, THE DISTRICT OF COLUMBIA, AND PUERTO RICO.—A minimum allocation of $150,000 shall be awarded in each fiscal year for each of the States, the District of Columbia, and Puerto Rico. A minimum allocation of $35,000 shall be awarded in each fiscal year for each Territory. Any unused or remaining funds shall be allotted to each State, the District of Columbia, and Puerto Rico on the basis of population.

(d) LIMITATIONS.—

(1) SUPPLEMENT NOT SUPPLANT.—Amounts provided to States under this section shall be used to supplement and not supplant other Federal, State, and local public funds expended to provide services of the type described in subsection (a).

(2) STUDIES.—A State may not use more than 2 percent of the amount received by the State under this section for each fiscal year for surveillance studies or prevalence studies.

(3) ADMINISTRATION.—A State may not use more than 5 percent of the amount received by the State under this section for each fiscal year for administrative expenses.

PREVENTION OF TRAUMATIC BRAIN INJURY.

SEC. 393B.[280b–1c] (a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may carry out projects to reduce the incidence of traumatic brain injury. Such projects may be carried out by the Secretary directly or through awards of grants or contracts to public or nonprofit private entities. The Secretary may directly or through such awards provide technical assistance with respect to the planning, development, and operation of such projects.

(b) CERTAIN ACTIVITIES.—Activities under subsection (a) may include—

(1) the conduct of research into identifying effective strategies for the prevention of traumatic brain injury;

(2) the implementation of public information and education programs for the prevention of such injury and for broadening the awareness of the public concerning the public health consequences of such injury; and

(3) the implementation of a national education and awareness campaign regarding such injury (in conjunction with the program of the Secretary regarding health-status goals for 2010, commonly referred to as Healthy People 2010), including—

(A) the national dissemination of information on—

(i) incidence and prevalence; and

(ii) information relating to traumatic brain injury and the sequelae of secondary conditions arising from traumatic brain injury upon discharge from hospitals and emergency departments; and

(B) the provision of information in primary care settings, including emergency rooms and trauma centers, concerning the availability of State level services and resources.

(c) COORDINATION OF ACTIVITIES.—The Secretary shall ensure that activities under this section are coordinated as appropriate with other agencies of the Public Health Service that carry out activities regarding traumatic brain injury.

(d) DEFINITION.—For purposes of this section, the term "traumatic brain injury" means an acquired injury to the brain. Such term does not include brain dysfunction caused by congenital or degenerative disorders, nor birth trauma, but may include brain injuries caused by anoxia due to trauma. The Secretary may revise the definition of such term as the Secretary determines necessary, after consultation with States and other appropriate public or nonprofit private entities.

NATIONAL PROGRAM FOR TRAUMATIC BRAIN INJURY SURVEILLANCE AND REGISTRIES.

SEC. 393C.[90] **[**280b–1d**]** (a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make grants to States or their designees to develop or operate the State's traumatic brain injury surveillance system or registry to determine the incidence and prevalence of traumatic brain injury and related disability, to ensure the uniformity of reporting under such system or registry, to link individuals with traumatic brain injury to services and supports, and to link such individuals with academic institutions to conduct applied research that will support the development of such surveillance systems and registries as may be necessary. A surveillance system or registry under this section shall provide for the collection of data concerning—

(1) demographic information about each traumatic brain injury;

(2) information about the circumstances surrounding the injury event associated with each traumatic brain injury;

(3) administrative information about the source of the collected information, dates of hospitalization and treatment, and the date of injury; and

(4) information characterizing the clinical aspects of the traumatic brain injury, including the severity of the injury, outcomes of the injury, the types of treatments received, and the types of services utilized.

(b) Not later than 18 months after the date of enactment of the Traumatic Brain Injury Act of 2008, the Secretary, acting through the Director of the Centers for Disease Control and Prevention and the Director of the National Institutes of Health and in consultation with the Secretary of Defense and the Secretary of Veterans Affairs, shall submit to the relevant committees of Congress a report that contains the findings derived from an evaluation con-

[90] The amendment by section 2(3) of Public Law 110–206 to redesignate section 393B (relating to traumatic brain injury registeries) as section 393C could not be executed because such section had already been redesignated as section 393C by section 2(1) of Public Law 110–202.

cerning activities and procedures that can be implemented by the Centers for Disease Control and Prevention to improve the collection and dissemination of compatible epidemiological studies on the incidence and prevalence of traumatic brain injury in individuals who were formerly in the military. The report shall include recommendations on the manner in which such agencies can further collaborate on the development and improvement of traumatic brain injury diagnostic tools and treatments.

SEC. 393C–1.[280b–1e] STUDY ON TRAUMATIC BRAIN INJURY.

(a) STUDY.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention with respect to paragraph (1) and in consultation with the Director of the National Institutes of Health and other appropriate entities with respect to paragraphs (2), (3), and (4), may conduct a study with respect to traumatic brain injury for the purpose of carrying out the following:

(1) In collaboration with appropriate State and local health-related agencies—

(A) determining the incidence of traumatic brain injury and prevalence of traumatic brain injury related disability and the clinical aspects of the disability in all age groups and racial and ethnic minority groups in the general population of the United States, including institutional settings, such as nursing homes, correctional facilities, psychiatric hospitals, child care facilities, and residential institutes for people with developmental disabilities; and

(B) reporting national trends in traumatic brain injury.

(2) Identifying common therapeutic interventions which are used for the rehabilitation of individuals with such injuries, and, subject to the availability of information, including an analysis of—

(A) the effectiveness of each such intervention in improving the functioning, including return to work or school and community participation, of individuals with brain injuries;

(B) the comparative effectiveness of interventions employed in the course of rehabilitation of individuals with brain injuries to achieve the same or similar clinical outcome; and

(C) the adequacy of existing measures of outcomes and knowledge of factors influencing differential outcomes.

(3) Identifying interventions and therapies that can prevent or remediate the development of secondary neurologic conditions related to traumatic brain injury.

(4) Developing practice guidelines for the rehabilitation of traumatic brain injury at such time as appropriate scientific research becomes available.

(b) DATES CERTAIN FOR REPORTS.—If the study is conducted under subsection (a), the Secretary shall, not later than 3 years after the date of the enactment of the Traumatic Brain Injury Act

of 2008, submit to Congress a report describing findings made as a result of carrying out such subsection (a).

(c) DEFINITION.—For purposes of this section, the term "traumatic brain injury" means an acquired injury to the brain. Such term does not include brain dysfunction caused by congenital or degenerative disorders, nor birth trauma, but may include brain injuries caused by anoxia due to trauma including near drowning. The Secretary may revise the definition of such term as the Secretary determines necessary.

SEC. 393D.[28b–1f] PREVENTION OF FALLS AMONG OLDER ADULTS.

(a) PUBLIC EDUCATION.—The Secretary may—

(1) oversee and support a national education campaign to be carried out by a nonprofit organization with experience in designing and implementing national injury prevention programs, that is directed principally to older adults, their families, and health care providers, and that focuses on reducing falls among older adults and preventing repeat falls; and

(2) award grants, contracts, or cooperative agreements to qualified organizations, institutions, or consortia of qualified organizations and institutions, specializing, or demonstrating expertise, in falls or fall prevention, for the purpose of organizing State-level coalitions of appropriate State and local agencies, safety, health, senior citizen, and other organizations to design and carry out local education campaigns, focusing on reducing falls among older adults and preventing repeat falls.

(b) RESEARCH.—

(1) IN GENERAL.—The Secretary may—

(A) conduct and support research to—

(i) improve the identification of older adults who have a high risk of falling;

(ii) improve data collection and analysis to identify fall risk and protective factors;

(iii) design, implement, and evaluate the most effective fall prevention interventions;

(iv) improve strategies that are proven to be effective in reducing falls by tailoring these strategies to specific populations of older adults;

(v) conduct research in order to maximize the dissemination of proven, effective fall prevention interventions;

(vi) intensify proven interventions to prevent falls among older adults;

(vii) improve the diagnosis, treatment, and rehabilitation of elderly fall victims and older adults at high risk for falls; and

(viii) assess the risk of falls occurring in various settings;

(B) conduct research concerning barriers to the adoption of proven interventions with respect to the prevention of falls among older adults;

(C) conduct research to develop, implement, and evaluate the most effective approaches to reducing falls among

high-risk older adults living in communities and long-term care and assisted living facilities; and

(D) evaluate the effectiveness of community programs designed to prevent falls among older adults.

(2) EDUCATIONAL SUPPORT.—The Secretary, either directly or through awarding grants, contracts, or cooperative agreements to qualified organizations, institutions, or consortia of qualified organizations and institutions, specializing, or demonstrating expertise, in falls or fall prevention, may provide professional education for physicians and allied health professionals, and aging service providers in fall prevention, evaluation, and management.

(c) DEMONSTRATION PROJECTS.—The Secretary may carry out the following:

(1) Oversee and support demonstration and research projects to be carried out by qualified organizations, institutions, or consortia of qualified organizations and institutions, specializing, or demonstrating expertise, in falls or fall prevention, in the following areas:

(A) A multistate demonstration project assessing the utility of targeted fall risk screening and referral programs.

(B) Programs designed for community-dwelling older adults that utilize multicomponent fall intervention approaches, including physical activity, medication assessment and reduction when possible, vision enhancement, and home modification strategies.

(C) Programs that are targeted to new fall victims who are at a high risk for second falls and which are designed to maximize independence and quality of life for older adults, particularly those older adults with functional limitations.

(D) Private sector and public-private partnerships to develop technologies to prevent falls among older adults and prevent or reduce injuries if falls occur.

(2)(A) Award grants, contracts, or cooperative agreements to qualified organizations, institutions, or consortia of qualified organizations and institutions, specializing, or demonstrating expertise, in falls or fall prevention, to design, implement, and evaluate fall prevention programs using proven intervention strategies in residential and institutional settings.

(B) Award 1 or more grants, contracts, or cooperative agreements to 1 or more qualified organizations, institutions, or consortia of qualified organizations and institutions, specializing, or demonstrating expertise, in falls or fall prevention, in order to carry out a multistate demonstration project to implement and evaluate fall prevention programs using proven intervention strategies designed for single and multifamily residential settings with high concentrations of older adults, including—

(i) identifying high-risk populations;

(ii) evaluating residential facilities;

(iii) conducting screening to identify high-risk individuals;

(iv) providing fall assessment and risk reduction interventions and counseling;

(v) coordinating services with health care and social service providers; and

(vi) coordinating post-fall treatment and rehabilitation.

(3) Award 1 or more grants, contracts, or cooperative agreements to qualified organizations, institutions, or consortia of qualified organizations and institutions, specializing, or demonstrating expertise, in falls or fall prevention, to conduct evaluations of the effectiveness of the demonstration projects described in this subsection.

(d) PRIORITY.—In awarding grants, contracts, or cooperative agreements under this section, the Secretary may give priority to entities that explore the use of cost-sharing with respect to activities funded under the grant, contract, or agreement to ensure the institutional commitment of the recipients of such assistance to the projects funded under the grant, contract, or agreement. Such non-Federal cost sharing contributions may be provided directly or through donations from public or private entities and may be in cash or in-kind, fairly evaluated, including plant, equipment, or services.

(e) STUDY OF EFFECTS OF FALLS ON HEALTH CARE COSTS.—

(1) IN GENERAL.—The Secretary may conduct a review of the effects of falls on health care costs, the potential for reducing falls, and the most effective strategies for reducing health care costs associated with falls.

(2) REPORT.—If the Secretary conducts the review under paragraph (1), the Secretary shall, not later than 36 months after the date of enactment of the Safety of Seniors Act of 2007, submit to Congress a report describing the findings of the Secretary in conducting such review.

GENERAL PROVISIONS.

SEC. 394.[280b–2] (a) The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish an advisory committee to advise the Secretary and such Director with respect to the prevention and control of injuries.

(b) The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may provide technical assistance to public and nonprofit private entities with respect to the planning, development, and operation of any program or service carried out pursuant to this part. The Secretary may provide such technical assistance directly or through grants or contracts.

(c) Not later than February 1 of 1995 and of every second year thereafter, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report describing the activities carried out under this part during the preceding 2 fiscal years. Such report shall include a description of such activities that were carried out with respect to interpersonal violence within families and among acquaintances and with respect to rural areas.

AUTHORIZATIONS OF APPROPRIATIONS.

SEC. 394A.[280b–3] For the purpose of carrying out this part, there are authorized to be appropriated $50,000,000 for fiscal year 1994, and[91] such sums as may be necessary for each of the fiscal years 1995 through 1998, and such sums as may be necessary for each of the fiscal years 2001 through 2005..

PART K—HEALTH CARE SERVICES IN THE HOME

Subpart I—Grants for Demonstration Projects

SEC. 395.[280c] ESTABLISHMENT OF PROGRAM.

(a) IN GENERAL.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall make not less than 5, and not more than 20, grants to States for the purpose of assisting grantees in carrying out demonstration projects—

(1) to identify low-income individuals who can avoid institutionalization or prolonged hospitalization if[92] skilled nursing care services, homemaker or home health aide services, or personal care services are provided in the homes of the individuals;

(2) to pay the costs of the provision of such services in the homes of such individuals; and

(3) to coordinate the provision by public and private entities of such services, and other long-term care services, in the homes of such individuals.

(b) REQUIREMENT WITH RESPECT TO AGE OF RECIPIENTS OF SERVICES.—The Secretary may not make a grant under subsection (a) to a State unless the State agrees to ensure that—

(1) not less than 25 percent of the grant is expended to provide services under such subsection to individuals who are not less than 65 years of age; and

(2) of the portion of the grant reserved by the State for purposes of complying with paragraph (1), not less than 10 percent is expended to provide such services to individuals who are not less than 85 years of age.

(c) RELATIONSHIP TO ITEMS AND SERVICES UNDER OTHER PROGRAMS.—A State may not make payments from a grant under subsection (a) for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to such item or service—

(1) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program; or

[91] So in law. Section 1306 of Public Law 106–310 (114 Stat. 1143) attempts to strike "and", but the amendment cannot be executed because the instructions were to strike "and" after "1994". (The word "and" appears after "1994,", not "1994".) Such section 1306 also added the superfluous period.

[92] Section 2(f) of Public Law 102–108 (105 Stat. 550) provides as follows: "(f) PUBLIC HEALTH SERVICE ACT TECHNICAL AMENDMENTS.—Section 395. [280c](a)(1) after the word 'if' insert the words 'skilled medical services,' ". The text of such section 2(f) does not provide sufficient amendatory instructions to execute an amendment. The apparent intent of the Congress was to amend section 395(a)(1) of the Public Health Service Act (42 U.S.C. 280c(a)(1)).

(2) by an entity that provides health services on a prepaid basis.

SEC. 396.[280c–1] LIMITATION ON DURATION OF GRANT AND REQUIREMENT OF MATCHING FUNDS.

(a) LIMITATION ON DURATION OF GRANT.—The period during which payments are made to a State from a grant under section 395(a) may not exceed 3 years. Such payments shall be subject to annual evaluation by the Secretary.

(b) REQUIREMENT OF MATCHING FUNDS.—

(1)(A) For the first year of payments to a State from a grant under section 395(a), the Secretary may not make such payments in an amount exceeding 75 percent of the costs of services to be provided by the State pursuant to such section.

(B) For the second year of such payments to a State, the Secretary may not make such payments in an amount exceeding 65 percent of the costs of such services.

(C) For the third year of such payments to a State, the Secretary may not make such payments in an amount exceeding 55 percent of the costs of such services.

(2) The Secretary may not make a grant under section 395(a) to a State unless the State agrees to make available, directly or through donations from public or private entities, non-Federal contributions toward the costs of services to be provided pursuant to such section in an amount equal to—

(A) for the first year of payments to the State from the grant, not less than $25 (in cash or in kind under subsection (c)) for each $75 of Federal funds provided in the grant;

(B) for the second year of such payments to the State, not less than $35 (in cash or in kind under subsection (c)) for each $65 of such Federal funds; and

(C) for the third year of such payments to the State, not less than $45 (in cash or in kind under subsection (c)) for each $55 of such Federal funds.

(c) DETERMINATION OF AMOUNT OF NON-FEDERAL CONTRIBUTION.—Non-Federal contributions required in subsection (b) may be in cash or in kind, fairly evaluated, including plant, equipment, or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

SEC. 397.[280c–2] GENERAL PROVISIONS.

(a) LIMITATION ON ADMINISTRATIVE EXPENSES.—The Secretary may not make a grant under section 395(a) to a State unless the State agrees that not more than 10 percent of the grant will be expended for administrative expenses with respect to the grant.

(b) DESCRIPTION OF INTENDED USE OF GRANT.—The Secretary may not make a grant under section 395(a) to a State unless—

(1) the State submits to the Secretary a description of the purposes for which the State intends to expend the grant; and

(2) such description provides information relating to the programs and activities to be supported and services to be provided, including—

(A) the number of individuals who will receive services pursuant to section 395(a) and the average costs of providing such services to each such individual; and

(B) a description of the manner in which such programs and activities will be coordinated with any similar programs and activities of public and private entities.

(c) REQUIREMENT OF APPLICATION.—The Secretary may not make a grant under section 395(a) to a State unless the State has submitted to the Secretary an application for the grant. The application shall—

(1) contain the description of intended expenditures required in subsection (b);

(2) with respect to carrying out the purpose for which the grant is to be made, provide assurances of compliance satisfactory to the Secretary; and

(3) otherwise be in such form, be made in such manner, and contain such information and agreements as the Secretary determines to be necessary to carry out this subpart.

(d) EVALUATIONS AND REPORT BY SECRETARY.—The Secretary shall—

(1) provide for an evaluation of each demonstration project for which a grant is made under section 395(a); and

(2) not later than 6 months after the completion of such evaluations, submit to the Congress a report describing the findings made as a result of the evaluations.

(e) AUTHORIZATIONS OF APPROPRIATIONS.—For the purpose of carrying out this subpart, there are authorized to be appropriated $5,000,000 for each of the fiscal years 1988 through 1990, $7,500,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 and 1993.

Subpart II—Grants for Demonstrations Projects With Respect to Alzheimer's Disease

SEC. 398.[280c–3] ESTABLISHMENT OF PROGRAM.

(a) IN GENERAL.—The Secretary shall make grants to States for the purpose of assisting grantees in carrying out demonstration projects for planning, establishing, and operating programs—

(1) to coordinate the development and operation with public and private organizations of diagnostic, treatment, care management, respite care, legal counseling, and education services provided within the State to individuals with Alzheimer's disease or related disorders and to the families and care providers of such individuals;

(2) to provide home health care, personal care, day care, companion services, short-term care in health facilities, and other respite care to individuals with Alzheimer's disease or related disorders who are living in single family homes or in congregate settings;

(3) to improve the access of such individuals to home-based or community-based long-term care services (subject to the services being provided by entities that were providing such services in the State involved as of October 1, 1995), particularly such individuals who are members of racial or ethnic mi-

nority groups, who have limited proficiency in speaking the English language, or who live in rural areas; and

(4) to provide to health care providers, to individuals with Alzheimer's disease or related disorders, to the families of such individuals, to organizations established for such individuals and such families, and to the general public, information with respect to—

(A) diagnostic services, treatment services, and related services available to such individuals and to the families of such individuals;

(B) sources of assistance in obtaining such services, including assistance under entitlement programs; and

(C) the legal rights of such individuals and such families.

(b) REQUIREMENT WITH RESPECT TO CERTAIN EXPENDITURES.—The Secretary may not make a grant under subsection (a) to a State unless the State agrees to expend not less than 50 percent of the grant for the provision of services described in subsection (a)(2).

(c) RELATIONSHIP TO ITEMS AND SERVICES UNDER OTHER PROGRAMS.—A State may not make payments from a grant under subsection (a) for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to such item or service—

(1) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program; or

(2) by an entity that provides health services on a prepaid basis.

SEC. 398A.[280c–4] REQUIREMENT OF MATCHING FUNDS[93].

(a) REQUIREMENT OF MATCHING FUNDS.—

(1)(A) For the first year of payments to a State from a grant under section 398(a), the Secretary may not make such payments in an amount exceeding 75 percent of the costs of services to be provided by the State pursuant to such section.

(B) For the second year of such payments to a State, the Secretary may not make such payments in an amount exceeding 65 percent of the costs of such services.

(C) For the third or subsequent year of such payments to a State, the Secretary may not make such payments in an amount exceeding 55 percent of the costs of such services.

(2) The Secretary may not make a grant under section 398(a) to a State unless the State agrees to make available, directly or through donations from public or private entities, non-Federal contributions toward the costs of services to be provided pursuant to such section in an amount equal to—

(A) for the first year of payments to the State from the grant, not less than $25 (in cash or in kind under subsection (c)) for each $75 of Federal funds provided in the grant;

[93] So in law. The section heading lacks a period. See section 301(b)(1) of Public Law 105–392 (112 Stat. 3586).

(B) for the second year of such payments to the State, not less than $35 (in cash or in kind under subsection (c)) for each $65 of such Federal funds; and

(C) for the third or subsequent year of such payments to the State, not less than $45 (in cash or in kind under subsection (c)) for each $55 of such Federal funds.

(b) DETERMINATION OF AMOUNT OF NON-FEDERAL CONTRIBUTION.—Non-Federal contributions required in subsection (b) may be in cash or in kind, fairly evaluated, including plant, equipment, or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

SEC. 398B.[280c–5] GENERAL PROVISIONS.

(a) LIMITATION ON ADMINISTRATIVE EXPENSES.—The Secretary may not make a grant under section 398(a) to a State unless the State agrees that not more than 10 percent of the grant will be expended for administrative expenses with respect to the grant.

(b) DESCRIPTION OF INTENDED USE OF GRANT.—The Secretary may not make a grant under section 398(a) to a State unless—

(1) the State submits to the Secretary a description of the purposes for which the State intends to expend the grant; and

(2) such description provides information relating to the programs and activities to be supported and services to be provided, including—

(A) the number of individuals who will receive services pursuant to section 398(a) and the average costs of providing such services to each such individual; and

(B) a description of the manner in which such programs and activities will be coordinated with any similar programs and activities of public and private entities.

(c) REQUIREMENT OF APPLICATION.—The Secretary may not make a grant under section 398(a) to a State unless the State has submitted to the Secretary an application for the grant. The application shall—

(1) contain the description of intended expenditures required in subsection (b);

(2) with respect to carrying out the purpose for which the grant is to be made, provide assurances of compliance satisfactory to the Secretary; and

(3) otherwise be in such form, be made in such manner, and contain such information and agreements as the Secretary determines to be necessary to carry out this subpart.

(d) EVALUATIONS AND REPORT BY SECRETARY.—The Secretary shall—

(1) provide for an evaluation of each demonstration project for which a grant is made under section 398(a); and

(2) not later than 6 months after the completion of such evaluations, submit to the Congress a report describing the findings made as a result of the evaluations.

(e) AUTHORIZATIONS OF APPROPRIATIONS.—For the purpose of carrying out this subpart, there are authorized to be appropriated $5,000,000 for each of the fiscal years 1988 through 1990,

$7,500,000 for fiscal year 1991, such sums as may be necessary for each of the fiscal years 1992 and 1993, $8,000,000 for fiscal year 1998, and such sums as may be necessary for each of the fiscal years 1999 through 2002.

Subpart III—Grants for Home Visiting Services for At-Risk Families

SEC. 399.[280c–6] PROJECTS TO IMPROVE MATERNAL, INFANT, AND CHILD HEALTH.

(a) IN GENERAL.—

(1) ESTABLISHMENT OF PROGRAM.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall make grants to eligible entities to pay the Federal share of the cost of providing the services specified in subsection (b) to families in which a member is—

(A) a pregnant woman at risk of delivering an infant with a health or developmental complication; or

(B) a child less than 3 years of age—

(i) who is experiencing or is at risk of a health or developmental complication, or of child abuse or neglect; or

(ii) who has been prenatally exposed to maternal substance abuse.

(2) MINIMUM PERIOD OF AWARDS; ADMINISTRATIVE CONSULTATIONS.—

(A) The Secretary shall award grants under paragraph (1) for periods of at least three years.

(B) The Administrator of the Administration for Children, Youth, and Families and the Director of the National Commission to Prevent Infant Mortality shall be consulted regarding the promulgation of program guidelines and funding priorities under this section.

(3) REQUIREMENT OF STATUS AS MEDICAID PROVIDER.—

(A) Subject to subparagraph (B), the Secretary may make a grant under paragraph (1) only if, in the case of any service under such paragraph that is covered in the State plan approved under title XIX of the Social Security Act for the State involved—

(i) the entity involved will provide the service directly, and the entity has entered into a participation agreement under the State plan and is qualified to receive payments under such plan; or

(ii) the entity will enter into an agreement with an organization under which the organization will provide the service, and the organization has entered into such a participation agreement and is qualified to receive such payments.

(B)(i) In the case of an organization making an agreement under subparagraph (A)(ii) regarding the provision of services under paragraph (1), the requirement established in such subparagraph regarding a participation agreement shall be waived by the Secretary if the organization does not, in providing health or mental health services, impose a charge or accept reimbursement available from any

third-party payor, including reimbursement under any insurance policy or under any Federal or State health benefits program.

(ii) A determination by the Secretary of whether an organization referred to in clause (i) meets the criteria for a waiver under such clause shall be made without regard to whether the organization accepts voluntary donations regarding the provision of services to the public.

(b) HOME VISITING SERVICES FOR ELIGIBLE FAMILIES.—With respect to an eligible family, each of the following services shall, directly or through arrangement with other public or nonprofit private entities, be available (as applicable to the family member involved) in each project operated with a grant under subsection (a):

(1) Prenatal and postnatal health care.

(2) Primary health care for the children, including developmental assessments.

(3) Education for the parents concerning infant care and child development, including the development and utilization of parent and teacher resource networks and other family resource and support networks where such networks are available.

(4) Upon the request of a parent, providing the education described in paragraph (3) to other individuals who have responsibility for caring for the children.

(5) Education for the parents concerning behaviors that adversely affect health.

(6) Assistance in obtaining necessary health, mental health, developmental, social, housing, and nutrition services and other assistance, including services and other assistance under maternal and child health programs; the special supplemental nutrition program for women, infants, and children; section 17 of the Child Nutrition Act of 1966; title V of the Social Security Act; title XIX of such Act (including the program for early and periodic screening, diagnostic, and treatment services described in section 1905(r) of such Act); titles IV and XIX of the Social Security Act; housing programs; other food assistance programs; and appropriate alcohol and drug dependency treatment programs, according to need.

(c) CONSIDERATIONS IN MAKING GRANTS.—In awarding grants under subsection (a), the Secretary shall take into consideration—

(1) the ability of the entity involved to provide, either directly or through linkages, a broad range of preventive and primary health care services and related social, family support, and developmental services;

(2) different combinations of professional and lay home visitors utilized within programs that are reflective of the identified service needs and characteristics of target populations;

(3) the extent to which the population to be targeted has limited access to health care, and related social, family support, and developmental services; and

(4) whether such grants are equitably distributed among urban and rural settings and whether entities serving Native American communities are represented among the grantees.

(d) FEDERAL SHARE.—With respect to the costs of carrying out a project under subsection (a), a grant under such subsection for the project may not exceed 90 percent of such costs. To be eligible to receive such a grant, an applicant must provide assurances that the applicant will obtain at least 10 percent of such costs from non-Federal funds (and such contributions to such costs may be in cash or in-kind, including facilities and personnel).

(e) RULE OF CONSTRUCTION REGARDING AT-RISK BIRTHS.—For purposes of subsection (a)(1), a pregnant woman shall be considered to be at risk of delivering an infant with a health or developmental complication if during the pregnancy the woman—

(1) lacks appropriate access to, or information concerning, early and routine prenatal care;

(2) lacks the transportation necessary to gain access to the services described in subsection (b);

(3) lacks appropriate child care assistance, which results in impeding the ability of such woman to utilize health and related social services;

(4) is fearful of accessing substance abuse services or child and family support services; or

(5) is a minor with a low income.

(f) DELIVERY OF SERVICES AND CASE MANAGEMENT.—

(1) CASE MANAGEMENT MODEL.—Home visiting services provided under this section shall be delivered according to a case management model, and a registered nurse, licensed social worker, or other licensed health care professional with experience and expertise in providing health and related social services in home and community settings shall be assigned as the case manager for individual cases under such model.

(2) CASE MANAGER.—A case manager assigned under paragraph (1) shall have primary responsibility for coordinating and overseeing the development of a plan for each family that is to receive home visiting services under this section, and for coordinating the delivery of such services provided through appropriate personnel.

(3) APPROPRIATE PERSONNEL.—In determining which personnel shall be utilized in the delivery of services, the case manager shall consider—

(A) the stated objective of the project to be operated with the grant, as determined after considering identified gaps in the current service delivery system; and

(B) the nature of the needs of the family to be served, as determined at the initial assessment of the family that is conducted by the case manager, and through follow-up contacts by other providers of home visiting services.

(4) FAMILY SERVICE PLAN.—A case manager, in consultation with a team established in accordance with paragraph (5) for the family involved, shall develop a plan for the family following the initial visit to the home of the family. Such plan shall reflect—

(A) an assessment of the health and related social service needs of the family;

(B) a structured plan for the delivery of home visiting services to meet the identified needs of the family;

(C) the frequency with which such services are to be provided to the family;

(D) ongoing revisions made as the needs of family members change; and

(E) the continuing voluntary participation of the family in the plan.

(5) HOME VISITING SERVICES TEAM.—The team to be consulted under paragraph (4) on behalf of a family shall include, as appropriate, other nursing professionals, physician assistants, social workers, child welfare professionals, infant and early childhood specialists, nutritionists, and laypersons trained as home visitors. The case manager shall ensure that the plan is coordinated with those physician services that may be required by the mother or child.

(g) OUTREACH.—Each grantee under subsection (a) shall provide outreach and casefinding services to inform eligible families of the availability of home visiting services from the project.

(h) CONFIDENTIALITY.—In accordance with applicable State law, an entity receiving a grant under subsection (a) shall maintain confidentiality with respect to services provided to families under this section.

(i) CERTAIN ASSURANCES.—The Secretary may award a grant under subsection (a) only if the entity involved provides assurances satisfactory to the Secretary that—

(1) the entity will provide home visiting services with reasonable frequency—

(A) to families with pregnant women, as early in the pregnancy as is practicable, and until the infant reaches at least 2 years of age; and

(B) to other eligible families, for at least 2 years; and

(2) the entity will coordinate with public health and related social service agencies to prevent duplication of effort and improve the delivery of comprehensive health and related social services.

(j) SUBMISSION TO SECRETARY OF CERTAIN INFORMATION.—The Secretary may award a grant under subsection (a) only if the entity involved submits to the Secretary—

(1) a description of the population to be targeted for home visiting services and methods of outreach and casefinding for identifying eligible families, including the use of lay home visitors where appropriate;

(2) a description of the types and qualifications of home visitors used by the entity and the process by which the entity will provide continuing training and sufficient support to the home visitors; and

(3) such other information as the Secretary determines to be appropriate.

(k) LIMITATION REGARDING ADMINISTRATIVE EXPENSES.—Not more than 10 percent of a grant under subsection (a) may be expended for administrative expenses with respect to the grant. The costs of training individuals to serve in the project involved are not subject to the preceding sentence.

(l) RESTRICTIONS ON USE OF GRANT.—To be eligible to receive a grant under this section, an entity must agree that the grant will not be expended—

(1) to provide inpatient hospital services;

(2) to make cash payments to intended recipients of services;

(3) to purchase or improve land, purchase, construct, or permanently improve (other than minor remodeling) any building or other facility, or purchase major medical equipment;

(4) to satisfy any requirement for the expenditure of non-Federal funds as a condition for the receipt of Federal funds; or

(5) to provide financial assistance to any entity other than a public or nonprofit private entity.

(m) REPORTS TO SECRETARY.—To be eligible to receive a grant under this section, an entity must agree to submit an annual report on the services provided under this section to the Secretary in such manner and containing such information as the Secretary by regulation requires. At a minimum, the entity shall report information concerning eligible families, including—

(1) the characteristics of the families and children receiving services under this section;

(2) the usage, nature, and location of the provider, of preventive health services, including prenatal, primary infant, and child health care;

(3) the incidence of low birthweight and premature infants;

(4) the length of hospital stays for pre- and post-partum women and their children;

(5) the incidence of substantiated child abuse and neglect for all children within participating families;

(6) the number of emergency room visits for routine health care;

(7) the source of payment for health care services and the extent to which the utilization of health care services, other than routine screening and medical care, available to the individuals under the program established under title XIX of the Social Security Act, and under other Federal, State, and local programs, is reduced;

(8) the number and type of referrals made for health and related social services, including alcohol and drug treatment services, and the utilization of such services provided by the grantee; and

(9) the incidence of developmental disabilities.

(n) REQUIREMENT OF APPLICATION.—The Secretary may make a grant under subsection (a) only if—

(1) an application for the grant is submitted to the Secretary;

(2) the application contains the agreements and assurances required in this section, and the information required in subsection (j);

(3) the application contains evidence that the preparation of the application has been coordinated with the State agencies responsible for maternal and child health and child welfare,

and coordinated with services provided under part C of the Individuals with Disabilities Education Act; and

(4) the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(o) PEER REVIEW.—

(1) REQUIREMENT.—In making determinations for awarding grants under subsection (a), the Secretary shall rely on the recommendations of the peer review panel established under paragraph (2).

(2) COMPOSITION.—The Secretary shall establish a review panel to make recommendations under paragraph (1) that shall be composed of—

(A) national experts in the fields of maternal and child health, child abuse and neglect, and the provision of community-based primary health services; and

(B) representatives of relevant Federal agencies, including the Health Resources and Services Administration, the Substance Abuse and Mental Health Services Administration, the Administration for Children, Youth, and Families, the U.S. Advisory Board on Child Abuse and Neglect, and the National Commission to Prevent Infant Mortality.

(p) EVALUATIONS.—

(1) IN GENERAL.—The Secretary shall, directly or through contracts with public or private entities—

(A) conduct evaluations to determine the effectiveness of projects under subsection (a) in reducing the incidence of children born with health or developmental complications, the incidence among children less than 3 years of age of such complications, and the incidence of child abuse and neglect; and

(B) not less than once during each 3-year period, prepare and submit to the appropriate committees of Congress a report concerning the results of such evaluations.

(2) CONTENTS.—The evaluations conducted under paragraph (1) shall—

(A) include a summary of the data contained in the annual reports submitted under subsection (m);

(B) assess the relative effectiveness of projects under subsection (a) in urban and rural areas, and among programs utilizing differing combinations of professionals and trained home visitors recruited from the community to meet the needs of defined target service populations; and

(C) make further recommendations necessary or desirable to increase the effectiveness of such projects.

(q) DEFINITIONS.—For purposes of this section:

(1) The term "eligible entity" includes public and nonprofit private entities that provide health or related social services, including community-based organizations, visiting nurse organizations, hospitals, local health departments, community health centers, Native Hawaiian health centers, nurse managed clinics, family service agencies, child welfare agencies, de-

velopmental service providers, family resource and support programs, and resource mothers projects.

(2) The term "eligible family" means a family described in subsection (a).

(3) The term "health or developmental complication", with respect to a child, means—

(A) being born in an unhealthy or potentially unhealthy condition, including premature birth, low birthweight, and prenatal exposure to maternal substance abuse;

(B) a condition arising from a condition described in subparagraph (A);

(C) a physical disability or delay; and

(D) a developmental disability or delay.

(4) The term "home visiting services" means the services specified in subsection (b), provided at the residence of the eligible family involved or provided pursuant to arrangements made for the family (including arrangements for services in community settings).

(5) The term "home visitors" means providers of home visiting services.

(r) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there is authorized to be appropriated $30,000,000 for each of the fiscal years 1993 and 1994.

SEC. 399A.[280d] GRANTS FOR SERVICES FOR CHILDREN OF SUBSTANCE ABUSERS..

(a) ESTABLISHMENT.—

(1) IN GENERAL.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall make grants to public and nonprofit private entities for the purpose of carrying out programs—

(A) to provide the services described in subsection (b) to children of substance abusers;

(B) to provide the applicable services described in subsection (c) to families in which a member is a substance abuser; and

(C) to identify such children and such families.

(2) ADMINISTRATIVE CONSULTATIONS.—The Administrator of the Administration for Children, Youth, and Families and the Administrator of the Substance Abuse and Mental Health Services Administration shall be consulted regarding the promulgation of program guidelines and funding priorities under this section.

(3) REQUIREMENT OF STATUS AS MEDICAID PROVIDER.—

(A) Subject to subparagraph (B), the Secretary may make a grant under paragraph (1) only if, in the case of any service under such paragraph that is covered in the State plan approved under title XIX of the Social Security Act for the State involved—

(i) the entity involved will provide the service directly, and the entity has entered into a participation agreement under the State plan and is qualified to receive payments under such plan; or

(ii) the entity will enter into an agreement with an organization under which the organization will provide the service, and the organization has entered into such a participation agreement and is qualified to receive such payments.

(B)(i) In the case of an organization making an agreement under subparagraph (A)(ii) regarding the provision of services under paragraph (1), the requirement established in such subparagraph regarding a participation agreement shall be waived by the Secretary if the organization does not, in providing health or mental health services, impose a charge or accept reimbursement available from any third-party payor, including reimbursement under any insurance policy or under any Federal or State health benefits program.

(ii) A determination by the Secretary of whether an organization referred to in clause (i) meets the criteria for a waiver under such clause shall be made without regard to whether the organization accepts voluntary donations regarding the provision of services to the public.

(b) SERVICES FOR CHILDREN OF SUBSTANCE ABUSERS.—The Secretary may make a grant under subsection (a) only if the applicant involved agrees to make available (directly or through agreements with other entities) to children of substance abusers each of the following services:

(1) Periodic evaluation of children for developmental, psychological, and medical problems.

(2) Primary pediatric care.

(3) Other necessary health and mental health services.

(4) Therapeutic intervention services for children, including provision of therapeutic child care.

(5) Preventive counseling services.

(6) Counseling related to the witnessing of chronic violence.

(7) Referrals for, and assistance in establishing eligibility for, services provided under—

(A) education and special education programs;

(B) Head Start programs established under the Head Start Act;

(C) other early childhood programs;

(D) employment and training programs;

(E) public assistance programs provided by Federal, State, or local governments; and

(F) programs offered by vocational rehabilitation agencies, recreation departments, and housing agencies.

(8) Additional developmental services that are consistent with the provision of early intervention services, as such term is defined in part C of the Individuals with Disabilities Education Act.

(c) SERVICES FOR AFFECTED FAMILIES.—The Secretary may make a grant under subsection (a) only if, in the case of families in which a member is a substance abuser, the applicant involved agrees to make available (directly or through agreements with

other entities) each of the following services, as applicable to the family member involved:

(1) Services as follows, to be provided by a public health nurse, social worker, or similar professional, or by a trained worker from the community who is supervised by a professional:

(A) Counseling to substance abusers on the benefits and availability of substance abuse treatment services and services for children of substance abusers.

(B) Assistance to substance abusers in obtaining and using substance abuse treatment services and in obtaining the services described in subsection (b) for their children.

(C) Visiting and providing support to substance abusers, especially pregnant women, who are receiving substance abuse treatment services or whose children are receiving services under subsection (b).

(2) In the case of substance abusers:

(A) Encouragement and, where necessary, referrals to participate in appropriate substance abuse treatment.

(B) Primary health care and mental health services, including prenatal and post partum care for pregnant women.

(C) Consultation and referral regarding subsequent pregnancies and life options, including education and career planning.

(D) Where appropriate, counseling regarding family conflict and violence.

(E) Remedial education services.

(F) Referrals for, and assistance in establishing eligibility for, services described in subsection (b)(7).

(3) In the case of substance abusers, spouses of substance abusers, extended family members of substance abusers, caretakers of children of substance abusers, and other people significantly involved in the lives of substance abusers or the children of substance abusers:

(A) An assessment of the strengths and service needs of the family and the assignment of a case manager who will coordinate services for the family.

(B) Therapeutic intervention services, such as parental counseling, joint counseling sessions for families and children, and family therapy.

(C) Child care or other care for the child to enable the parent to attend treatment or other activities and respite care services.

(D) Parenting education services and parent support groups.

(E) Support services, including, where appropriate, transportation services.

(F) Where appropriate, referral of other family members to related services such as job training.

(G) Aftercare services, including continued support through parent groups and home visits.

(d) CONSIDERATIONS IN MAKING GRANTS.—In making grants under subsection (a), the Secretary shall ensure that the grants are reasonably distributed among the following types of entities:

(1) Alcohol and drug treatment programs, especially those providing treatment to pregnant women and mothers and their children.

(2) Public or nonprofit private entities that provide health or social services to disadvantaged populations, and that have—

(A) expertise in applying the services to the particular problems of substance abusers and the children of substance abusers; and

(B) an affiliation or contractual relationship with one or more substance abuse treatment programs.

(3) Consortia of public or nonprofit private entities that include at least one substance abuse treatment program.

(4) Indian tribes.

(e) FEDERAL SHARE.—The Federal share of a program carried out under subsection (a) shall be 90 percent. The Secretary shall accept the value of in-kind contributions, including facilities and personnel, made by the grant recipient as a part or all of the non-Federal share of grants.

(f) COORDINATION WITH OTHER PROVIDERS.—The Secretary may make a grant under subsection (a) only if the applicant involved agrees to coordinate its activities with those of the State lead agency, and the State Interagency Coordinating Council, under part C of the Individuals with Disabilities Education Act.

(g) RESTRICTIONS ON USE OF GRANT.—The Secretary may make a grant under subsection (a) only if the applicant involved agrees that the grant will not be expended—

(1) to provide inpatient hospital services;

(2) to make cash payments to intended recipients of services;

(3) to purchase or improve land, purchase, construct, or permanently improve (other than minor remodeling) any building or other facility, or purchase major medical equipment;

(4) to satisfy any requirement for the expenditure of non-Federal funds as a condition for the receipt of Federal funds; or

(5) to provide financial assistance to any entity other than a public or nonprofit private entity.

(h) SUBMISSION TO SECRETARY OF CERTAIN INFORMATION.—The Secretary may make a grant under subsection (a) only if the applicant involved submits to the Secretary—

(1) a description of the population that is to receive services under this section and a description of such services that are to be provided and measurable goals and objectives;

(2) a description of the mechanism that will be used to involve the local public agencies responsible for health, mental health, child welfare, education, juvenile justice, developmental disabilities, and substance abuse treatment programs in planning and providing services under this section, as well as evidence that the proposal has been coordinated with the State agencies responsible for administering those programs and the

State agency responsible for administering public maternal and child health services;

(3) information demonstrating that the applicant has established a collaborative relationship with child welfare agencies and child protective services that will enable the applicant, where appropriate, to—

(A) provide advocacy on behalf of substance abusers and the children of substance abusers in child protective services cases;

(B) provide services to help prevent the unnecessary placement of children in substitute care; and

(C) promote reunification of families or permanent plans for the placement of the child; and

(4) such other information as the Secretary determines to be appropriate.

(i) REPORTS TO SECRETARY.—The Secretary may make a grant under subsection (a) only if the applicant involved agrees that for each fiscal year for which the applicant receives such a grant the applicant, in accordance with uniform standards developed by the Secretary, will submit to the Secretary a report containing—

(1) a description of specific services and activities provided under the grant;

(2) information regarding progress toward meeting the program's stated goals and objectives;

(3) information concerning the extent of use of services provided under the grant, including the number of referrals to related services and information on other programs or services accessed by children, parents, and other caretakers;

(4) information concerning the extent to which parents were able to access and receive treatment for alcohol and drug abuse and sustain participation in treatment over time until the provider and the individual receiving treatment agree to end such treatment, and the extent to which parents re-enter treatment after the successful or unsuccessful termination of treatment;

(5) information concerning the costs of the services provided and the source of financing for health care services;

(6) information concerning—

(A) the number and characteristics of families, parents, and children served, including a description of the type and severity of childhood disabilities, and an analysis of the number of children served by age;

(B) the number of children served who remained with their parents during the period in which entities provided services under this section;

(C) the number of children served who were placed in out-of-home care during the period in which entities provided services under this section;

(D) the number of children described in subparagraph (C) who were reunited with their families; and

(E) the number of children described in subparagraph (C) for whom a permanent plan has not been made or for whom the permanent plan is other than family reunification;

(7) information on hospitalization or emergency room use by the family members participating in the program; and

(8) such other information as the Secretary determines to be appropriate.

(j) REQUIREMENT OF APPLICATION.—The Secretary may make any grant under subsection (a) only if—

(1) an application for the grant is submitted to the Secretary;

(2) the application contains the agreements required in this section and the information required in subsection (h); and

(3) the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(k) PEER REVIEW.—

(1) REQUIREMENT.—In making determinations for awarding grants under subsection (a), the Secretary shall rely on the recommendations of the peer review panel established under paragraph (2).

(2) COMPOSITION.—The Secretary shall establish a review panel to make recommendations under paragraph (1) that shall be composed of—

(A) national experts in the fields of maternal and child health, substance abuse treatment, and child welfare; and

(B) representatives of relevant Federal agencies, including the Health Resources and Services Administration, the Substance Abuse and Mental Health Services Administration, and the Administration for Children, Youth, and Families.

(l) EVALUATIONS.—The Secretary shall periodically conduct evaluations to determine the effectiveness of programs supported under subsection (a)—

(1) in reducing the incidence of alcohol and drug abuse among substance abusers participating in the programs;

(2) in preventing adverse health conditions in children of substance abusers;

(3) in promoting better utilization of health and developmental services and improving the health, developmental, and psychological status of children receiving services under the program;

(4) in improving parental and family functioning;

(5) in reducing the incidence of out-of-home placement for children whose parents receive services under the program; and

(6) in facilitating the reunification of families after children have been placed in out-of-home care.

(m) REPORT TO CONGRESS.—Not later than 2 years after the date on which amounts are first appropriated under subjection (o), the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report that contains a description of programs carried out under this section. At a minimum, the report shall contain—

(1) information concerning the number and type of programs receiving grants;

(2) information concerning the type and use of services offered;

(3) information concerning—

(A) the number and characteristics of families, parents, and children served;

(B) the number of children served who remained with their parents during or after the period in which entities provided services under this section;

(C) the number of children served who were placed in out-of-home care during the period in which entities provided services under this section;

(D) the number of children described in subparagraph (C) who were reunited with their families; and

(E) the number of children described in subparagraph (C) who were permanently placed in out-of-home care;

analyzed by the type of entity described in subsection (d) that provided services;

(4) an analysis of the access provided to, and use of, related services and alcohol and drug treatment through programs carried out under this section; and

(5) a comparison of the costs of providing services through each of the types of entities described in subsection (d).

(n) DATA COLLECTION.—The Secretary shall periodically collect and report on information concerning the numbers of children in substance abusing families, including information on the age, gender and ethnicity of the children, the composition and income of the family, and the source of health care finances.

(o) DEFINITIONS.—For purposes of this section:

(1) The term "caretaker", with respect to a child of a substance abuser, means any individual acting in a parental role regarding the child (including any birth parent, foster parent, adoptive parent, relative of such a child, or other individual acting in such a role).

(2) The term "children of substance abusers" means—

(A) children who have lived or are living in a household with a substance abuser who is acting in a parental role regarding the children; and

(B) children who have been prenatally exposed to alcohol or other dangerous drugs.

(3) The term "Indian tribe" means any tribe, band, nation, or other organized group or community of Indians, including any Alaska Native village (as defined in, or established pursuant to, the Alaska Native Claims Settlement Act), that is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians.

(4) The term "public or nonprofit private entities that provide health or social services to disadvantaged populations" includes community-based organizations, local public health departments, community action agencies, hospitals, community health centers, child welfare agencies, developmental disabil-

ities service providers, and family resource and support programs.

(5) The term "substance abuse" means the abuse of alcohol or other drugs.

PART M—NATIONAL PROGRAM OF CANCER REGISTRIES

SEC. 399B.[280e] NATIONAL PROGRAM OF CANCER REGISTRIES.

(a) IN GENERAL.—

(1) STATEWIDE CANCER REGISTRIES.—The Secretary, acting through the Director of the Centers for Disease Control, may make grants to States, or may make grants or enter into contracts with academic or nonprofit organizations designated by the State to operate the State's cancer registry in lieu of making a grant directly to the State, to support the operation of population-based, statewide registries to collect, for each condition specified in paragraph (2)(A), data concerning—

(A) demographic information about each case of cancer;

(B) information on the industrial or occupational history of the individuals with the cancers, to the extent such information is available from the same record;

(C) administrative information, including date of diagnosis and source of information;

(D) pathological data characterizing the cancer, including the cancer site, stage of disease (pursuant to Staging Guide), incidence, and type of treatment; and

(E) other elements determined appropriate by the Secretary.

(2) CANCER; BENIGN BRAIN-RELATED TUMORS.—

(A) IN GENERAL.—For purposes of paragraph (1), the conditions referred to in this paragraph are the following:

(i) Each form of in-situ and invasive cancer (with the exception of basal cell and squamous cell carcinoma of the skin), including malignant brain-related tumors.

(ii) Benign brain-related tumors.

(B) BRAIN-RELATED TUMOR.—For purposes of subparagraph (A):

(i) The term "brain-related tumor" means a listed primary tumor (whether malignant or benign) occurring in any of the following sites:

(I) The brain, meninges, spinal cord, cauda equina, a cranial nerve or nerves, or any other part of the central nervous system.

(II) The pituitary gland, pineal gland, or craniopharyngeal duct.

(ii) The term "listed", with respect to a primary tumor, means a primary tumor that is listed in the International Classification of Diseases for Oncology (commonly referred to as the ICD–O).

(iii) The term "International Classification of Diseases for Oncology" means a classification system that includes topography (site) information and histology

(cell type information) developed by the World Health Organization, in collaboration with international centers, to promote international comparability in the collection, classification, processing, and presentation of cancer statistics. The ICD–O system is a supplement to the International Statistical Classification of Diseases and Related Health Problems (commonly known as the ICD) and is the standard coding system used by cancer registries worldwide. Such term includes any modification made to such system for purposes of the United States. Such term further includes any published classification system that is internationally recognized as a successor to the classification system referred to in the first sentence of this clause.

(C) STATEWIDE CANCER REGISTRY.—References in this section to cancer registries shall be considered to be references to registries described in this subsection.

(b) MATCHING FUNDS.—

(1) IN GENERAL.—The Secretary may make a grant under subsection (a) only if the State, or the academic or nonprofit private organization designated by the State to operate the cancer registry of the State, involved agrees, with respect to the costs of the program, to make available (directly or through donations from public or private entities) non-Federal contributions toward such costs in an amount that is not less than 25 percent of such costs or $1 for every $3 of Federal funds provided in the grant.

(2) DETERMINATION OF AMOUNT OF NON-FEDERAL CONTRIBUTION; MAINTENANCE OF EFFORT.—

(A) Non-Federal contributions required in paragraph (1) may be in cash or in kind, fairly evaluated, including plant, equipment, or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

(B) With respect to a State in which the purpose described in subsection (a) is to be carried out, the Secretary, in making a determination of the amount of non-Federal contributions provided under paragraph (1), may include only such contributions as are in excess of the amount of such contributions made by the State toward the collection of data on cancer for the fiscal year preceding the first year for which a grant under subsection (a) is made with respect to the State. The Secretary may decrease the amount of non-Federal contributions that otherwise would have been required by this subsection in those cases in which the State can demonstrate that decreasing such amount is appropriate because of financial hardship.

(c) ELIGIBILITY FOR GRANTS.—

(1) IN GENERAL.—No grant shall be made by the Secretary under subsection (a) unless an application has been submitted to, and approved by, the Secretary. Such application shall be in such form, submitted in such a manner, and be accompanied

by such information, as the Secretary may specify. No such application may be approved unless it contains assurances that the applicant will use the funds provided only for the purposes specified in the approved application and in accordance with the requirements of this section, that the application will establish such fiscal control and fund accounting procedures as may be necessary to assure proper disbursement and accounting of Federal funds paid to the applicant under subsection (a) of this section, and that the applicant will comply with the peer review requirements under sections 491 and 492.

(2) ASSURANCES.—Each applicant, prior to receiving Federal funds under subsection (a), shall provide assurances satisfactory to the Secretary that the applicant will—

(A) provide for the establishment of a registry in accordance with subsection (a);

(B) comply with appropriate standards of completeness, timeliness, and quality of population-based cancer registry data;

(C) provide for the annual publication of reports of cancer data under subsection (a); and

(D) provide for the authorization under State law of the statewide cancer registry, including promulgation of regulations providing—

(i) a means to assure complete reporting of cancer cases (as described in subsection (a)) to the statewide cancer registry by hospitals or other facilities providing screening, diagnostic or therapeutic services to patients with respect to cancer;

(ii) a means to assure the complete reporting of cancer cases (as defined in subsection (a)) to the statewide cancer registry by physicians, surgeons, and all other health care practitioners diagnosing or providing treatment for cancer patients, except for cases directly referred to or previously admitted to a hospital or other facility providing screening, diagnostic or therapeutic services to patients in that State and reported by those facilities;

(iii) a means for the statewide cancer registry to access all records of physicians and surgeons, hospitals, outpatient clinics, nursing homes, and all other facilities, individuals, or agencies providing such services to patients which would identify cases of cancer or would establish characteristics of the cancer, treatment of the cancer, or medical status of any identified patient;

(iv) for the reporting of cancer case data to the statewide cancer registry in such a format, with such data elements, and in accordance with such standards of quality timeliness and completeness, as may be established by the Secretary;

(v) for the protection of the confidentiality of all cancer case data reported to the statewide cancer registry, including a prohibition on disclosure to any person of information reported to the statewide cancer

registry that identifies, or could lead to the identification of, an individual cancer patient, except for disclosure to other State cancer registries and local and State health officers;

(vi) for a means by which confidential case data may in accordance with State law be disclosed to cancer researchers for the purposes of cancer prevention, control and research;

(vii) for the authorization or the conduct, by the statewide cancer registry or other persons and organizations, of studies utilizing statewide cancer registry data, including studies of the sources and causes of cancer, evaluations of the cost, quality, efficacy, and appropriateness of diagnostic, therapeutic, rehabilitative, and preventative services and programs relating to cancer, and any other clinical, epidemiological, or other cancer research; and

(viii) for protection for individuals complying with the law, including provisions specifying that no person shall be held liable in any civil action with respect to a cancer case report provided to the statewide cancer registry, or with respect to access to cancer case information provided to the statewide cancer registry.

(d) RELATIONSHIP TO CERTAIN PROGRAMS.—

(1) IN GENERAL.—This section may not be construed to act as a replacement for or diminishment of the program carried out by the Director of the National Cancer Institute and designated by such Director as the Surveillance, Epidemiology, and End Results Program (SEER).

(2) SUPPLANTING OF ACTIVITIES.—In areas where both such programs exist, the Secretary shall ensure that SEER support is not supplanted and that any additional activities are consistent with the guidelines provided for in subsection (c)(2) (C) and (D) and are appropriately coordinated with the existing SEER program.

(3) TRANSFER OF RESPONSIBILITY.—The Secretary may not transfer administration responsibility for such SEER program from such Director.

(4) COORDINATION.—To encourage the greatest possible efficiency and effectiveness of Federally supported efforts with respect to the activities described in this subsection, the Secretary shall take steps to assure the appropriate coordination of programs supported under this part with existing Federally supported cancer registry programs.

(e) REQUIREMENT REGARDING CERTAIN STUDY ON BREAST CANCER.—In the case of a grant under subsection (a) to any State specified in subsection (b) of section 399E, the Secretary may establish such conditions regarding the receipt of the grant as the Secretary determines are necessary to facilitate the collection of data for the study carried out under such section.

SEC. 399C.[280e–1] PLANNING GRANTS REGARDING REGISTRIES.

(a) IN GENERAL.—

(1) STATES.—The Secretary, acting through the Director of the Centers for Disease Control, may make grants to States for the purpose of developing plans that meet the assurances required by the Secretary under section 399B(c)(2).

(2) OTHER ENTITIES.—For the purpose described in paragraph (1), the Secretary may make grants to public entities other than States and to nonprofit private entities. Such a grant may be made to an entity only if the State in which the purpose is to be carried out has certified that the State approves the entity as qualified to carry out the purpose.

(b) APPLICATION.—The Secretary may make a grant under subsection (a) only if an application for the grant is submitted to the Secretary, the application contains the certification required in subsection (a)(2) (if the application is for a grant under such subsection), and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

SEC. 399D.[280e–2] TECHNICAL ASSISTANCE IN OPERATIONS OF STATEWIDE CANCER REGISTRIES.

The Secretary, acting through the Director of the Centers for Disease Control, may, directly or through grants and contracts, or both, provide technical assistance to the States in the establishment and operation of statewide registries, including assistance in the development of model legislation for statewide cancer registries and assistance in establishing a computerized reporting and data processing system.

SEC. 399E.[280e–3] STUDY IN CERTAIN STATES TO DETERMINE THE FACTORS CONTRIBUTING TO THE ELEVATED BREAST CANCER MORTALITY RATES.

(a) IN GENERAL.—Subject to subsections (c) and (d), the Secretary, acting through the Director of the National Cancer Institute, shall conduct a study for the purpose of determining the factors contributing to the fact that breast cancer mortality rates in the States specified in subsection (b) are elevated compared to rates in other States.

(b) RELEVANT STATES.—The States referred to in subsection (a) are Connecticut, Delaware, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Rhode Island, Vermont, and the District of Columbia.

(c) COOPERATION OF STATE.—The Secretary may conduct the study required in subsection (a) in a State only if the State agrees to cooperate with the Secretary in the conduct of the study, including providing information from any registry operated by the State pursuant to section 399B(a).

(d) PLANNING, COMMENCEMENT, AND DURATION.—The Secretary shall, during each of the fiscal years 1993 and 1994, develop a plan for conducting the study required in subsection (a). The study shall be initiated by the Secretary not later than fiscal year 1994, and the collection of data under the study may continue through fiscal year 1998.

SEC. 399E–1.[280e–3a] NATIONAL CHILDHOOD CANCER REGISTRY.

(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall award a

grant to enhance and expand infrastructure to track the epidemiology of pediatric cancer into a comprehensive nationwide registry of actual occurrences of pediatric cancer. Such registry shall be updated to include an actual occurrence within weeks of the date of such occurrence.

(b) INFORMED CONSENT AND PRIVACY REQUIREMENTS AND COORDINATION WITH EXISTING PROGRAMS.—The registry established pursuant to subsection (a) shall be subject to section 552a of title 5, United States Code, the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996, applicable Federal and State informed consent regulations, any other applicable Federal and State laws relating to the privacy of patient information, and section 399B(d)(4) of this Act.

SEC. 399F.[280e–4] AUTHORIZATION OF APPROPRIATIONS.

(a) REGISTRIES.—For the purpose of carrying out this part (other than section 399E–1), there are authorized to be appropriated $30,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 through 2003. Of the amounts appropriated under the preceding sentence for any such fiscal year, the Secretary may obligate not more than 25 percent for carrying out section 399C, and not more than 10 percent may be expended for assessing the accuracy, completeness and quality of data collected, and not more than 10 percent of which is to be expended under section 399D.

(b) BREAST CANCER STUDY.—Of the amounts appropriated for the National Cancer Institute under subpart 1 of part C of title IV for any fiscal year in which the study required in section 399K[100] is being carried out, the Secretary shall expend not less than $1,000,000 for the study.

PART N—NATIONAL FOUNDATION FOR THE CENTERS FOR DISEASE CONTROL AND PREVENTION

SEC. 399G.[280e–11] ESTABLISHMENT AND DUTIES OF FOUNDATION.

(a) IN GENERAL.—There shall be established in accordance with this section a nonprofit private corporation to be known as the National Foundation for the Centers for Disease Control and Prevention (in this part referred to as the "Foundation"). The Foundation shall not be an agency or instrumentality of the Federal Government, and officers, employees, and members of the board of the Foundation shall not be officers or employees of the Federal Government.

(b) PURPOSE OF FOUNDATION.—The purpose of the Foundation shall be to support and carry out activities for the prevention and control of diseases, disorders, injuries, and disabilities, and for promotion of public health.

(c) ENDOWMENT FUND.—

(1) IN GENERAL.—In carrying out subsection (b), the Foundation shall establish a fund for providing endowments for positions that are associated with the Centers for Disease Control

[100] Probably should be a reference to section 399E. Section 502(2)(D)(iii) of Public Law 106–310 (114 Stat. 1115) provides that subsection (b) above is amended by striking "subsection 399K" and inserting "section 399E". The amendment cannot be executed because the term to be struck does not appear in subsection (b). (Compare "subsection 399K" and "section 399K".)

and Prevention and dedicated to the purpose described in such subsection. Subject to subsection (f)(1)(B), the fund shall consist of such donations as may be provided by non-Federal entities and such non-Federal assets of the Foundation (including earnings of the Foundation and the fund) as the Foundation may elect to transfer to the fund.

(2) AUTHORIZED EXPENDITURES OF FUND.—The provision of endowments under paragraph (1) shall be the exclusive function of the fund established under such paragraph. Such endowments may be expended only for the compensation of individuals holding the positions, for staff, equipment, quarters, travel, and other expenditures that are appropriate in supporting the positions, and for recruiting individuals to hold the positions endowed by the fund.

(d) CERTAIN ACTIVITIES OF FOUNDATION.—In carrying out subsection (b), the Foundation may provide for the following with respect to the purpose described in such subsection:

(1) Programs of fellowships for State and local public health officials to work and study in association with the Centers for Disease Control and Prevention.

(2) Programs of international arrangements to provide opportunities for public health officials of other countries to serve in public health capacities in the United States in association with the Centers for Disease Control and Prevention or elsewhere, or opportunities for employees of such Centers (or other public health officials in the United States) to serve in such capacities in other countries, or both.

(3) Studies, projects, and research (which may include applied research on the effectiveness of prevention activities, demonstration projects, and programs and projects involving international, Federal, State, and local governments).

(4) Forums for government officials and appropriate private entities to exchange information. Participants in such forums may include institutions of higher education and appropriate international organizations.

(5) Meetings, conferences, courses, and training workshops.

(6) Programs to improve the collection and analysis of data on the health status of various populations.

(7) Programs for writing, editing, printing, and publishing of books and other materials.

(8) Other activities to carry out the purpose described in subsection (b).

(e) GENERAL STRUCTURE OF FOUNDATION; NONPROFIT STATUS.—

(1) BOARD OF DIRECTORS.—The Foundation shall have a board of directors (in this part referred to as the "Board"), which shall be established and conducted in accordance with subsection (f). The Board shall establish the general policies of the Foundation for carrying out subsection (b), including the establishment of the bylaws of the Foundation.

(2) EXECUTIVE DIRECTOR.—The Foundation shall have an executive director (in this part referred to as the "Director"), who shall be appointed by the Board, who shall serve at the pleasure of the Board, and for whom the Board shall establish

the rate of compensation. Subject to compliance with the policies and bylaws established by the Board pursuant to paragraph (1), the Director shall be responsible for the daily operations of the Foundation in carrying out subsection (b).

(3) NONPROFIT STATUS.—In carrying out subsection (b), the Board shall establish such policies and bylaws under paragraph (1), and the Director shall carry out such activities under paragraph (2), as may be necessary to ensure that the Foundation maintains status as an organization that—

(A) is described in subsection (c)(3) of section 501 of the Internal Revenue Code of 1986; and

(B) is, under subsection (a) of such section, exempt from taxation.

(f) BOARD OF DIRECTORS.—

(1) CERTAIN BYLAWS.—

(A) In establishing bylaws under subsection (e)(1), the Board shall ensure that the bylaws of the Foundation include bylaws for the following:

(i) Policies for the selection of the officers, employees, agents, and contractors of the Foundation.

(ii) Policies, including ethical standards, for the acceptance and disposition of donations to the Foundation and for the disposition of the assets of the Foundation.

(iii) Policies for the conduct of the general operations of the Foundation.

(iv) Policies for writing, editing, printing, and publishing of books and other materials, and the acquisition of patents and licenses for devices and procedures developed by the Foundation.

(B) In establishing bylaws under subsection (e)(1), the Board shall ensure that the bylaws of the Foundation (and activities carried out under the bylaws) do not—

(i) reflect unfavorably upon the ability of the Foundation, or the Centers for Disease Control and Prevention, to carry out its responsibilities or official duties in a fair and objective manner; or

(ii) compromise, or appear to compromise, the integrity of any governmental program or any officer or employee involved in such program.

(2) COMPOSITION.—

(A) Subject to subparagraph (B), the Board shall be composed of 7 individuals, appointed in accordance with paragraph (4), who collectively possess education or experience appropriate for representing the general field of public health, the general field of international health, and the general public. Each such individual shall be a voting member of the Board.

(B) The Board may, through amendments to the bylaws of the Foundation, provide that the number of members of the Board shall be a greater number than the number specified in subparagraph (A).

(3) CHAIR.—The Board shall, from among the members of the Board, designate an individual to serve as the chair of the Board (in this subsection referred to as the "Chair").

(4) APPOINTMENTS, VACANCIES, AND TERMS.—Subject to subsection (j) (regarding the initial membership of the Board), the following shall apply to the Board:

(A) Any vacancy in the membership of the Board shall be filled by appointment by the Board, after consideration of suggestions made by the Chair and the Director regarding the appointments. Any such vacancy shall be filled not later than the expiration of the 180-day period beginning on the date on which the vacancy occurs.

(B) The term of office of each member of the Board appointed under subparagraph (A) shall be 5 years. A member of the Board may continue to serve after the expiration of the term of the member until the expiration of the 180-day period beginning on the date on which the term of the member expires.

(C) A vacancy in the membership of the Board shall not affect the power of the Board to carry out the duties of the Board. If a member of the Board does not serve the full term applicable under subparagraph (B), the individual appointed to fill the resulting vacancy shall be appointed for the remainder of the term of the predecessor of the individual.

(5) COMPENSATION.—Members of the Board may not receive compensation for service on the Board. The members may be reimbursed for travel, subsistence, and other necessary expenses incurred in carrying out the duties of the Board.

(g) CERTAIN RESPONSIBILITIES OF EXECUTIVE DIRECTOR.—In carrying out subsection (e)(2), the Director shall carry out the following functions:

(1) Hire, promote, compensate, and discharge officers and employees of the Foundation, and define the duties of the officers and employees.

(2) Accept and administer donations to the Foundation, and administer the assets of the Foundation.

(3) Establish a process for the selection of candidates for holding endowed positions under subsection (c).

(4) Enter into such financial agreements as are appropriate in carrying out the activities of the Foundation.

(5) Take such action as may be necessary to acquire patents and licenses for devices and procedures developed by the Foundation and the employees of the Foundation.

(6) Adopt, alter, and use a corporate seal, which shall be judicially noticed.

(7) Commence and respond to judicial proceedings in the name of the Foundation.

(8) Other functions that are appropriate in the determination of the Director.

(h) GENERAL PROVISIONS.—

(1) AUTHORITY FOR ACCEPTING FUNDS.—The Director of the Centers for Disease Control and Prevention may accept and utilize, on behalf of the Federal Government, any gift, dona-

tion, bequest, or devise of real or personal property from the Foundation for the purpose of aiding or facilitating the work of such Centers. Funds may be accepted and utilized by such Director under the preceding sentence without regard to whether the funds are designated as general-purpose funds or special-purpose funds.

(2) AUTHORITY FOR ACCEPTANCE OF VOLUNTARY SERVICES.—

(A) The Director of the Centers for Disease Control and Prevention may accept, on behalf of the Federal Government, any voluntary services provided to such Centers by the Foundation for the purpose of aiding or facilitating the work of such Centers. In the case of an individual, such Director may accept the services provided under the preceding sentence by the individual until such time as the private funding for such individual ends.

(B) The limitation established in subparagraph (A) regarding the period of time in which services may be accepted applies to each individual who is not an employee of the Federal Government and who serves in association with the Centers for Disease Control and Prevention pursuant to financial support from the Foundation.

(3) ADMINISTRATIVE CONTROL.—No officer, employee, or member of the Board of the Foundation may exercise any administrative or managerial control over any Federal employee.

(4) APPLICABILITY OF CERTAIN STANDARDS TO NON-FEDERAL EMPLOYEES.—In the case of any individual who is not an employee of the Federal Government and who serves in association with the Centers for Disease Control and Prevention pursuant to financial support from the Foundation, the Foundation shall negotiate a memorandum of understanding with the individual and the Director of the Centers for Disease Control and Prevention specifying that the individual—

(A) shall be subject to the ethical and procedural standards regulating Federal employment, scientific investigation, and research findings (including publications and patents) that are required of individuals employed by the Centers for Disease Control and Prevention, including standards under this Act, the Ethics in Government Act, and the Technology Transfer Act; and

(B) shall be subject to such ethical and procedural standards under chapter 11 of title 18, United States Code (relating to conflicts of interest), as the Director of such Centers determines is appropriate, except such memorandum may not provide that the individual shall be subject to the standards of section 209 of such chapter.

(5) FINANCIAL CONFLICTS OF INTEREST.—Any individual who is an officer, employee, or member of the Board of the Foundation may not directly or indirectly participate in the consideration or determination by the Foundation of any question affecting—

(A) any direct or indirect financial interest of the individual; or

(B) any direct or indirect financial interest of any business organization or other entity of which the individual is an officer or employee or in which the individual has a direct or indirect financial interest.

(6) AUDITS; AVAILABILITY OF RECORDS.—The Foundation shall—

(A) provide for biennial audits of the financial condition of the Foundation; and

(B) make such audits, and all other records, documents, and other papers of the Foundation, available to the Secretary and the Comptroller General of the United States for examination or audit.

(7) REPORTS.—

(A) Not later than February 1 of each fiscal year, the Foundation shall publish a report describing the activities of the Foundation during the preceding fiscal year. Each such report shall include for the fiscal year involved a comprehensive statement of the operations, activities, financial condition, and accomplishments of the Foundation, including an accounting of the use of amounts provided for under subsection (i).

(B) With respect to the financial condition of the Foundation, each report under subparagraph (A) shall include the source, and a description of, all gifts to the Foundation of real or personal property, and the source and amount of all gifts to the Foundation of money. Each such report shall include a specification of any restrictions on the purposes for which gifts to the Foundation may be used.

(C) The Foundation shall make copies of each report submitted under subparagraph (A) available—

(i) for public inspection, and shall upon request provide a copy of the report to any individual for a charge not to exceed the cost of providing the copy; and

(ii) to the appropriate committees of Congress.

(8) LIAISON FROM CENTERS FOR DISEASE CONTROL AND PREVENTION.—The Director of the Centers for Disease Control and Prevention shall serve as the liaison representative of such Centers to the Board and the Foundation.

(i) FEDERAL FUNDING.—

(1) AUTHORITY FOR ANNUAL GRANTS.—

(A) The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall—

(i) for fiscal year 1993, make a grant to an entity described in subsection (j)(9) (relating to the establishment of a committee to establish the Foundation);

(ii) for fiscal year 1994, make a grant to the committee established under such subsection, or if the Foundation has been established, to the Foundation; and

(iii) for fiscal year 1995 and each subsequent fiscal year, make a grant to the Foundation.

(B) A grant under subparagraph (A) may be expended—

(i) in the case of an entity receiving the grant under subparagraph (A)(i), only for the purpose of carrying out the duties established in subsection (j)(9) for the entity;

(ii) in the case of the committee established under such subsection, only for the purpose of carrying out the duties established in subsection (j) for the committee; and

(iii) in the case of the Foundation, only for the purpose of the administrative expenses of the Foundation.

(C) A grant under subparagraph (A) may not be expended to provide amounts for the fund established under subsection (c).

(D) For the purposes described in subparagraph (B)—

(i) any portion of the grant made under subparagraph (A)(i) for fiscal year 1993 that remains unobligated after the entity receiving the grant completes the duties established in subsection (j)(9) for the entity shall be available to the committee established under such subsection; and

(ii) any portion of a grant under subparagraph (A) made for fiscal year 1993 or 1994 that remains unobligated after such committee completes the duties established in such subsection for the committee shall be available to the Foundation.

(2) FUNDING FOR GRANTS.—

(A) For the purpose of grants under paragraph (1), there is authorized to be appropriated $1,250,000 for each fiscal year.

(B) For the purpose of grants under paragraph (1), the Secretary may for each fiscal year make available not less than $500,000, and not more than $1,250,000 from the amounts appropriated for the fiscal year for the programs of the Department of Health and Human Services. Such amounts may be made available without regard to whether amounts have been appropriated under subparagraph (A).

(3) CERTAIN RESTRICTION.—If the Foundation receives Federal funds for the purpose of serving as a fiscal intermediary between Federal agencies, the Foundation may not receive such funds for the indirect costs of carrying out such purpose in an amount exceeding 10 percent of the direct costs of carrying out such purpose. The preceding sentence may not be construed as authorizing the expenditure of any grant under paragraph (1) for such purpose.

(4) SUPPORT SERVICES.—The Director of the Centers for Disease Control and Prevention may provide facilities, utilities, and support services to the Foundation if it is determined by the Director to be advantageous to the programs of such Centers.

(j) COMMITTEE FOR ESTABLISHMENT OF FOUNDATION.—

(1) IN GENERAL.—There shall be established in accordance with this subsection a committee to carry out the functions de-

scribed in paragraph (2) (which committee is referred to in this subsection as the "Committee").

(2) FUNCTIONS.—The functions referred to in paragraph (1) for the Committee are as follows:

(A) To carry out such activities as may be necessary to incorporate the Foundation under the laws of the State involved, including serving as incorporators for the Foundation. Such activities shall include ensuring that the articles of incorporation for the Foundation require that the Foundation be established and operated in accordance with the applicable provisions of this part (or any successor to this part), including such provisions as may be in effect pursuant to amendments enacted after the date of the enactment of the Preventive Health Amendments of 1992[101].

(B) To ensure that the Foundation qualifies for and maintains the status described in subsection (e)(3) (regarding taxation).

(C) To establish the general policies and initial bylaws of the Foundation, which bylaws shall include the bylaws described in subsections (e)(3) and (f)(1).

(D) To provide for the initial operation of the Foundation, including providing for quarters, equipment, and staff.

(E) To appoint the initial members of the Board in accordance with the requirements established in subsection (f)(2)(A) for the composition of the Board, and in accordance with such other qualifications as the Committee may determine to be appropriate regarding such composition. Of the members so appointed—

(i) 2 shall be appointed to serve for a term of 3 years;

(ii) 2 shall be appointed to serve for a term of 4 years; and

(iii) 3 shall be appointed to serve for a term of 5 years.

(3) COMPLETION OF FUNCTIONS OF COMMITTEE; INITIAL MEETING OF BOARD.—

(A) The Committee shall complete the functions required in paragraph (1) not later than September 30, 1994. The Committee shall terminate upon the expiration of the 30-day period beginning on the date on which the Secretary determines that the functions have been completed.

(B) The initial meeting of the Board shall be held not later than November 1, 1994.

(4) COMPOSITION.—The Committee shall be composed of 5 members, each of whom shall be a voting member. Of the members of the Committee—

(A) no fewer than 2 shall have broad, general experience in public health; and

[101] Enacted October 27, 1992.

(B) no fewer than 2 shall have broad, general experience in nonprofit private organizations (without regard to whether the individuals have experience in public health).

(5) CHAIR.—The Committee shall, from among the members of the Committee, designate an individual to serve as the chair of the Committee.

(6) TERMS; VACANCIES.—The term of members of the Committee shall be for the duration of the Committee. A vacancy in the membership of the Committee shall not affect the power of the Committee to carry out the duties of the Committee. If a member of the Committee does not serve the full term, the individual appointed to fill the resulting vacancy shall be appointed for the remainder of the term of the predecessor of the individual.

(7) COMPENSATION.—Members of the Committee may not receive compensation for service on the Committee. Members of the Committee may be reimbursed for travel, subsistence, and other necessary expenses incurred in carrying out the duties of the Committee.

(8) COMMITTEE SUPPORT.—The Director of the Centers for Disease Control and Prevention may, from amounts available to the Director for the general administration of such Centers, provide staff and financial support to assist the Committee with carrying out the functions described in paragraph (2). In providing such staff and support, the Director may both detail employees and contract for assistance.

(9) GRANT FOR ESTABLISHMENT OF COMMITTEE.—

(A) With respect to a grant under paragraph (1)(A)(i) of subsection (i) for fiscal year 1993, an entity described in this paragraph is a private nonprofit entity with significant experience in domestic and international issues of public health. Not later than 180 days after the date of the enactment of the Preventive Health Amendments of 1992 [102], the Secretary shall make the grant to such an entity (subject to the availability of funds under paragraph (2) of such subsection).

(B) The grant referred to in subparagraph (A) may be made to an entity only if the entity agrees that—

(i) the entity will establish a committee that is composed in accordance with paragraph (4); and

(ii) the entity will not select an individual for membership on the Committee unless the individual agrees that the Committee will operate in accordance with each of the provisions of this subsection that relate to the operation of the Committee.

(C) The Secretary may make a grant referred to in subparagraph (A) only if the applicant for the grant makes an agreement that the grant will not be expended for any purpose other than carrying out subparagraph (B). Such a grant may be made only if an application for the grant is submitted to the Secretary containing such agreement, and the application is in such form, is made in such manner,

[102] Enacted October 27, 1992.

and contains such other agreements and such assurances and information as the Secretary determines to be necessary to carry out this paragraph.

PART O—FETAL ALCOHOL SYNDROME PREVENTION AND SERVICES PROGRAM

SEC. 399H.[280f] ESTABLISHMENT OF FETAL ALCOHOL SYNDROME PREVENTION AND SERVICES PROGRAM.

(a) FETAL ALCOHOL SYNDROME PREVENTION, INTERVENTION AND SERVICES DELIVERY PROGRAM.—The Secretary shall establish a comprehensive Fetal Alcohol Syndrome and Fetal Alcohol Effect prevention, intervention and services delivery program that shall include—

(1) an education and public awareness program to support, conduct, and evaluate the effectiveness of—

(A) educational programs targeting medical schools, social and other supportive services, educators and counselors and other service providers in all phases of childhood development, and other relevant service providers, concerning the prevention, identification, and provision of services for children, adolescents and adults with Fetal Alcohol Syndrome and Fetal Alcohol Effect;

(B) strategies to educate school-age children, including pregnant and high risk youth, concerning Fetal Alcohol Syndrome and Fetal Alcohol Effect;

(C) public and community awareness programs concerning Fetal Alcohol Syndrome and Fetal Alcohol Effect; and

(D) strategies to coordinate information and services across affected community agencies, including agencies providing social services such as foster care, adoption, and social work, medical and mental health services, and agencies involved in education, vocational training and civil and criminal justice;

(2) a prevention and diagnosis program to support clinical studies, demonstrations and other research as appropriate to—

(A) develop appropriate medical diagnostic methods for identifying Fetal Alcohol Syndrome and Fetal Alcohol Effect; and

(B) develop effective prevention services and interventions for pregnant, alcohol-dependent women; and

(3) an applied research program concerning intervention and prevention to support and conduct service demonstration projects, clinical studies and other research models providing advocacy, educational and vocational training, counseling, medical and mental health, and other supportive services, as well as models that integrate and coordinate such services, that are aimed at the unique challenges facing individuals with Fetal Alcohol Syndrome or Fetal Alcohol Effect and their families.

(b) GRANTS AND TECHNICAL ASSISTANCE.—The Secretary may award grants, cooperative agreements and contracts and provide technical assistance to eligible entities described in section 399I to carry out subsection (a).

(c) DISSEMINATION OF CRITERIA.—In carrying out this section, the Secretary shall develop a procedure for disseminating the Fetal Alcohol Syndrome and Fetal Alcohol Effect diagnostic criteria developed pursuant to section 705 of the ADAMHA Reorganization Act (42 U.S.C. 485n note) to health care providers, educators, social workers, child welfare workers, and other individuals.

(d) NATIONAL TASK FORCE.—

(1) IN GENERAL.—The Secretary shall establish a task force to be known as the National Task Force on Fetal Alcohol Syndrome and Fetal Alcohol Effect (referred to in this subsection as the "Task Force") to foster coordination among all governmental agencies, academic bodies and community groups that conduct or support Fetal Alcohol Syndrome and Fetal Alcohol Effect research, programs, and surveillance, and otherwise meet the general needs of populations actually or potentially impacted by Fetal Alcohol Syndrome and Fetal Alcohol Effect.

(2) MEMBERSHIP.—The Task Force established pursuant to paragraph (1) shall—

(A) be chaired by an individual to be appointed by the Secretary and staffed by the Administration; and

(B) include the Chairperson of the Interagency Coordinating Committee on Fetal Alcohol Syndrome of the Department of Health and Human Services, individuals with Fetal Alcohol Syndrome and Fetal Alcohol Effect, and representatives from advocacy and research organizations such as the Research Society on Alcoholism, the FAS Family Resource Institute, the National Organization of Fetal Alcohol Syndrome, the Arc, the academic community, and Federal, State and local government agencies and offices.

(3) FUNCTIONS.—The Task Force shall—

(A) advise Federal, State and local programs and research concerning Fetal Alcohol Syndrome and Fetal Alcohol Effect, including programs and research concerning education and public awareness for relevant service providers, school-age children, women at-risk, and the general public, medical diagnosis, interventions for women at-risk of giving birth to children with Fetal Alcohol Syndrome and Fetal Alcohol Effect, and beneficial services for individuals with Fetal Alcohol Syndrome and Fetal Alcohol Effect and their families;

(B) coordinate its efforts with the Interagency Coordinating Committee on Fetal Alcohol Syndrome of the Department of Health and Human Services; and

(C) report on a biennial basis to the Secretary and relevant committees of Congress on the current and planned activities of the participating agencies.

(4) TIME FOR APPOINTMENT.—The members of the Task Force shall be appointed by the Secretary not later than 6 months after the date of enactment of this part.

SEC. 399I.[280f–1] ELIGIBILITY.

To be eligible to receive a grant, or enter into a cooperative agreement or contract under this part, an entity shall—

(1) be a State, Indian tribal government, local government, scientific or academic institution, or nonprofit organization; and

(2) prepare and submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may prescribe, including a description of the activities that the entity intends to carry out using amounts received under this part.

SEC. 399J.[280f–2] AUTHORIZATION OF APPROPRIATIONS.

(a) IN GENERAL.—There are authorized to be appropriated to carry out this part, $27,000,000 for each of the fiscal years 1999 through 2003.

(b) TASK FORCE.—From amounts appropriated for a fiscal year under subsection (a), the Secretary may use not to exceed $2,000,000 of such amounts for the operations of the National Task Force under section 399H(d).

SEC. 399K.[280f–3] SUNSET PROVISION.

This part shall not apply on the date that is 7 years after the date on which all members of the National Task Force have been appointed under section 399H(d)(1).

PART P—ADDITIONAL PROGRAMS

SEC. 399L.[280g] CHILDREN'S ASTHMA TREATMENT GRANTS PROGRAM.

(a) AUTHORITY TO MAKE GRANTS.—

(1) IN GENERAL.—In addition to any other payments made under this Act or title V of the Social Security Act, the Secretary shall award grants to eligible entities to carry out the following purposes:

(A) To provide access to quality medical care for children who live in areas that have a high prevalence of asthma and who lack access to medical care.

(B) To provide on-site education to parents, children, health care providers, and medical teams to recognize the signs and symptoms of asthma, and to train them in the use of medications to treat asthma and prevent its exacerbations.

(C) To decrease preventable trips to the emergency room by making medication available to individuals who have not previously had access to treatment or education in the management of asthma.

(D) To provide other services, such as smoking cessation programs, home modification, and other direct and support services that ameliorate conditions that exacerbate or induce asthma.

(2) CERTAIN PROJECTS.—In making grants under paragraph (1), the Secretary may make grants designed to develop and expand the following projects:

(A) Projects to provide comprehensive asthma services to children in accordance with the guidelines of the National Asthma Education and Prevention Program (through the National Heart, Lung and Blood Institute),

including access to care and treatment for asthma in a community-based setting.

(B) Projects to fully equip mobile health care clinics that provide preventive asthma care including diagnosis, physical examinations, pharmacological therapy, skin testing, peak flow meter testing, and other asthma-related health care services.

(C) Projects to conduct validated asthma management education programs for patients with asthma and their families, including patient education regarding asthma management, family education on asthma management, and the distribution of materials, including displays and videos, to reinforce concepts presented by medical teams.

(2)[103] AWARD OF GRANTS.—

(A) APPLICATION.—

(i) IN GENERAL.—An eligible entity shall submit an application to the Secretary for a grant under this section in such form and manner as the Secretary may require.

(ii) REQUIRED INFORMATION.—An application submitted under this subparagraph shall include a plan for the use of funds awarded under the grant and such other information as the Secretary may require.

(B) REQUIREMENT.—In awarding grants under this section, the Secretary shall give preference to eligible entities that demonstrate that the activities to be carried out under this section shall be in localities within areas of known or suspected high prevalence of childhood asthma or high asthma-related mortality or high rate of hospitalization or emergency room visits for asthma (relative to the average asthma prevalence rates and associated mortality rates in the United States). Acceptable data sets to demonstrate a high prevalence of childhood asthma or high asthma-related mortality may include data from Federal, State, or local vital statistics, claims data under title XIX or XXI of the Social Security Act, other public health statistics or surveys, or other data that the Secretary, in consultation with the Director of the Centers for Disease Control and Prevention, deems appropriate.

(3) DEFINITION OF ELIGIBLE ENTITY.—For purposes of this section, the term "eligible entity" means a public or nonprofit private entity (including a State or political subdivision of a State), or a consortium of any of such entities.

(b) COORDINATION WITH OTHER CHILDREN'S PROGRAMS.—An eligible entity shall identify in the plan submitted as part of an application for a grant under this section how the entity will coordinate operations and activities under the grant with—

(1) other programs operated in the State that serve children with asthma, including any such programs operated under title V, XIX, or XXI of the Social Security Act; and

(2) one or more of the following—

[103] So in law. There are two paragraphs (2) in subsection (a). The second paragraph (2) and paragraph (3) probably should be redesignated as paragraphs (3) and (4), respectively. See section 501 of Public Law 106–310 (114 Stat. 1113).

(A) the child welfare and foster care and adoption assistance programs under parts B and E of title IV of such Act;

(B) the head start program established under the Head Start Act (42 U.S.C. 9831 et seq.);

(C) the program of assistance under the special supplemental nutrition program for women, infants and children (WIC) under section 17 of the Child Nutrition Act of 1966 (42 U.S.C. 1786);

(D) local public and private elementary or secondary schools; or

(E) public housing agencies, as defined in section 3 of the United States Housing Act of 1937 (42 U.S.C. 1437a).

(c) EVALUATION.—An eligible entity that receives a grant under this section shall submit to the Secretary an evaluation of the operations and activities carried out under the grant that includes—

(1) a description of the health status outcomes of children assisted under the grant;

(2) an assessment of the utilization of asthma-related health care services as a result of activities carried out under the grant;

(3) the collection, analysis, and reporting of asthma data according to guidelines prescribed by the Director of the Centers for Disease Control and Prevention; and

(4) such other information as the Secretary may require.

(d) PREFERENCE FOR STATES THAT ALLOW STUDENTS TO SELF-ADMINISTER MEDICATION TO TREAT ASTHMA AND ANAPHYLAXIS.—[104]

(1) PREFERENCE.—The Secretary, in making any grant under this section or any other grant that is asthma-related (as determined by the Secretary) to a State, shall give preference to any State that satisfies the following:

(A) IN GENERAL.—The State must require that each public elementary school and secondary school in that State will grant to any student in the school an authorization for the self-administration of medication to treat that student's asthma or anaphylaxis, if—

(i) a health care practitioner prescribed the medication for use by the student during school hours and instructed the student in the correct and responsible use of the medication;

(ii) the student has demonstrated to the health care practitioner (or such practitioner's designee) and the school nurse (if available) the skill level necessary to use the medication and any device that is necessary to administer such medication as prescribed;

(iii) the health care practitioner formulates a written treatment plan for managing asthma or anaphylaxis episodes of the student and for medication use by the student during school hours; and

[104] Subsection (d) was added by section 3(a) of Public Law 108–377 (118 Stat. 2203), which was enacted October 30, 2004. Section 3(b) of such Public Law provides as follows: "The amendments made by this section shall apply only with respect to grants made on or after the date that is 9 months after the date of the enactment of this Act.".

(iv) the student's parent or guardian has completed and submitted to the school any written documentation required by the school, including the treatment plan formulated under clause (iii) and other documents related to liability.

(B) SCOPE.—An authorization granted under subparagraph (A) must allow the student involved to possess and use his or her medication—

(i) while in school;

(ii) while at a school-sponsored activity, such as a sporting event; and

(iii) in transit to or from school or school-sponsored activities.

(C) DURATION OF AUTHORIZATION.—An authorization granted under subparagraph (A)—

(i) must be effective only for the same school and school year for which it is granted; and

(ii) must be renewed by the parent or guardian each subsequent school year in accordance with this subsection.

(D) BACKUP MEDICATION.—The State must require that backup medication, if provided by a student's parent or guardian, be kept at a student's school in a location to which the student has immediate access in the event of an asthma or anaphylaxis emergency.

(E) MAINTENANCE OF INFORMATION.—The State must require that information described in subparagraphs (A)(iii) and (A)(iv) be kept on file at the student's school in a location easily accessible in the event of an asthma or anaphylaxis emergency.

(F) SCHOOL PERSONNEL ADMINISTRATION OF EPINEPHRINE.—In determining the preference (if any) to be given to a State under this subsection, the Secretary shall give additional preference to a State that provides to the Secretary the certification described in subparagraph (G) and that requires that each public elementary school and secondary school in the State—

(i) permits trained personnel of the school to administer epinephrine to any student of the school reasonably believed to be having an anaphylactic reaction;

(ii) maintains a supply of epinephrine in a secure location that is easily accessible to trained personnel of the school for the purpose of administration to any student of the school reasonably believed to be having an anaphylactic reaction; and

(iii) has in place a plan for having on the premises of the school during all operating hours of the school one or more individuals who are trained personnel of the school.

(G) CIVIL LIABILITY PROTECTION LAW.—The certification required in subparagraph (F) shall be a certification made by the State attorney general that the State has reviewed any applicable civil liability protection law to deter-

mine the application of such law with regard to elementary and secondary school trained personnel who may administer epinephrine to a student reasonably believed to be having an anaphylactic reaction and has concluded that such law provides adequate civil liability protection applicable to such trained personnel. For purposes of the previous sentence, the term "civil liability protection law" means a State law offering legal protection to individuals who give aid on a voluntary basis in an emergency to an individual who is ill, in peril, or otherwise incapacitated.

(2) RULE OF CONSTRUCTION.—Nothing in this subsection creates a cause of action or in any other way increases or diminishes the liability of any person under any other law.

(3) DEFINITIONS.—For purposes of this subsection:

(A) The terms "elementary school" and "secondary school" have the meaning given to those terms in section 9101 of the Elementary and Secondary Education Act of 1965.

(B) The term "health care practitioner" means a person authorized under law to prescribe drugs subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act.

(C) The term "medication" means a drug as that term is defined in section 201 of the Federal Food, Drug, and Cosmetic Act and includes inhaled bronchodilators and auto-injectable epinephrine.

(D) The term "self-administration" means a student's discretionary use of his or her prescribed asthma or anaphylaxis medication, pursuant to a prescription or written direction from a health care practitioner.

(E) The term "trained personnel" means, with respect to an elementary or secondary school, an individual—

(i) who has been designated by the principal (or other appropriate administrative staff) of the school to administer epinephrine on a voluntary basis outside their scope of employment;

(ii) who has received training in the administration of epinephrine; and

(iii) whose training in the administration of epinephrine meets appropriate medical standards and has been documented by appropriate administrative staff of the school.

(e) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005.

SEC. 399M.[280g–1] EARLY DETECTION, DIAGNOSIS, AND TREATMENT REGARDING HEARING LOSS IN NEWBORNS AND INFANTS.

(a) STATEWIDE NEWBORN AND INFANT HEARING SCREENING, EVALUATION AND INTERVENTION PROGRAMS AND SYSTEMS.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall make awards of grants or cooperative agreements to develop statewide newborn and infant hearing screening, evaluation, diagnosis, and intervention programs and systems, and to assist in the recruitment, retention,

education, and training of qualified personnel and health care providers, for the following purposes:

(1) To develop and monitor the efficacy of statewide programs and systems for hearing screening of newborns and infants; prompt evaluation and diagnosis of children referred from screening programs; and appropriate educational, audiological, and medical interventions for children identified with hearing loss. Early intervention includes referral to and delivery of information and services by schools and agencies, including community, consumer, and parent-based agencies and organizations and other programs mandated by part C of the Individuals with Disabilities Education Act, which offer programs specifically designed to meet the unique language and communication needs of deaf and hard of hearing newborns, infants, toddlers, and children. Programs and systems under this paragraph shall establish and foster family-to-family support mechanisms that are critical in the first months after a child is identified with hearing loss.

(2) To collect data on statewide newborn and infant hearing screening, evaluation and intervention programs and systems that can be used for applied research, program evaluation and policy development.

(3) Other activities may include developing efficient models to ensure that newborns and infants who are identified with a hearing loss through screening receive follow-up by a qualified health care provider, and State agencies shall be encouraged to adopt models that effectively increase the rate of occurrence of such follow-up.

(b) TECHNICAL ASSISTANCE, DATA MANAGEMENT, AND APPLIED RESEARCH.—

(1) CENTERS FOR DISEASE CONTROL AND PREVENTION.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall make awards of grants or cooperative agreements to provide technical assistance to State agencies to complement an intramural program and to conduct applied research related to newborn and infant hearing screening, evaluation and intervention programs and systems. The program shall develop standardized procedures for data management and program effectiveness and costs, such as—

(A) to ensure quality monitoring of newborn and infant hearing loss screening, evaluation, diagnosis, and intervention programs and systems;

(B) to provide technical assistance on data collection and management;

(C) to study the costs and effectiveness of newborn and infant hearing screening, evaluation and intervention programs and systems conducted by State-based programs in order to answer issues of importance to State and national policymakers;

(D) to identify the causes and risk factors for congenital hearing loss;

(E) to study the effectiveness of newborn and infant hearing screening, audiologic and medical evaluations and intervention programs and systems by assessing the

health, intellectual and social developmental, cognitive, and language status of these children at school age; and

(F) to promote the sharing of data regarding early hearing loss with State-based birth defects and developmental disabilities monitoring programs for the purpose of identifying previously unknown causes of hearing loss.

(2) NATIONAL INSTITUTES OF HEALTH.—The Director of the National Institutes of Health, acting through the Director of the National Institute on Deafness and Other Communication Disorders, shall for purposes of this section, continue a program of research and development on the efficacy of new screening techniques and technology, including clinical studies of screening methods, studies on efficacy of intervention, and related research.

(c) COORDINATION AND COLLABORATION.—

(1) IN GENERAL.—In carrying out programs under this section, the Administrator of the Health Resources and Services Administration, the Director of the Centers for Disease Control and Prevention, and the Director of the National Institutes of Health shall collaborate and consult with other Federal agencies; State and local agencies, including those responsible for early intervention services pursuant to title XIX of the Social Security Act (Medicaid Early and Periodic Screening, Diagnosis and Treatment Program); title XXI of the Social Security Act (State Children's Health Insurance Program); title V of the Social Security Act (Maternal and Child Health Block Grant Program); and part C of the Individuals with Disabilities Education Act; consumer groups of and that serve individuals who are deaf and hard-of-hearing and their families; appropriate national medical and other health and education specialty organizations; persons who are deaf and hard-of-hearing and their families; other qualified professional personnel who are proficient in deaf or hard-of-hearing children's language and who possess the specialized knowledge, skills, and attributes needed to serve deaf and hard-of-hearing newborns, infants, toddlers, children, and their families; third-party payers and managed care organizations; and related commercial industries.

(2) POLICY DEVELOPMENT.—The Administrator of the Health Resources and Services Administration, the Director of the Centers for Disease Control and Prevention, and the Director of the National Institutes of Health shall coordinate and collaborate on recommendations for policy development at the Federal and State levels and with the private sector, including consumer, medical and other health and education professional-based organizations, with respect to newborn and infant hearing screening, evaluation, diagnosis, and intervention programs and systems.

(3) STATE EARLY DETECTION, DIAGNOSIS, AND INTERVENTION PROGRAMS AND SYSTEMS; DATA COLLECTION.—The Administrator of the Health Resources and Services Administration and the Director of the Centers for Disease Control and Prevention shall coordinate and collaborate in assisting States to establish newborn and infant hearing screening, evaluation, di-

agnosis, and intervention programs and systems under subsection (a) and to develop a data collection system under subsection (b).

(d) RULE OF CONSTRUCTION; RELIGIOUS ACCOMMODATION.—Nothing in this section shall be construed to preempt or prohibit any State law, including State laws which do not require the screening for hearing loss of newborn infants or young children of parents who object to the screening on the grounds that such screening conflicts with the parents' religious beliefs.

(e) DEFINITIONS.—For purposes of this section:

(1) The term "audiologic evaluation" refers to procedures to assess the status of the auditory system; to establish the site of the auditory disorder; the type and degree of hearing loss, and the potential effects of hearing loss on communication; and to identify appropriate treatment and referral options. Referral options should include linkage to State coordinating agencies under part C of the Individuals with Disabilities Education Act or other appropriate agencies, medical evaluation, hearing aid/sensory aid assessment, audiologic rehabilitation treatment, national and local consumer, self-help, parent, and education organizations, and other family-centered services.

(2) The terms "audiologic rehabilitation" and "audiologic intervention" refer to procedures, techniques, and technologies to facilitate the receptive and expressive communication abilities of a child with hearing loss.

(3) The term "early intervention" refers to providing appropriate services for the child with hearing loss, including nonmedical services, and ensuring that families of the child are provided comprehensive, consumer-oriented information about the full range of family support, training, information services, and language and communication options and are given the opportunity to consider and obtain the full range of such appropriate services, educational and program placements, and other options for their child from highly qualified providers.

(4) The term "medical evaluation by a physician" refers to key components including history, examination, and medical decision making focused on symptomatic and related body systems for the purpose of diagnosing the etiology of hearing loss and related physical conditions, and for identifying appropriate treatment and referral options.

(5) The term "medical intervention" refers to the process by which a physician provides medical diagnosis and direction for medical and/or surgical treatment options of hearing loss and/or related medical disorder associated with hearing loss.

(6) The term "newborn and infant hearing screening" refers to objective physiologic procedures to detect possible hearing loss and to identify newborns and infants who require further audiologic and medical evaluations.

(f) AUTHORIZATION OF APPROPRIATIONS.—

(1) STATEWIDE NEWBORN AND INFANT HEARING SCREENING, EVALUATION AND INTERVENTION PROGRAMS AND SYSTEMS.—For the purpose of carrying out subsection (a), there are authorized to be appropriated to the Health Resources and Services Ad-

ministration such sums as may be necessary for fiscal years 2011 through 2015.

(2) TECHNICAL ASSISTANCE, DATA MANAGEMENT, AND APPLIED RESEARCH; CENTERS FOR DISEASE CONTROL AND PREVENTION.—For the purpose of carrying out subsection (b)(1), there are authorized to be appropriated to the Centers for Disease Control and Prevention such sums as may be necessary for fiscal years 2011 through 2015.

(3) TECHNICAL ASSISTANCE, DATA MANAGEMENT, AND APPLIED RESEARCH; NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION DISORDERS.—For the purpose of carrying out subsection (b)(2), there are authorized to be appropriated to the National Institute on Deafness and Other Communication Disorders such sums as may be necessary for fiscal years 2011 through 2015.

SEC. 399N.[280g–2] CHILDHOOD MALIGNANCIES.

(a) IN GENERAL.—The Secretary, acting as appropriate through the Director of the Centers for Disease Control and Prevention and the Director of the National Institutes of Health, shall study environmental and other risk factors for childhood cancers (including skeletal malignancies, leukemias, malignant tumors of the central nervous system, lymphomas, soft tissue sarcomas, and other malignant neoplasms) and carry out projects to improve outcomes among children with childhood cancers and resultant secondary conditions, including limb loss, anemia, rehabilitation, and palliative care. Such projects shall be carried out by the Secretary directly and through awards of grants or contracts.

(b) CERTAIN ACTIVITIES.—Activities under subsection (a) include—

(1) the expansion of current demographic data collection and population surveillance efforts to include childhood cancers nationally;

(2) the development of a uniform reporting system under which treating physicians, hospitals, clinics, and States report the diagnosis of childhood cancers, including relevant associated epidemiological data; and

(3) support for the National Limb Loss Information Center to address, in part, the primary and secondary needs of persons who experience childhood cancers in order to prevent or minimize the disabling nature of these cancers.

(c) COORDINATION OF ACTIVITIES.—The Secretary shall assure that activities under this section are coordinated as appropriate with other agencies of the Public Health Service that carry out activities focused on childhood cancers and limb loss.

(d) DEFINITION.—For purposes of this section, the term "childhood cancer" refers to a spectrum of different malignancies that vary by histology, site of disease, origin, race, sex, and age. The Secretary may for purposes of this section revise the definition of such term to the extent determined by the Secretary to be appropriate.

(e) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated

such sums as may be necessary for each of the fiscal years 2001 through 2005.

SEC. 399O.[280g–3] CONTROLLED SUBSTANCE MONITORING PROGRAM.

(a) GRANTS.—

(1) IN GENERAL.—Each fiscal year, the Secretary shall award a grant to each State with an application approved under this section to enable the State—

(A) to establish and implement a State controlled substance monitoring program; or

(B) to make improvements to an existing State controlled substance monitoring program.

(2) DETERMINATION OF AMOUNT.—

(A) MINIMUM AMOUNT.—In making payments under a grant under paragraph (1) for a fiscal year, the Secretary shall allocate to each State with an application approved under this section an amount that equals 1.0 percent of the amount appropriated to carry out this section for that fiscal year.

(B) ADDITIONAL AMOUNTS.—In making payments under a grant under paragraph (1) for a fiscal year, the Secretary shall allocate to each State with an application approved under this section an additional amount which bears the same ratio to the amount appropriated to carry out this section for that fiscal year and remaining after amounts are made available under subparagraph (A) as the number of pharmacies of the State bears to the number of pharmacies of all States with applications approved under this section (as determined by the Secretary), except that the Secretary may adjust the amount allocated to a State under this subparagraph after taking into consideration the budget cost estimate for the State's controlled substance monitoring program.

(3) TERM OF GRANTS.—Grants awarded under this section shall be obligated in the year in which funds are allotted.

(b) DEVELOPMENT OF MINIMUM REQUIREMENTS.—Prior to awarding a grant under this section, and not later than 6 months after the date on which funds are first appropriated to carry out this section, after seeking consultation with States and other interested parties, the Secretary shall, after publishing in the Federal Register proposed minimum requirements and receiving public comments, establish minimum requirements for criteria to be used by States for purposes of clauses (ii), (v), (vi), and (vii) of subsection (c)(1)(A).

(c) APPLICATION APPROVAL PROCESS.—

(1) IN GENERAL.—To be eligible to receive a grant under this section, a State shall submit an application to the Secretary at such time, in such manner, and containing such assurances and information as the Secretary may reasonably require. Each such application shall include—

(A) with respect to a State that intends to use funds under the grant as provided for in subsection (a)(1)(A)—

(i) a budget cost estimate for the controlled substance monitoring program to be implemented under the grant;

(ii) criteria for security for information handling and for the database maintained by the State under subsection (e) generally including efforts to use appropriate encryption technology or other appropriate technology to protect the security of such information;

(iii) an agreement to adopt health information interoperability standards, including health vocabulary and messaging standards, that are consistent with any such standards generated or identified by the Secretary or his or her designee;

(iv) criteria for meeting the uniform electronic format requirement of subsection (h);

(v) criteria for availability of information and limitation on access to program personnel;

(vi) criteria for access to the database, and procedures to ensure that information in the database is accurate;

(vii) criteria for the use and disclosure of information, including a description of the certification process to be applied to requests for information under subsection (f);

(viii) penalties for the unauthorized use and disclosure of information maintained in the State controlled substance monitoring program in violation of applicable State law or regulation;

(ix) information on the relevant State laws, policies, and procedures, if any, regarding purging of information from the database; and

(x) assurances of compliance with all other requirements of this section; or

(B) with respect to a State that intends to use funds under the grant as provided for in subsection (a)(1)(B)—

(i) a budget cost estimate for the controlled substance monitoring program to be improved under the grant;

(ii) a plan for ensuring that the State controlled substance monitoring program is in compliance with the criteria and penalty requirements described in clauses (ii) through (viii) of subparagraph (A);

(iii) a plan to enable the State controlled substance monitoring program to achieve interoperability with at least one other State controlled substance monitoring program; and

(iv) assurances of compliance with all other requirements of this section or a statement describing why such compliance is not feasible or is contrary to the best interests of public health in such State.

(2) STATE LEGISLATION.—As part of an application under paragraph (1), the Secretary shall require a State to demonstrate that the State has enacted legislation or regulations to permit the implementation of the State controlled substance

monitoring program and the imposition of appropriate penalties for the unauthorized use and disclosure of information maintained in such program.

(3) INTEROPERABILITY.—If a State that submits an application under this subsection geographically borders another State that is operating a controlled substance monitoring program under subsection (a)(1) on the date of submission of such application, and such applicant State has not achieved interoperability for purposes of information sharing between its monitoring program and the monitoring program of such border State, such applicant State shall, as part of the plan under paragraph (1)(B)(iii), describe the manner in which the applicant State will achieve interoperability between the monitoring programs of such States.

(4) APPROVAL.—If a State submits an application in accordance with this subsection, the Secretary shall approve such application.

(5) RETURN OF FUNDS.—If the Secretary withdraws approval of a State's application under this section, or the State chooses to cease to implement or improve a controlled substance monitoring program under this section, a funding agreement for the receipt of a grant under this section is that the State will return to the Secretary an amount which bears the same ratio to the overall grant as the remaining time period for expending the grant funds bears to the overall time period for expending the grant (as specified by the Secretary at the time of the grant).

(d) REPORTING REQUIREMENTS.—In implementing or improving a controlled substance monitoring program under this section, a State shall comply, or with respect to a State that applies for a grant under subsection (a)(1)(B) submit to the Secretary for approval a statement of why such compliance is not feasible or is contrary to the best interests of public health in such State, with the following:

(1) The State shall require dispensers to report to such State each dispensing in the State of a controlled substance to an ultimate user not later than 1 week after the date of such dispensing.

(2) The State may exclude from the reporting requirement of this subsection—

(A) the direct administration of a controlled substance to the body of an ultimate user;

(B) the dispensing of a controlled substance in a quantity limited to an amount adequate to treat the ultimate user involved for 48 hours or less; or

(C) the administration or dispensing of a controlled substance in accordance with any other exclusion identified by the Secretary for purposes of this paragraph.

(3) The information to be reported under this subsection with respect to the dispensing of a controlled substance shall include the following:

(A) Drug Enforcement Administration Registration Number (or other identifying number used in lieu of such Registration Number) of the dispenser.

(B) Drug Enforcement Administration Registration Number (or other identifying number used in lieu of such Registration Number) and name of the practitioner who prescribed the drug.

(C) Name, address, and telephone number of the ultimate user or such contact information of the ultimate user as the Secretary determines appropriate.

(D) Identification of the drug by a national drug code number.

(E) Quantity dispensed.

(F) Number of refills ordered.

(G) Whether the drug was dispensed as a refill of a prescription or as a first-time request.

(H) Date of the dispensing.

(I) Date of origin of the prescription.

(J) Such other information as may be required by State law to be reported under this subsection.

(4) The State shall require dispensers to report information under this section in accordance with the electronic format specified by the Secretary under subsection (h), except that the State may waive the requirement of such format with respect to an individual dispenser that is unable to submit such information by electronic means.

(e) DATABASE.—In implementing or improving a controlled substance monitoring program under this section, a State shall comply with the following:

(1) The State shall establish and maintain an electronic database containing the information reported to the State under subsection (d).

(2) The database must be searchable by any field or combination of fields.

(3) The State shall include reported information in the database in a manner consistent with criteria established by the Secretary, with appropriate safeguards for ensuring the accuracy and completeness of the database.

(4) The State shall take appropriate security measures to protect the integrity of, and access to, the database.

(f) USE AND DISCLOSURE OF INFORMATION.—

(1) IN GENERAL.—Subject to subsection (g), in implementing or improving a controlled substance monitoring program under this section, a State may disclose information from the database established under subsection (e) and, in the case of a request under subparagraph (D), summary statistics of such information, only in response to a request by—

(A) a practitioner (or the agent thereof) who certifies, under the procedures determined by the State, that the requested information is for the purpose of providing medical or pharmaceutical treatment or evaluating the need for such treatment to a bona fide current patient;

(B) any local, State, or Federal law enforcement, narcotics control, licensure, disciplinary, or program authority, who certifies, under the procedures determined by the State, that the requested information is related to an individual investigation or proceeding involving the unlawful

diversion or misuse of a schedule II, III, or IV substance, and such information will further the purpose of the investigation or assist in the proceeding;

(C) the controlled substance monitoring program of another State or group of States with whom the State has established an interoperability agreement;

(D) any agent of the Department of Health and Human Services, a State medicaid program, a State health department, or the Drug Enforcement Administration who certifies that the requested information is necessary for research to be conducted by such department, program, or administration, respectively, and the intended purpose of the research is related to a function committed to such department, program, or administration by law that is not investigative in nature; or

(E) an agent of the State agency or entity of another State that is responsible for the establishment and maintenance of that State's controlled substance monitoring program, who certifies that—

(i) the State has an application approved under this section; and

(ii) the requested information is for the purpose of implementing the State's controlled substance monitoring program under this section.

(2) DRUG DIVERSION.—In consultation with practitioners, dispensers, and other relevant and interested stakeholders, a State receiving a grant under subsection (a)—

(A) shall establish a program to notify practitioners and dispensers of information that will help identify and prevent the unlawful diversion or misuse of controlled substances; and

(B) may, to the extent permitted under State law, notify the appropriate authorities responsible for carrying out drug diversion investigations if the State determines that information in the database maintained by the State under subsection (e) indicates an unlawful diversion or abuse of a controlled substance.

(g) LIMITATIONS.—In implementing or improving a controlled substance monitoring program under this section, a State—

(1) shall limit the information provided pursuant to a valid request under subsection (f)(1) to the minimum necessary to accomplish the intended purpose of the request; and

(2) shall limit information provided in response to a request under subsection (f)(1)(D) to nonidentifiable information.

(h) ELECTRONIC FORMAT.—The Secretary shall specify a uniform electronic format for the reporting, sharing, and disclosure of information under this section.

(i) RULES OF CONSTRUCTION.—

(1) FUNCTIONS OTHERWISE AUTHORIZED BY LAW.—Nothing in this section shall be construed to restrict the ability of any authority, including any local, State, or Federal law enforcement, narcotics control, licensure, disciplinary, or program authority, to perform functions otherwise authorized by law.

(2) NO PREEMPTION.—Nothing in this section shall be construed as preempting any State law, except that no such law may relieve any person of a requirement otherwise applicable under this Act.

(3) ADDITIONAL PRIVACY PROTECTIONS.—Nothing in this section shall be construed as preempting any State from imposing any additional privacy protections.

(4) FEDERAL PRIVACY REQUIREMENTS.—Nothing in this section shall be construed to supersede any Federal privacy or confidentiality requirement, including the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191; 110 Stat. 2033) and section 543 of the Public Health Service Act.

(5) NO FEDERAL PRIVATE CAUSE OF ACTION.—Nothing in this section shall be construed to create a Federal private cause of action.

(j) STUDIES AND REPORTS.—

(1) IMPLEMENTATION REPORT.—

(A) IN GENERAL.—Not later than 180 days after the date of enactment of this section, the Secretary, based on a review of existing State controlled substance monitoring programs and other relevant information, shall determine whether the implementation of such programs has had a substantial negative impact on—

(i) patient access to treatment, including therapy for pain or controlled substance abuse;

(ii) pediatric patient access to treatment; or

(iii) patient enrollment in research or clinical trials in which, following the protocol that has been approved by the relevant institutional review board for the research or clinical trial, the patient has obtained a controlled substance from either the scientific investigator conducting such research or clinical trial or the agent thereof.

(B) ADDITIONAL CATEGORIES OF EXCLUSION.—If the Secretary determines under subparagraph (A) that a substantial negative impact has been demonstrated with regard to one or more of the categories of patients described in such subparagraph, the Secretary shall identify additional appropriate categories of exclusion from reporting as authorized under subsection (d)(2)(C).

(2) PROGRESS REPORT.—Not later than 3 years after the date on which funds are first appropriated under this section, the Secretary shall—

(A) complete a study that—

(i) determines the progress of States in establishing and implementing controlled substance monitoring programs under this section;

(ii) provides an analysis of the extent to which the operation of controlled substance monitoring programs have reduced inappropriate use, abuse, or diversion of controlled substances or affected patient access to appropriate pain care in States operating such programs;

(iii) determines the progress of States in achieving interoperability between controlled substance monitoring programs, including an assessment of technical and legal barriers to such activities and recommendations for addressing these barriers;

(iv) determines the feasibility of implementing a real-time electronic controlled substance monitoring program, including the costs associated with establishing such a program;

(v) provides an analysis of the privacy protections in place for the information reported to the controlled substance monitoring program in each State receiving a grant for the establishment or operation of such program, and any recommendations for additional requirements for protection of this information;

(vi) determines the feasibility of implementing technological alternatives to centralized data storage, such as peer-to-peer file sharing or data pointer systems, in controlled substance monitoring programs and the potential for such alternatives to enhance the privacy and security of individually identifiable data; and

(vii) evaluates the penalties that States have enacted for the unauthorized use and disclosure of information maintained in the controlled substance monitoring program, and reports on the criteria used by the Secretary to determine whether such penalties qualify as appropriate pursuant to this section; and

(B) submit a report to the Congress on the results of the study.

(k) PREFERENCE.—Beginning 3 years after the date on which funds are first appropriated to carry out this section, the Secretary, in awarding any competitive grant that is related to drug abuse (as determined by the Secretary) and for which only States are eligible to apply, shall give preference to any State with an application approved under this section. The Secretary shall have the discretion to apply such preference to States with existing controlled substance monitoring programs that meet minimum requirements under this section or to States that put forth a good faith effort to meet those requirements (as determined by the Secretary).

(l) ADVISORY COUNCIL.—

(1) ESTABLISHMENT.—A State may establish an advisory council to assist in the establishment, implementation, or improvement of a controlled substance monitoring program under this section.

(2) LIMITATION.—A State may not use amounts received under a grant under this section for the operations of an advisory council established under paragraph (1).

(3) SENSE OF CONGRESS.—It is the sense of the Congress that, in establishing an advisory council under this subsection, a State should consult with appropriate professional boards and other interested parties.

(m) DEFINITIONS.—For purposes of this section:

(1) The term "bona fide patient" means an individual who is a patient of the practitioner involved.

(2) The term "controlled substance" means a drug that is included in schedule II, III, or IV of section 202(c) of the Controlled Substance Act.

(3) The term "dispense" means to deliver a controlled substance to an ultimate user by, or pursuant to the lawful order of, a practitioner, irrespective of whether the dispenser uses the Internet or other means to effect such delivery.

(4) The term "dispenser" means a physician, pharmacist, or other person that dispenses a controlled substance to an ultimate user.

(5) The term "interoperability" with respect to a State controlled substance monitoring program means the ability of the program to electronically share reported information, including each of the required report components described in subsection (d), with another State if the information concerns either the dispensing of a controlled substance to an ultimate user who resides in such other State, or the dispensing of a controlled substance prescribed by a practitioner whose principal place of business is located in such other State.

(6) The term "nonidentifiable information" means information that does not identify a practitioner, dispenser, or an ultimate user and with respect to which there is no reasonable basis to believe that the information can be used to identify a practitioner, dispenser, or an ultimate user.

(7) The term "practitioner" means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he or she practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

(8) The term "State" means each of the 50 States and the District of Columbia.

(9) The term "ultimate user" means a person who has obtained from a dispenser, and who possesses, a controlled substance for his or her own use, for the use of a member of his or her household, or for the use of an animal owned by him or her or by a member of his or her household.

(n) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated—

(1) $15,000,000 for each of fiscal years 2006 and 2007; and

(2) $10,000,000 for each of fiscal years 2008, 2009, and 2010.

SEC. 399P.[280g–4] GRANTS TO STRENGTHEN THE HEALTHCARE SYSTEM'S RESPONSE TO DOMESTIC VIOLENCE, DATING VIOLENCE, SEXUAL ASSAULT, AND STALKING.

(a) IN GENERAL.—The Secretary shall award grants for—

(1) the development or enhancement and implementation of interdisciplinary training for health professionals, public health staff, and allied health professionals;

(2) the development or enhancement and implementation of education programs for medical, nursing, dental, and other health profession students and residents to prevent and respond to domestic violence, dating violence, sexual assault, and stalking; and

(3) the development or enhancement and implementation of comprehensive statewide strategies to improve the response of clinics, public health facilities, hospitals, and other health settings (including behavioral and mental health programs) to domestic violence, dating violence, sexual assault, and stalking.

(b) USE OF FUNDS.—

(1) REQUIRED USES.—Amounts provided under a grant under this section shall be used to—

(A) fund interdisciplinary training and education programs under paragraphs (1) and (2) of subsection (a) that—

(i) are designed to train medical, psychology, dental, social work, nursing, and other health profession students, interns, residents, fellows, or current health care providers to identify and provide health care services (including mental or behavioral health care services and referrals to appropriate community services) to individuals who are or who have been victims of domestic violence, dating violence, sexual assault, or stalking; and

(ii) plan and develop culturally competent clinical training components for integration into approved internship, residency, and fellowship training or continuing medical or other health education training that address physical, mental, and behavioral health issues, including protective factors, related to domestic violence, dating violence, sexual assault, stalking, and other forms of violence and abuse, focus on reducing health disparities and preventing violence and abuse, and include the primacy of victim safety and confidentiality;

(B) design and implement comprehensive strategies to improve the response of the health care system to domestic or sexual violence in clinical and public health settings, hospitals, clinics, and other health settings (including behavioral and mental health), under subsection (a)(3) through—

(i) the implementation, dissemination, and evaluation of policies and procedures to guide health professionals and public health staff in identifying and responding to domestic violence, dating violence, sexual assault, and stalking, including strategies to ensure that health information is maintained in a manner that protects the patient's privacy and safety, and safely uses health information technology to improve documentation, identification, assessment, treatment, and follow-up care;

(ii) the development of on-site access to services to address the safety, medical, and mental health needs

of patients by increasing the capacity of existing health care professionals and public health staff to address domestic violence, dating violence, sexual assault, and stalking, or by contracting with or hiring domestic or sexual assault advocates to provide such services or to model other services appropriate to the geographic and cultural needs of a site;

(iii) the development of measures and methods for the evaluation of the practice of identification, intervention, and documentation regarding victims of domestic violence, dating violence, sexual assault, and stalking, including the development and testing of quality improvement measurements, in accordance with the multi-stakeholder and quality measurement processes established under paragraphs (7) and (8) of section 1890(b) and section 1890A of the Social Security Act (42 U.S.C. 1395aaa(b)(7) and (8); 42 U.S.C. 1890A); and

(iv) the provision of training and follow-up technical assistance to health care professionals, and public health staff, and allied health professionals to identify, assess, treat, and refer clients who are victims of domestic violence, dating violence, sexual assault, or stalking, including using tools and training materials already developed.

(2) PERMISSIBLE USES.—

(A) CHILD AND ELDER ABUSE.—To the extent consistent with the purpose of this section, a grantee may use amounts received under this section to address, as part of a comprehensive programmatic approach implemented under the grant, issues relating to child or elder abuse.

(B) RURAL AREAS.—Grants funded under paragraphs (1) and (2) of subsection (a) may be used to offer to rural areas community-based training opportunities, which may include the use of distance learning networks and other available technologies needed to reach isolated rural areas, for medical, nursing, and other health profession students and residents on domestic violence, dating violence, sexual assault, stalking, and, as appropriate, other forms of violence and abuse.

(C) OTHER USES.—Grants funded under subsection (a)(3) may be used for—

(i) the development of training modules and policies that address the overlap of child abuse, domestic violence, dating violence, sexual assault, and stalking and elder abuse, as well as childhood exposure to domestic and sexual violence;

(ii) the development, expansion, and implementation of sexual assault forensic medical examination or sexual assault nurse examiner programs;

(iii) the inclusion of the health effects of lifetime exposure to violence and abuse as well as related protective factors and behavioral risk factors in health professional training schools including medical, dental,

nursing, social work, and mental and behavioral health curricula, and allied health service training courses; or

(iv) the integration of knowledge of domestic violence, dating violence, sexual assault, and stalking into health care accreditation and professional licensing examinations, such as medical, dental, social work, and nursing boards, and where appropriate, other allied health exams.

(c) REQUIREMENTS FOR GRANTEES.—

(1) CONFIDENTIALITY AND SAFETY.—

(A) IN GENERAL.—Grantees under this section shall ensure that all programs developed with grant funds address issues of confidentiality and patient safety and comply with applicable confidentiality and nondisclosure requirements under section 40002(b)(2) of the Violence Against Women Act of 1994 and the Family Violence Prevention and Services Act, and that faculty and staff associated with delivering educational components are fully trained in procedures that will protect the immediate and ongoing security and confidentiality of the patients, patient records, and staff. Such grantees shall consult entities with demonstrated expertise in the confidentiality and safety needs of victims of domestic violence, dating violence, sexual assault, and stalking on the development and adequacy of confidentially and security procedures, and provide documentation of such consultation.

(B) ADVANCE NOTICE OF INFORMATION DISCLOSURE.—Grantees under this section shall provide to patients advance notice about any circumstances under which information may be disclosed, such as mandatory reporting laws, and shall give patients the option to receive information and referrals without affirmatively disclosing abuse.

(2) LIMITATION ON ADMINISTRATIVE EXPENSES.—A grantee shall use not more than 10 percent of the amounts received under a grant under this section for administrative expenses.

(3) APPLICATION.—

(A) PREFERENCE.—In selecting grant recipients under this section, the Secretary shall give preference to applicants based on the strength of their evaluation strategies, with priority given to outcome based evaluations.

(B) SUBSECTION (A)(1) AND (2) GRANTEES.—Applications for grants under paragraphs (1) and (2) of subsection (a) shall include—

(i) documentation that the applicant represents a team of entities working collaboratively to strengthen the response of the health care system to domestic violence, dating violence, sexual assault, or stalking, and which includes at least one of each of—

(I) an accredited school of allopathic or osteopathic medicine, psychology, nursing, dentistry, social work, or other health field;

(II) a health care facility or system; or

(III) a government or nonprofit entity with a history of effective work in the fields of domestic violence, dating violence, sexual assault, or stalking; and

(ii) strategies for the dissemination and sharing of curricula and other educational materials developed under the grant, if any, with other interested health professions schools and national resource repositories for materials on domestic violence, dating violence, sexual assault, and stalking.

(C) SUBSECTION (A)(3) GRANTEES.—An entity desiring a grant under subsection (a)(3) shall submit an application to the Secretary at such time, in such a manner, and containing such information and assurances as the Secretary may require, including—

(i) documentation that all training, education, screening, assessment, services, treatment, and any other approach to patient care will be informed by an understanding of violence and abuse victimization and trauma-specific approaches that will be integrated into prevention, intervention, and treatment activities;

(ii) strategies for the development and implementation of policies to prevent and address domestic violence, dating violence, sexual assault, and stalking over the lifespan in health care settings;

(iii) a plan for consulting with State and tribal domestic violence or sexual assault coalitions, national nonprofit victim advocacy organizations, State or tribal law enforcement task forces (where appropriate), and population specific organizations with demonstrated expertise in domestic violence, dating violence, sexual assault, or stalking;

(iv) with respect to an application for a grant under which the grantee will have contact with patients, a plan, developed in collaboration with local victim service providers, to respond appropriately to and make correct referrals for individuals who disclose that they are victims of domestic violence, dating violence, sexual assault, stalking, or other types of violence, and documentation provided by the grantee of an ongoing collaborative relationship with a local victim service provider; and

(v) with respect to an application for a grant proposing to fund a program described in subsection (b)(2)(C)(ii), a certification that any sexual assault forensic medical examination and sexual assault nurse examiner programs supported with such grant funds will adhere to the guidelines set forth by the Attorney General.

(d) ELIGIBLE ENTITIES.—

(1) IN GENERAL.—To be eligible to receive funding under paragraph (1) or (2) of subsection (a), an entity shall be—

(A) a nonprofit organization with a history of effective work in the field of training health professionals with an

understanding of, and clinical skills pertinent to, domestic violence, dating violence, sexual assault, or stalking, and lifetime exposure to violence and abuse;

(B) an accredited school of allopathic or osteopathic medicine, psychology, nursing, dentistry, social work, or allied health;

(C) a health care provider membership or professional organization, or a health care system; or

(D) a State, tribal, territorial, or local entity.

(2) SUBSECTION (A)(3) GRANTEES.—To be eligible to receive funding under subsection (a)(3), an entity shall be—

(A) a State department (or other division) of health, a State, tribal, or territorial domestic violence or sexual assault coalition or victim service provider, or any other nonprofit, nongovernmental organization with a history of effective work in the fields of domestic violence, dating violence, sexual assault, or stalking, and health care, including physical or mental health care; or

(B) a local victim service provider, a local department (or other division) of health, a local health clinic, hospital, or health system, or any other community-based organization with a history of effective work in the field of domestic violence, dating violence, sexual assault, or stalking and health care, including physical or mental health care.

(e) TECHNICAL ASSISTANCE.—

(1) IN GENERAL.—Of the funds made available to carry out this section for any fiscal year, the Secretary may make grants or enter into contracts to provide technical assistance with respect to the planning, development, and operation of any program, activity or service carried out pursuant to this section. Not more than 8 percent of the funds appropriated under this section in each fiscal year may be used to fund technical assistance under this subsection.

(2) AVAILABILITY OF MATERIALS.—The Secretary shall make publicly available materials developed by grantees under this section, including materials on training, best practices, and research and evaluation.

(3) REPORTING.—The Secretary shall publish a biennial report on—

(A) the distribution of funds under this section; and

(B) the programs and activities supported by such funds.

(f) RESEARCH AND EVALUATION.—

(1) IN GENERAL.—Of the funds made available to carry out this section for any fiscal year, the Secretary may use not more than 20 percent to make a grant or enter into a contract for research and evaluation of—

(A) grants awarded under this section; and

(B) other training for health professionals and effective interventions in the health care setting that prevent domestic violence, dating violence, and sexual assault across the lifespan, prevent the health effects of such violence, and improve the safety and health of individuals who are currently being victimized.

(2) RESEARCH.—Research authorized in paragraph (1) may include—

(A) research on the effects of domestic violence, dating violence, sexual assault, and childhood exposure to domestic, dating or sexual violence on health behaviors, health conditions, and health status of individuals, families, and populations, including underserved populations;

(B) research to determine effective health care interventions to respond to and prevent domestic violence, dating violence, sexual assault, and stalking;

(C) research on the impact of domestic, dating and sexual violence, childhood exposure to such violence, and stalking on the health care system, health care utilization, health care costs, and health status; and

(D) research on the impact of adverse childhood experiences on adult experience with domestic violence, dating violence, sexual assault, stalking, and adult health outcomes, including how to reduce or prevent the impact of adverse childhood experiences through the health care setting.

(g) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $10,000,000 for each of fiscal years 2014 through 2018.

(h) DEFINITIONS.—Except as otherwise provided herein, the definitions provided for in section 40002 of the Violence Against Women Act of 1994 shall apply to this section.

SEC. 399Q.[280g–4] PUBLIC AND HEALTH CARE PROVIDER EDUCATION AND SUPPORT SERVICES.

(a) IN GENERAL.—The Secretary, directly or through the awarding of grants to public or private nonprofit entities, may conduct demonstration projects for the purpose of improving the provision of information on prematurity to health professionals and other health care providers and the public and improving the treatment and outcomes for babies born preterm.

(b) ACTIVITIES.—Activities to be carried out under the demonstration project under subsection (a) may include the establishment of—

(1) programs to test and evaluate various strategies to provide information and education to health professionals, other health care providers, and the public concerning—

(A) the signs of preterm labor, updated as new research results become available;

(B) the screening for and the treating of infections;

(c) counseling on optimal weight and good nutrition, including folic acid;

(D) smoking cessation education and counseling;

(E) stress management; and

(F) appropriate prenatal care;

(2) programs to improve the treatment and outcomes for babies born premature, including the use of evidence-based standards of care by health care professionals for pregnant women at risk of preterm labor or other serious complications and for infants born preterm and at a low birthweight;

(3) programs to respond to the informational needs of families during the stay of an infant in a neonatal intensive care unit, during the transition of the infant to the home, and in the event of a newborn death; and

(4) such other programs as the Secretary determines appropriate to achieve the purpose specified in subsection (a).

(c) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $5,000,000 for each of fiscal years 2007 through 2011.

SEC. 399R.[280g–6] CHRONIC KIDNEY DISEASE INITIATIVES.

(a) IN GENERAL.—The Secretary shall establish pilot projects to—

(1) increase public and medical community awareness (particularly of those who treat patients with diabetes and hypertension) regarding chronic kidney disease, focusing on prevention;

(2) increase screening for chronic kidney disease, focusing on Medicare beneficiaries at risk of chronic kidney disease; and

(3) enhance surveillance systems to better assess the prevalence and incidence of chronic kidney disease.

(b) SCOPE AND DURATION.—

(1) SCOPE.—The Secretary shall select at least 3 States in which to conduct pilot projects under this section.

(2) DURATION.—The pilot projects under this section shall be conducted for a period that is not longer than 5 years and shall begin on January 1, 2009.

(c) EVALUATION AND REPORT.—The Comptroller General of the United States shall conduct an evaluation of the pilot projects conducted under this section. Not later than 12 months after the date on which the pilot projects are completed, the Comptroller General shall submit to Congress a report on the evaluation.

(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary for the purpose of carrying out this section.

SEC. 399S.[280g–7] AMYOTROPHIC LATERAL SCLEROSIS REGISTRY.

(a) ESTABLISHMENT.—

(1) IN GENERAL.—Not later than 1 year after the receipt of the report described in subsection (b)(2)(A), the Secretary, acting through the Director of the Centers for Disease Control and Prevention, may, if scientifically advisable—

(A) develop a system to collect data on amyotrophic lateral sclerosis (referred to in this section as "ALS") and other motor neuron disorders that can be confused with ALS, misdiagnosed as ALS, and in some cases progress to ALS, including information with respect to the incidence and prevalence of the disease in the United States; and

(B) establish a national registry for the collection and storage of such data to develop a population-based registry of cases in the United States of ALS and other motor neuron disorders that can be confused with ALS, misdiagnosed as ALS, and in some cases progress to ALS.

(2) PURPOSE.—It is the purpose of the registry established under paragraph (1)(B) to—

(A) better describe the incidence and prevalence of ALS in the United States;

(B) examine appropriate factors, such as environmental and occupational, that may be associated with the disease;

(C) better outline key demographic factors (such as age, race or ethnicity, gender, and family history of individuals who are diagnosed with the disease) associated with the disease;

(D) better examine the connection between ALS and other motor neuron disorders that can be confused with ALS, misdiagnosed as ALS, and in some cases progress to ALS; and

(E) other matters as recommended by the Advisory Committee established under subsection (b).

(b) ADVISORY COMMITTEE.—

(1) ESTABLISHMENT.—Not later than 180 days after the date of the enactment of this section, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, may establish a committee to be known as the Advisory Committee on the National ALS Registry (referred to in this section as the "Advisory Committee"). The Advisory Committee shall be composed of not more than 27 members to be appointed by the Secretary, acting through the Centers for Disease Control and Prevention, of which—

(A) two-thirds of such members shall represent governmental agencies—

(i) including at least one member representing—

(I) the National Institutes of Health, to include, upon the recommendation of the Director of the National Institutes of Health, representatives from the National Institute of Neurological Disorders and Stroke and the National Institute of Environmental Health Sciences;

(II) the Department of Veterans Affairs;

(III) the Agency for Toxic Substances and Disease Registry; and

(IV) the Centers for Disease Control and Prevention; and

(ii) of which at least one such member shall be a clinician with expertise on ALS and related diseases, an epidemiologist with experience in data registries, a statistician, an ethicist, and a privacy expert (relating to the privacy regulations under the Health Insurance Portability and Accountability Act of 1996); and

(B) one-third of such members shall be public members, including at least one member representing—

(i) national and voluntary health associations;

(ii) patients with ALS or their family members;

(iii) clinicians with expertise on ALS and related diseases;

(iv) epidemiologists with experience in data registries;

(v) geneticists or experts in genetics who have experience with the genetics of ALS or other neurological diseases and

(vi) other individuals with an interest in developing and maintaining the National ALS Registry.

(2) DUTIES.—The Advisory Committee may review information and make recommendations to the Secretary concerning—

(A) the development and maintenance of the National ALS Registry;

(B) the type of information to be collected and stored in the Registry;

(C) the manner in which such data is to be collected;

(D) the use and availability of such data including guidelines for such use; and

(E) the collection of information about diseases and disorders that primarily affect motor neurons that are considered essential to furthering the study and cure of ALS.

(3) REPORT.—Not later than 270 days after the date on which the Advisory Committee is established, the Advisory Committee may submit a report to the Secretary concerning the review conducted under paragraph (2) that contains the recommendations of the Advisory Committee with respect to the results of such review.

(c) GRANTS.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may award grants to, and enter into contracts and cooperative agreements with, public or private nonprofit entities for the collection, analysis, and reporting of data on ALS and other motor neuron disorders that can be confused with ALS, misdiagnosed as ALS, and in some cases progress to ALS after receiving the report under subsection (b)(3).

(d) COORDINATION WITH STATE, LOCAL, AND FEDERAL REGISTRIES.—

(1)[105] IN GENERAL.—In establishing the National ALS Registry under subsection (a), the Secretary, acting through the Director of the Centers for Disease Control and Prevention, may—

(A) identify, build upon, expand, and coordinate among existing data and surveillance systems, surveys, registries, and other Federal public health and environmental infrastructure wherever possible, which may include—

(i) any registry pilot projects previously supported by the Centers for Disease Control and Prevention;

(ii) the Department of Veterans Affairs ALS Registry;

(iii) the DNA and Cell Line Repository of the National Institute of Neurological Disorders and Stroke Human Genetics Resource Center at the National Institutes of Health;

(iv) Agency for Toxic Substances and Disease Registry studies, including studies conducted in Illinois,

[105] So in law. Subsection (d) (as added by section 2 of Public Law 110–373) does not include a paragraph (2).

Missouri, El Paso and San Antonio, Texas, and Massachusetts;

(v) State-based ALS registries;

(vi) the National Vital Statistics System; and

(vii) any other existing or relevant databases that collect or maintain information on those motor neuron diseases recommended by the Advisory Committee established in subsection (b); and

(B) provide for research access to ALS data as recommended by the Advisory Committee established in subsection (b) to the extent permitted by applicable statutes and regulations and in a manner that protects personal privacy consistent with applicable privacy statutes and regulations.

(C) COORDINATION WITH NIH AND DEPARTMENT OF VETERANS AFFAIRS.—Consistent with applicable privacy statutes and regulations, the Secretary may ensure that epidemiological and other types of information obtained under subsection (a) is made available to the National Institutes of Health and the Department of Veterans Affairs.

(e) DEFINITION.—For the purposes of this section, the term "national voluntary health association" means a national non-profit organization with chapters or other affiliated organizations in States throughout the United States with experience serving the population of individuals with ALS and have demonstrated experience in ALS research, care, and patient services.

SEC. 399T.[280g–8] SUPPORT FOR PATIENTS RECEIVING A POSITIVE DIAGNOSIS OF DOWN SYNDROME OR OTHER PRENATALLY OR POSTNATALLY DIAGNOSED CONDITIONS.

(a) DEFINITIONS.—In this section:

(1) DOWN SYNDROME.—The term "Down syndrome" refers to a chromosomal disorder caused by an error in cell division that results in the presence of an extra whole or partial copy of chromosome 21.

(2) HEALTH CARE PROVIDER.—The term "health care provider" means any person or entity required by State or Federal law or regulation to be licensed, registered, or certified to provide health care services, and who is so licensed, registered, or certified.

(3) POSTNATALLY DIAGNOSED CONDITION.—The term "postnatally diagnosed condition" means any health condition identified during the 12-month period beginning at birth.

(4) PRENATALLY DIAGNOSED CONDITION.—The term "prenatally diagnosed condition" means any fetal health condition identified by prenatal genetic testing or prenatal screening procedures.

(5) PRENATAL TEST.—The term "prenatal test" means diagnostic or screening tests offered to pregnant women seeking routine prenatal care that are administered on a required or recommended basis by a health care provider based on medical history, family background, ethnic background, previous test results, or other risk factors.

(b) INFORMATION AND SUPPORT SERVICES.—

(1) IN GENERAL.—The Secretary, acting through the Director of the National Institutes of Health, the Director of the Centers for Disease Control and Prevention, or the Administrator of the Health Resources and Services Administration, may authorize and oversee certain activities, including the awarding of grants, contracts or cooperative agreements to eligible entities, to—

(A) collect, synthesize, and disseminate current evidence-based information relating to Down syndrome or other prenatally or postnatally diagnosed conditions; and

(B) coordinate the provision of, and access to, new or existing supportive services for patients receiving a positive diagnosis for Down syndrome or other prenatally or postnatally diagnosed conditions, including—

(i) the establishment of a resource telephone hotline accessible to patients receiving a positive test result or to the parents of newly diagnosed infants with Down syndrome and other diagnosed conditions;

(ii) the expansion and further development of the National Dissemination Center for Children with Disabilities, so that such Center can more effectively conduct outreach to new and expecting parents and provide them with up-to-date information on the range of outcomes for individuals living with the diagnosed condition, including physical, developmental, educational, and psychosocial outcomes;

(iii) the expansion and further development of national and local peer-support programs, so that such programs can more effectively serve women who receive a positive diagnosis for Down syndrome or other prenatal conditions or parents of infants with a postnatally diagnosed condition;

(iv) the establishment of a national registry, or network of local registries, of families willing to adopt newborns with Down syndrome or other prenatally or postnatally diagnosed conditions, and links to adoption agencies willing to place babies with Down syndrome or other prenatally or postnatally diagnosed conditions, with families willing to adopt; and

(v) the establishment of awareness and education programs for health care providers who provide, interpret, or inform parents of the results of prenatal tests for Down syndrome or other prenatally or postnatally diagnosed conditions, to patients, consistent with the purpose described in section 2(b)(1)[106] of the Prenatally and Postnatally Diagnosed Conditions Awareness Act.

(2) ELIGIBLE ENTITY.—In this subsection, the term "eligible entity" means—

(A) a State or a political subdivision of a State;

(B) a consortium of 2 or more States or political subdivisions of States;

[106] So in law. Probably should read "section 2(1)".

(C) a territory;

(D) a health facility or program operated by or pursuant to a contract with or grant from the Indian Health Service; or

(E) any other entity with appropriate expertise in prenatally and postnatally diagnosed conditions (including nationally recognized disability groups), as determined by the Secretary.

(3) DISTRIBUTION.—In distributing funds under this subsection, the Secretary shall place an emphasis on funding partnerships between health care professional groups and disability advocacy organizations.

(c) PROVISION OF INFORMATION TO PROVIDERS.—

(1) IN GENERAL.—A grantee under this section shall make available to health care providers of parents who receive a prenatal or postnatal diagnosis the following:

(A) Up-to-date, evidence-based, written information concerning the range of outcomes for individuals living with the diagnosed condition, including physical, developmental, educational, and psychosocial outcomes.

(B) Contact information regarding support services, including information hotlines specific to Down syndrome or other prenatally or postnatally diagnosed conditions, resource centers or clearinghouses, national and local peer support groups, and other education and support programs as described in subsection (b)(2).

(2) INFORMATIONAL REQUIREMENTS.—Information provided under this subsection shall be—

(A) culturally and linguistically appropriate as needed by women receiving a positive prenatal diagnosis or the family of infants receiving a postnatal diagnosis; and

(B) approved by the Secretary.

(d) REPORT.—Not later than 2 years after the date of enactment of this section, the Government Accountability Office shall submit a report to Congress concerning the effectiveness of current healthcare and family support programs serving as resources for the families of children with disabilities.

SEC. 399U.[280g–10] COMMUNITY PREVENTIVE SERVICES TASK FORCE.

(a) ESTABLISHMENT AND PURPOSE.—The Director of the Centers for Disease Control and Prevention shall convene an independent Community Preventive Services Task Force (referred to in this subsection as the "Task Force") to be composed of individuals with appropriate expertise. Such Task Force shall review the scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of community preventive interventions for the purpose of developing recommendations, to be published in the Guide to Community Preventive Services (referred to in this section as the "Guide"), for individuals and organizations delivering population-based services, including primary care professionals, health care systems, professional societies, employers, community organizations, non-profit organizations, schools, governmental public health agencies, Indian tribes, tribal organizations and urban Indian organizations, medical groups, Congress and other policy-

makers. Community preventive services include any policies, programs, processes or activities designed to affect or otherwise affecting health at the population level.

(b) DUTIES.—The duties of the Task Force shall include—

(1) the development of additional topic areas for new recommendations and interventions related to those topic areas, including those related to specific populations and age groups, as well as the social, economic and physical environments that can have broad effects on the health and disease of populations and health disparities among sub-populations and age groups;

(2) at least once during every 5-year period, review interventions and update recommendations related to existing topic areas, including new or improved techniques to assess the health effects of interventions, including health impact assessment and population health modeling;

(3) improved integration with Federal Government health objectives and related target setting for health improvement;

(4) the enhanced dissemination of recommendations;

(5) the provision of technical assistance to those health care professionals, agencies, and organizations that request help in implementing the Guide recommendations; and

(6) providing yearly reports to Congress and related agencies identifying gaps in research and recommending priority areas that deserve further examination, including areas related to populations and age groups not adequately addressed by current recommendations.

(c) ROLE OF AGENCY.—The Director shall provide ongoing administrative, research, and technical support for the operations of the Task Force, including coordinating and supporting the dissemination of the recommendations of the Task Force, ensuring adequate staff resources, and assistance to those organizations requesting it for implementation of Guide recommendations.

(d) COORDINATION WITH PREVENTIVE SERVICES TASK FORCE.—The Task Force shall take appropriate steps to coordinate its work with the U.S. Preventive Services Task Force and the Advisory Committee on Immunization Practices, including the examination of how each task force's recommendations interact at the nexus of clinic and community.

(e) OPERATION.—In carrying out the duties under subsection (b), the Task Force shall not be subject to the provisions of Appendix 2 of title 5, United States Code.

(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary for each fiscal year to carry out the activities of the Task Force.

SEC. 399V.[280g–11] GRANTS TO PROMOTE POSITIVE HEALTH BEHAVIORS AND OUTCOMES.

(a) GRANTS AUTHORIZED.—The Director of the Centers for Disease Control and Prevention, in collaboration with the Secretary, shall award grants to eligible entities to promote positive health behaviors and outcomes for populations in medically underserved communities through the use of community health workers.

(b) USE OF FUNDS.—Grants awarded under subsection (a) shall be used to support community health workers—

(1) to educate, guide, and provide outreach in a community setting regarding health problems prevalent in medically underserved communities, particularly racial and ethnic minority populations;

(2) to educate and provide guidance regarding effective strategies to promote positive health behaviors and discourage risky health behaviors;

(3) to educate and provide outreach regarding enrollment in health insurance including the Children's Health Insurance Program under title XXI of the Social Security Act, Medicare under title XVIII of such Act and Medicaid under title XIX of such Act;

(4) to identify and refer underserved populations to appropriate healthcare agencies and community-based programs and organizations in order to increase access to quality healthcare services and to eliminate duplicative care; or

(5) to educate, guide, and provide home visitation services regarding maternal health and prenatal care.

(c) APPLICATION.—Each eligible entity that desires to receive a grant under subsection (a) shall submit an application to the Secretary, at such time, in such manner, and accompanied by such information as the Secretary may require.

(d) PRIORITY.—In awarding grants under subsection (a), the Secretary shall give priority to applicants that—

(1) propose to target geographic areas—

(A) with a high percentage of residents who are eligible for health insurance but are uninsured or underinsured;

(B) with a high percentage of residents who suffer from chronic diseases; or

(C) with a high infant mortality rate;

(2) have experience in providing health or health-related social services to individuals who are underserved with respect to such services; and

(3) have documented community activity and experience with community health workers.

(e) COLLABORATION WITH ACADEMIC INSTITUTIONS AND THE ONE-STOP DELIVERY SYSTEM.—The Secretary shall encourage community health worker programs receiving funds under this section to collaborate with academic institutions and one-stop delivery systems under section 134(c) of the Workforce Investment Act of 1998. Nothing in this section shall be construed to require such collaboration.

(f) EVIDENCE-BASED INTERVENTIONS.—The Secretary shall encourage community health worker programs receiving funding under this section to implement a process or an outcome-based payment system that rewards community health workers for connecting underserved populations with the most appropriate services at the most appropriate time. Nothing in this section shall be construed to require such a payment.

(g) QUALITY ASSURANCE AND COST EFFECTIVENESS.—The Secretary shall establish guidelines for assuring the quality of the training and supervision of community health workers under the

programs funded under this section and for assuring the cost-effectiveness of such programs.

(h) MONITORING.—The Secretary shall monitor community health worker programs identified in approved applications under this section and shall determine whether such programs are in compliance with the guidelines established under subsection (g).

(i) TECHNICAL ASSISTANCE.—The Secretary may provide technical assistance to community health worker programs identified in approved applications under this section with respect to planning, developing, and operating programs under the grant.

(j) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated, such sums as may be necessary to carry out this section for each of fiscal years 2010 through 2014.

(k) DEFINITIONS.—In this section:

(1) COMMUNITY HEALTH WORKER.—The term "community health worker" means an individual who promotes health or nutrition within the community in which the individual resides—

(A) by serving as a liaison between communities and healthcare agencies;

(B) by providing guidance and social assistance to community residents;

(C) by enhancing community residents' ability to effectively communicate with healthcare providers;

(D) by providing culturally and linguistically appropriate health or nutrition education;

(E) by advocating for individual and community health;

(F) by providing referral and follow-up services or otherwise coordinating care; and

(G) by proactively identifying and enrolling eligible individuals in Federal, State, local, private or nonprofit health and human services programs.

(2) COMMUNITY SETTING.—The term "community setting" means a home or a community organization located in the neighborhood in which a participant in the program under this section resides.

(3) ELIGIBLE ENTITY.—The term "eligible entity" means a public or nonprofit private entity (including a State or public subdivision of a State, a public health department, a free health clinic, a hospital, or a Federally-qualified health center (as defined in section 1861(aa) of the Social Security Act)), or a consortium of any such entities.

(4) MEDICALLY UNDERSERVED COMMUNITY.—The term "medically underserved community" means a community identified by a State—

(A) that has a substantial number of individuals who are members of a medically underserved population, as defined by section 330(b)(3); and

(B) a significant portion of which is a health professional shortage area as designated under section 332.

SEC. 399V–1.[280g–12] PRIMARY CARE EXTENSION PROGRAM.

(a) ESTABLISHMENT, PURPOSE AND DEFINITION.—

(1) IN GENERAL.—The Secretary, acting through the Director of the Agency for Healthcare Research and Quality, shall establish a Primary Care Extension Program.

(2) PURPOSE.—The Primary Care Extension Program shall provide support and assistance to primary care providers to educate providers about preventive medicine, health promotion, chronic disease management, mental and behavioral health services (including substance abuse prevention and treatment services), and evidence-based and evidence-informed therapies and techniques, in order to enable providers to incorporate such matters into their practice and to improve community health by working with community-based health connectors (referred to in this section as "Health Extension Agents").

(3) DEFINITIONS.—In this section:

(A) HEALTH EXTENSION AGENT.—The term "Health Extension Agent" means any local, community-based health worker who facilitates and provides assistance to primary care practices by implementing quality improvement or system redesign, incorporating the principles of the patient-centered medical home to provide high-quality, effective, efficient, and safe primary care and to provide guidance to patients in culturally and linguistically appropriate ways, and linking practices to diverse health system resources.

(B) PRIMARY CARE PROVIDER.—The term "primary care provider" means a clinician who provides integrated, accessible health care services and who is accountable for addressing a large majority of personal health care needs, including providing preventive and health promotion services for men, women, and children of all ages, developing a sustained partnership with patients, and practicing in the context of family and community, as recognized by a State licensing or regulatory authority, unless otherwise specified in this section.

(b) GRANTS TO ESTABLISH STATE HUBS AND LOCAL PRIMARY CARE EXTENSION AGENCIES.—

(1) GRANTS.—The Secretary shall award competitive grants to States for the establishment of State- or multistate-level primary care Primary Care Extension Program State Hubs (referred to in this section as "Hubs").

(2) COMPOSITION OF HUBS.—A Hub established by a State pursuant to paragraph (1)—

(A) shall consist of, at a minimum, the State health department, the entity responsible for administering the State Medicaid program (if other than the State health department), the State-level entity administering the Medicare program, and the departments that train providers in primary care in 1 or more health professions schools in the State; and

(B) may include entities such as hospital associations, primary care practice-based research networks, health professional societies, State primary care associations, State licensing boards, organizations with a contract with the

Secretary under section 1153 of the Social Security Act, consumer groups, and other appropriate entities.

(c) STATE AND LOCAL ACTIVITIES.—

(1) HUB ACTIVITIES.—Hubs established under a grant under subsection (b) shall—

(A) submit to the Secretary a plan to coordinate functions with quality improvement organizations and area health education centers if such entities are members of the Hub not described in subsection (b)(2)(A);

(B) contract with a county- or local-level entity that shall serve as the Primary Care Extension Agency to administer the services described in paragraph (2);

(C) organize and administer grant funds to county- or local-level Primary Care Extension Agencies that serve a catchment area, as determined by the State; and

(D) organize State-wide or multistate networks of local-level Primary Care Extension Agencies to share and disseminate information and practices.

(2) LOCAL PRIMARY CARE EXTENSION AGENCY ACTIVITIES.—

(A) REQUIRED ACTIVITIES.—Primary Care Extension Agencies established by a Hub under paragraph (1) shall—

(i) assist primary care providers to implement a patient-centered medical home to improve the accessibility, quality, and efficiency of primary care services, including health homes;

(ii) develop and support primary care learning communities to enhance the dissemination of research findings for evidence-based practice, assess implementation of practice improvement, share best practices, and involve community clinicians in the generation of new knowledge and identification of important questions for research;

(iii) participate in a national network of Primary Care Extension Hubs and propose how the Primary Care Extension Agency will share and disseminate lessons learned and best practices; and

(iv) develop a plan for financial sustainability involving State, local, and private contributions, to provide for the reduction in Federal funds that is expected after an initial 6-year period of program establishment, infrastructure development, and planning.

(B) DISCRETIONARY ACTIVITIES.—Primary Care Extension Agencies established by a Hub under paragraph (1) may—

(i) provide technical assistance, training, and organizational support for community health teams established under section 3602 of the Patient Protection and Affordable Care Act;

(ii) collect data and provision of primary care provider feedback from standardized measurements of processes and outcomes to aid in continuous performance improvement;

(iii) collaborate with local health departments, community health centers, tribes and tribal entities,

and other community agencies to identify community health priorities and local health workforce needs, and participate in community-based efforts to address the social and primary determinants of health, strengthen the local primary care workforce, and eliminate health disparities;

(iv) develop measures to monitor the impact of the proposed program on the health of practice enrollees and of the wider community served; and

(v) participate in other activities, as determined appropriate by the Secretary.

(d) FEDERAL PROGRAM ADMINISTRATION.—

(1) GRANTS; TYPES.—Grants awarded under subsection (b) shall be—

(A) program grants, that are awarded to State or multistate entities that submit fully-developed plans for the implementation of a Hub, for a period of 6 years; or

(B) planning grants, that are awarded to State or multistate entities with the goal of developing a plan for a Hub, for a period of 2 years.

(2) APPLICATIONS.—To be eligible for a grant under subsection (b), a State or multistate entity shall submit to the Secretary an application, at such time, in such manner, and containing such information as the Secretary may require.

(3) EVALUATION.—A State that receives a grant under subsection (b) shall be evaluated at the end of the grant period by an evaluation panel appointed by the Secretary.

(4) CONTINUING SUPPORT.—After the sixth year in which assistance is provided to a State under a grant awarded under subsection (b), the State may receive additional support under this section if the State program has received satisfactory evaluations with respect to program performance and the merits of the State sustainability plan, as determined by the Secretary.

(5) LIMITATION.—A State shall not use in excess of 10 percent of the amount received under a grant to carry out administrative activities under this section. Funds awarded pursuant to this section shall not be used for funding direct patient care.

(e) REQUIREMENTS ON THE SECRETARY.—In carrying out this section, the Secretary shall consult with the heads of other Federal agencies with demonstrated experience and expertise in health care and preventive medicine, such as the Centers for Disease Control and Prevention, the Substance Abuse and Mental Health Administration, the Health Resources and Services Administration, the National Institutes of Health, the Office of the National Coordinator for Health Information Technology, the Indian Health Service, the Agricultural Cooperative Extension Service of the Department of Agriculture, and other entities, as the Secretary determines appropriate.

(f) AUTHORIZATION OF APPROPRIATIONS.—To awards grants as provided in subsection (d), there are authorized to be appropriated $120,000,000 for each of fiscal years 2011 and 2012, and such sums as may be necessary to carry out this section for each of fiscal years 2013 through 2014.

SEC. 399V–2.[280g–13] NATIONAL CONGENITAL HEART DISEASE SURVEILLANCE SYSTEM.

(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may—

(1) enhance and expand infrastructure to track the epidemiology of congenital heart disease and to organize such information into a nationally-representative, population-based surveillance system that compiles data concerning actual occurrences of congenital heart disease, to be known as the "National Congenital Heart Disease Surveillance System"; or

(2) award a grant to one eligible entity to undertake the activities described in paragraph (1).

(b) PURPOSE.—The purpose of the Congenital Heart Disease Surveillance System shall be to facilitate further research into the types of health services patients use and to identify possible areas for educational outreach and prevention in accordance with standard practices of the Centers for Disease Control and Prevention.

(c) CONTENT.—The Congenital Heart Disease Surveillance System—

(1) may include information concerning the incidence and prevalence of congenital heart disease in the United States;

(2) may be used to collect and store data on congenital heart disease, including data concerning—

(A) demographic factors associated with congenital heart disease, such as age, race, ethnicity, sex, and family history of individuals who are diagnosed with the disease;

(B) risk factors associated with the disease;

(C) causation of the disease;

(D) treatment approaches; and

(E) outcome measures, such that analysis of the outcome measures will allow derivation of evidence-based best practices and guidelines for congenital heart disease patients; and

(3) may ensure the collection and analysis of longitudinal data related to individuals of all ages with congenital heart disease, including infants, young children, adolescents, and adults of all ages.

(d) PUBLIC ACCESS.—The Congenital Heart Disease Surveillance System shall be made available to the public, as appropriate, including congenital heart disease researchers.

(e) PATIENT PRIVACY.—The Secretary shall ensure that the Congenital Heart Disease Surveillance System is maintained in a manner that complies with the regulations promulgated under section 264 of the Health Insurance Portability and Accountability Act of 1996.

(f) ELIGIBILITY FOR GRANT.—To be eligible to receive a grant under subsection (a)(2), an entity shall—

(1) be a public or private nonprofit entity with specialized experience in congenital heart disease; and

(2) submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

SEC. 399V–3.[280g–14] NATIONAL DIABETES PREVENTION PROGRAM.

(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish a national diabetes prevention program (referred to in this section as the "program") targeted at adults at high risk for diabetes in order to eliminate the preventable burden of diabetes.

(b) PROGRAM ACTIVITIES.—The program described in subsection (a) shall include—

(1) a grant program for community-based diabetes prevention program model sites;

(2) a program within the Centers for Disease Control and Prevention to determine eligibility of entities to deliver community-based diabetes prevention services;

(3) a training and outreach program for lifestyle intervention instructors; and

(4) evaluation, monitoring and technical assistance, and applied research carried out by the Centers for Disease Control and Prevention.

(c) ELIGIBLE ENTITIES.—To be eligible for a grant under subsection (b)(1), an entity shall be a State or local health department, a tribal organization, a national network of community-based nonprofits focused on health and wellbeing, an academic institution, or other entity, as the Secretary determines.

(d) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of fiscal years 2010 through 2014.

SEC. 399V–4.[280g–15] STATE DEMONSTRATION PROGRAMS TO EVALUATE ALTERNATIVES TO CURRENT MEDICAL TORT LITIGATION.

(a) IN GENERAL.—The Secretary is authorized to award demonstration grants to States for the development, implementation, and evaluation of alternatives to current tort litigation for resolving disputes over injuries allegedly caused by health care providers or health care organizations. In awarding such grants, the Secretary shall ensure the diversity of the alternatives so funded.

(b) DURATION.—The Secretary may award grants under subsection (a) for a period not to exceed 5 years.

(c) CONDITIONS FOR DEMONSTRATION GRANTS.—

(1) REQUIREMENTS.—Each State desiring a grant under subsection (a) shall develop an alternative to current tort litigation that—

(A) allows for the resolution of disputes over injuries allegedly caused by health care providers or health care organizations; and

(B) promotes a reduction of health care errors by encouraging the collection and analysis of patient safety data related to disputes resolved under subparagraph (A) by organizations that engage in efforts to improve patient safety and the quality of health care.

(2) ALTERNATIVE TO CURRENT TORT LITIGATION.—Each State desiring a grant under subsection (a) shall demonstrate how the proposed alternative described in paragraph (1)(A)—

(A) makes the medical liability system more reliable by increasing the availability of prompt and fair resolution of disputes;

(B) encourages the efficient resolution of disputes;

(C) encourages the disclosure of health care errors;

(D) enhances patient safety by detecting, analyzing, and helping to reduce medical errors and adverse events;

(E) improves access to liability insurance;

(F) fully informs patients about the differences in the alternative and current tort litigation;

(G) provides patients the ability to opt out of or voluntarily withdraw from participating in the alternative at any time and to pursue other options, including litigation, outside the alternative;

(H) would not conflict with State law at the time of the application in a way that would prohibit the adoption of an alternative to current tort litigation; and

(I) would not limit or curtail a patient's existing legal rights, ability to file a claim in or access a State's legal system, or otherwise abrogate a patient's ability to file a medical malpractice claim.

(3) SOURCES OF COMPENSATION.—Each State desiring a grant under subsection (a) shall identify the sources from and methods by which compensation would be paid for claims resolved under the proposed alternative to current tort litigation, which may include public or private funding sources, or a combination of such sources. Funding methods shall to the extent practicable provide financial incentives for activities that improve patient safety.

(4) SCOPE.—

(A) IN GENERAL.—Each State desiring a grant under subsection (a) shall establish a scope of jurisdiction (such as Statewide, designated geographic region, a designated area of health care practice, or a designated group of health care providers or health care organizations) for the proposed alternative to current tort litigation that is sufficient to evaluate the effects of the alternative. No scope of jurisdiction shall be established under this paragraph that is based on a health care payer or patient population.

(B) NOTIFICATION OF PATIENTS.—A State shall demonstrate how patients would be notified that they are receiving health care services that fall within such scope, and the process by which they may opt out of or voluntarily withdraw from participating in the alternative. The decision of the patient whether to participate or continue participating in the alternative process shall be made at any time and shall not be limited in any way.

(5) PREFERENCE IN AWARDING DEMONSTRATION GRANTS.—In awarding grants under subsection (a), the Secretary shall give preference to States—

(A) that have developed the proposed alternative through substantive consultation with relevant stakeholders, including patient advocates, health care providers and health care organizations, attorneys with expertise in

representing patients and health care providers, medical malpractice insurers, and patient safety experts;

(B) that make proposals that are likely to enhance patient safety by detecting, analyzing, and helping to reduce medical errors and adverse events; and

(C) that make proposals that are likely to improve access to liability insurance.

(d) APPLICATION.—

(1) IN GENERAL.—Each State desiring a grant under subsection (a) shall submit to the Secretary an application, at such time, in such manner, and containing such information as the Secretary may require.

(2) REVIEW PANEL.—

(A) IN GENERAL.—In reviewing applications under paragraph (1), the Secretary shall consult with a review panel composed of relevant experts appointed by the Comptroller General.

(B) COMPOSITION.—

(i) NOMINATIONS.—The Comptroller General shall solicit nominations from the public for individuals to serve on the review panel.

(ii) APPOINTMENT.—The Comptroller General shall appoint, at least 9 but not more than 13, highly qualified and knowledgeable individuals to serve on the review panel and shall ensure that the following entities receive fair representation on such panel:

(I) Patient advocates.

(II) Health care providers and health care organizations.

(III) Attorneys with expertise in representing patients and health care providers.

(IV) Medical malpractice insurers.

(V) State officials.

(VI) Patient safety experts.

(C) CHAIRPERSON.—The Comptroller General, or an individual within the Government Accountability Office designated by the Comptroller General, shall be the chairperson of the review panel.

(D) AVAILABILITY OF INFORMATION.—The Comptroller General shall make available to the review panel such information, personnel, and administrative services and assistance as the review panel may reasonably require to carry out its duties.

(E) INFORMATION FROM AGENCIES.—The review panel may request directly from any department or agency of the United States any information that such panel considers necessary to carry out its duties. To the extent consistent with applicable laws and regulations, the head of such department or agency shall furnish the requested information to the review panel.

(e) REPORTS.—

(1) BY STATE.—Each State receiving a grant under subsection (a) shall submit to the Secretary an annual report evaluating the effectiveness of activities funded with grants award-

ed under such subsection. Such report shall, at a minimum, include the impact of the activities funded on patient safety and on the availability and price of medical liability insurance.

(2) BY SECRETARY.—The Secretary shall submit to Congress an annual compendium of the reports submitted under paragraph (1) and an analysis of the activities funded under subsection (a) that examines any differences that result from such activities in terms of the quality of care, number and nature of medical errors, medical resources used, length of time for dispute resolution, and the availability and price of liability insurance.

(f) TECHNICAL ASSISTANCE.—

(1) IN GENERAL.—The Secretary shall provide technical assistance to the States applying for or awarded grants under subsection (a).

(2) REQUIREMENTS.—Technical assistance under paragraph (1) shall include—

(A) guidance on non-economic damages, including the consideration of individual facts and circumstances in determining appropriate payment, guidance on identifying avoidable injuries, and guidance on disclosure to patients of health care errors and adverse events; and

(B) the development, in consultation with States, of common definitions, formats, and data collection infrastructure for States receiving grants under this section to use in reporting to facilitate aggregation and analysis of data both within and between States.

(3) USE OF COMMON DEFINITIONS, FORMATS, AND DATA COLLECTION INFRASTRUCTURE.—States not receiving grants under this section may also use the common definitions, formats, and data collection infrastructure developed under paragraph (2)(B).

(g) EVALUATION.—

(1) IN GENERAL.—The Secretary, in consultation with the review panel established under subsection (d)(2), shall enter into a contract with an appropriate research organization to conduct an overall evaluation of the effectiveness of grants awarded under subsection (a) and to annually prepare and submit a report to Congress. Such an evaluation shall begin not later than 18 months following the date of implementation of the first program funded by a grant under subsection (a).

(2) CONTENTS.—The evaluation under paragraph (1) shall include—

(A) an analysis of the effects of the grants awarded under subsection (a) with regard to the measures described in paragraph (3);

(B) for each State, an analysis of the extent to which the alternative developed under subsection (c)(1) is effective in meeting the elements described in subsection (c)(2);

(C) a comparison among the States receiving grants under subsection (a) of the effectiveness of the various alternatives developed by such States under subsection (c)(1);

(D) a comparison, considering the measures described in paragraph (3), of States receiving grants approved under subsection (a) and similar States not receiving such grants; and

(E) a comparison, with regard to the measures described in paragraph (3), of—

(i) States receiving grants under subsection (a);

(ii) States that enacted, prior to the date of enactment of the Patient Protection and Affordable Care Act, any cap on non-economic damages; and

(iii) States that have enacted, prior to the date of enactment of the Patient Protection and Affordable Care Act, a requirement that the complainant obtain an opinion regarding the merit of the claim, although the substance of such opinion may have no bearing on whether the complainant may proceed with a case.

(3) MEASURES.—The evaluations under paragraph (2) shall analyze and make comparisons on the basis of—

(A) the nature and number of disputes over injuries allegedly caused by health care providers or health care organizations;

(B) the nature and number of claims in which tort litigation was pursued despite the existence of an alternative under subsection (a);

(C) the disposition of disputes and claims, including the length of time and estimated costs to all parties;

(D) the medical liability environment;

(E) health care quality;

(F) patient safety in terms of detecting, analyzing, and helping to reduce medical errors and adverse events;

(G) patient and health care provider and organization satisfaction with the alternative under subsection (a) and with the medical liability environment; and

(H) impact on utilization of medical services, appropriately adjusted for risk.

(4) FUNDING.—The Secretary shall reserve 5 percent of the amount appropriated in each fiscal year under subsection (k) to carry out this subsection.

(h) MEDPAC AND MACPAC REPORTS.—

(1) MEDPAC.—The Medicare Payment Advisory Commission shall conduct an independent review of the alternatives to current tort litigation that are implemented under grants under subsection (a) to determine the impact of such alternatives on the Medicare program under title XVIII of the Social Security Act, and its beneficiaries.

(2) MACPAC.—The Medicaid and CHIP Payment and Access Commission shall conduct an independent review of the alternatives to current tort litigation that are implemented under grants under subsection (a) to determine the impact of such alternatives on the Medicaid or CHIP programs under titles XIX and XXI of the Social Security Act, and their beneficiaries.

(3) REPORTS.—Not later than December 31, 2016, the Medicare Payment Advisory Commission and the Medicaid and

CHIP Payment and Access Commission shall each submit to Congress a report that includes the findings and recommendations of each respective Commission based on independent reviews conducted under paragraphs (1) and (2), including an analysis of the impact of the alternatives reviewed on the efficiency and effectiveness of the respective programs.

(i) OPTION TO PROVIDE FOR INITIAL PLANNING GRANTS.—Of the funds appropriated pursuant to subsection (k), the Secretary may use a portion not to exceed $500,000 per State to provide planning grants to such States for the development of demonstration project applications meeting the criteria described in subsection (c). In selecting States to receive such planning grants, the Secretary shall give preference to those States in which State law at the time of the application would not prohibit the adoption of an alternative to current tort litigation.

(j) DEFINITIONS.—In this section:

(1) HEALTH CARE SERVICES.—The term "health care services" means any services provided by a health care provider, or by any individual working under the supervision of a health care provider, that relate to—

(A) the diagnosis, prevention, or treatment of any human disease or impairment; or

(B) the assessment of the health of human beings.

(2) HEALTH CARE ORGANIZATION.—The term "health care organization" means any individual or entity which is obligated to provide, pay for, or administer health benefits under any health plan.

(3) HEALTH CARE PROVIDER.—The term "health care provider" means any individual or entity—

(A) licensed, registered, or certified under Federal or State laws or regulations to provide health care services; or

(B) required to be so licensed, registered, or certified but that is exempted by other statute or regulation.

(k) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, $50,000,000 for the 5-fiscal year period beginning with fiscal year 2011.

(l) CURRENT STATE EFFORTS TO ESTABLISH ALTERNATIVE TO TORT LITIGATION.—Nothing in this section shall be construed to limit any prior, current, or future efforts of any State to establish any alternative to tort litigation.

(m) RULE OF CONSTRUCTION.—Nothing in this section shall be construed as limiting states' authority over or responsibility for their state justice systems.

SEC. 399V–5.[280g–16] FOOD SAFETY INTEGRATED CENTERS OF EXCELLENCE.

(a) IN GENERAL.—Not later than 1 year after the date of enactment of the FDA Food Safety Modernization Act, the Secretary, acting through the Director of the Centers for Disease Control and Prevention and in consultation with the working group described in subsection (b)(2), shall designate 5 Integrated Food Safety Centers of Excellence (referred to in this section as the "Centers of Excellence") to serve as resources for Federal, State, and local public health professionals to respond to foodborne illness outbreaks. The

Centers of Excellence shall be headquartered at selected State health departments.

(b) SELECTION OF CENTERS OF EXCELLENCE.—

(1) ELIGIBLE ENTITIES.—To be eligible to be designated as a Center of Excellence under subsection (a), an entity shall—

(A) be a State health department;

(B) partner with 1 or more institutions of higher education that have demonstrated knowledge, expertise, and meaningful experience with regional or national food production, processing, and distribution, as well as leadership in the laboratory, epidemiological, and environmental detection and investigation of foodborne illness; and

(C) provide to the Secretary such information, at such time, and in such manner, as the Secretary may require.

(2) WORKING GROUP.—Not later than 180 days after the date of enactment of the FDA Food Safety Modernization Act, the Secretary shall establish a diverse working group of experts and stakeholders from Federal, State, and local food safety and health agencies, the food industry, including food retailers and food manufacturers, consumer organizations, and academia to make recommendations to the Secretary regarding designations of the Centers of Excellence.

(3) ADDITIONAL CENTERS OF EXCELLENCE.—The Secretary may designate eligible entities to be regional Food Safety Centers of Excellence, in addition to the 5 Centers designated under subsection (a).

(c) ACTIVITIES.—Under the leadership of the Director of the Centers for Disease Control and Prevention, each Center of Excellence shall be based out of a selected State health department, which shall provide assistance to other regional, State, and local departments of health through activities that include—

(1) providing resources, including timely information concerning symptoms and tests, for frontline health professionals interviewing individuals as part of routine surveillance and outbreak investigations;

(2) providing analysis of the timeliness and effectiveness of foodborne disease surveillance and outbreak response activities;

(3) providing training for epidemiological and environmental investigation of foodborne illness, including suggestions for streamlining and standardizing the investigation process;

(4) establishing fellowships, stipends, and scholarships to train future epidemiological and food-safety leaders and to address critical workforce shortages;

(5) training and coordinating State and local personnel;

(6) strengthening capacity to participate in existing or new foodborne illness surveillance and environmental assessment information systems; and

(7) conducting research and outreach activities focused on increasing prevention, communication, and education regarding food safety.

(d) REPORT TO CONGRESS.—Not later than 2 years after the date of enactment of the FDA Food Safety Modernization Act, the Secretary shall submit to Congress a report that—

(1) describes the effectiveness of the Centers of Excellence; and

(2) provides legislative recommendations or describes additional resources required by the Centers of Excellence.

(e) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated such sums as may be necessary to carry out this section.

(f) NO DUPLICATION OF EFFORT.—In carrying out activities of the Centers of Excellence or other programs under this section, the Secretary shall not duplicate other Federal foodborne illness response efforts.

PART Q—PROGRAMS TO IMPROVE THE HEALTH OF CHILDREN

SEC. 399W.[280h] GRANTS TO PROMOTE CHILDHOOD NUTRITION AND PHYSICAL ACTIVITY.

(a) IN GENERAL.—The Secretary, acting though the Director of the Centers for Disease Control and Prevention, shall award competitive grants to States and political subdivisions of States for the development and implementation of State and community-based intervention programs to promote good nutrition and physical activity in children and adolescents.

(b) ELIGIBILITY.—To be eligible to receive a grant under this section a State or political subdivision of a State shall prepare and submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require, including a plan that describes—

(1) how the applicant proposes to develop a comprehensive program of school- and community-based approaches to encourage and promote good nutrition and appropriate levels of physical activity with respect to children or adolescents in local communities;

(2) the manner in which the applicant shall coordinate with appropriate State and local authorities, such as State and local school departments, State departments of health, chronic disease directors, State directors of programs under section 17 of the Child Nutrition Act of 1966, 5-a-day coordinators, governors councils for physical activity and good nutrition, and State and local parks and recreation departments; and

(3) the manner in which the applicant will evaluate the effectiveness of the program carried out under this section.

(c) USE OF FUNDS.—A State or political subdivision of a State shall use amount received under a grant under this section to—

(1) develop, implement, disseminate, and evaluate school- and community-based strategies in States to reduce inactivity and improve dietary choices among children and adolescents;

(2) expand opportunities for physical activity programs in school- and community-based settings; and

(3) develop, implement, and evaluate programs that promote good eating habits and physical activity including opportunities for children with cognitive and physical disabilities.

(d) TECHNICAL ASSISTANCE.—The Secretary may set-aside an amount not to exceed 10 percent of the amount appropriated for a

fiscal year under subsection (h) to permit the Director of the Centers for Disease Control and Prevention to—

(1) provide States and political subdivisions of States with technical support in the development and implementation of programs under this section; and

(2) disseminate information about effective strategies and interventions in preventing and treating obesity through the promotion of good nutrition and physical activity.

(e) LIMITATION ON ADMINISTRATIVE COSTS.—Not to exceed 10 percent of the amount of a grant awarded to the State or political subdivision under subsection (a) for a fiscal year may be used by the State or political subdivision for administrative expenses.

(f) TERM.—A grant awarded under subsection (a) shall be for a term of 3 years.

(g) DEFINITION.—In this section, the term "children and adolescents" means individuals who do not exceed 18 years of age.

(h) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section such sums as may be necessary for each of the fiscal years 2001 through 2005.

SEC. 399X.[280h–1] APPLIED RESEARCH PROGRAM.

(a) IN GENERAL.—The Secretary, acting through the Centers for Disease Control and Prevention and in consultation with the Director of the National Institutes of Health, shall—

(1) conduct research to better understand the relationship between physical activity, diet, and health and factors that influence health-related behaviors;

(2) develop and evaluate strategies for the prevention and treatment of obesity to be used in community-based interventions and by health professionals;

(3) develop and evaluate strategies for the prevention and treatment of eating disorders, such as anorexia and bulimia;

(4) conduct research to establish the prevalence, consequences, and costs of childhood obesity and its effects in adulthood;

(5) identify behaviors and risk factors that contribute to obesity;

(6) evaluate materials and programs to provide nutrition education to parents and teachers of children in child care or pre-school and the food service staff of such child care and preschool entities; and

(7) evaluate materials and programs that are designed to educate and encourage physical activity in child care and preschool facilities.

(b) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section such sums as may be necessary for each of the fiscal years 2001 through 2005.

SEC. 399Y.[280h–2] EDUCATION CAMPAIGN.

(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, and in collaboration with national, State, and local partners, physical activity organizations, nutrition experts, and health professional organizations, shall develop a national public campaign to promote and educate children and their parents concerning—

(1) the health risks associated with obesity, inactivity, and poor nutrition;

(2) ways in which to incorporate physical activity into daily living; and

(3) the benefits of good nutrition and strategies to improve eating habits.

(b) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section such sums as may be necessary for each of the fiscal years 2001 through 2005.

SEC. 399Z.[280h–3] HEALTH PROFESSIONAL EDUCATION AND TRAINING.

(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, in collaboration with the Administrator of the Health Resources and Services Administration and the heads of other agencies, and in consultation with appropriate health professional associations, shall develop and carry out a program to educate and train health professionals in effective strategies to—

(1) better identify and assess patients with obesity or an eating disorder or patients at-risk of becoming obese or developing an eating disorder;

(2) counsel, refer, or treat patients with obesity or an eating disorder; and

(3) educate patients and their families about effective strategies to improve dietary habits and establish appropriate levels of physical activity.

(b) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section such sums as may be necessary for each of the fiscal years 2001 through 2005.

SEC. 399Z–1.[280h–5] SCHOOL-BASED HEALTH CENTERS.

(a) DEFINITIONS; ESTABLISHMENT OF CRITERIA.—In this section:

(1) COMPREHENSIVE PRIMARY HEALTH SERVICES.—The term "comprehensive primary health services" means the core services offered by school-based health centers, which shall include the following:

(A) PHYSICAL.—Comprehensive health assessments, diagnosis, and treatment of minor, acute, and chronic medical conditions, and referrals to, and follow-up for, specialty care and oral and vision health services.

(B) MENTAL HEALTH.—Mental health and substance use disorder assessments, crisis intervention, counseling, treatment, and referral to a continuum of services including emergency psychiatric care, community support programs, inpatient care, and outpatient programs.

(2) MEDICALLY UNDERSERVED CHILDREN AND ADOLESCENTS.—

(A) IN GENERAL.—The term "medically underserved children and adolescents" means a population of children and adolescents who are residents of an area designated as a medically underserved area or a health professional shortage area by the Secretary.

(B) CRITERIA.—The Secretary shall prescribe criteria for determining the specific shortages of personal health

services for medically underserved children and adolescents under subparagraph (A) that shall—

(i) take into account any comments received by the Secretary from the chief executive officer of a State and local officials in a State; and

(ii) include factors indicative of the health status of such children and adolescents of an area, including the ability of the residents of such area to pay for health services, the accessibility of such services, the availability of health professionals to such children and adolescents, and other factors as determined appropriate by the Secretary.

(3) SCHOOL-BASED HEALTH CENTER.—The term "school-based health center" means a health clinic that—

(A) meets the definition of a school-based health center under section 2110(c)(9)(A) of the Social Security Act and is administered by a sponsoring facility (as defined in section 2110(c)(9)(B) of the Social Security Act);

(B) provides, at a minimum, comprehensive primary health services during school hours to children and adolescents by health professionals in accordance with established standards, community practice, reporting laws, and other State laws, including parental consent and notification laws that are not inconsistent with Federal law; and

(C) does not perform abortion services.

(b) AUTHORITY TO AWARD GRANTS.—The Secretary shall award grants for the costs of the operation of school-based health centers (referred to in this section as "SBHCs") that meet the requirements of this section.

(c) APPLICATIONS.—To be eligible to receive a grant under this section, an entity shall—

(1) be an SBHC (as defined in subsection (a)(3)); and

(2) submit to the Secretary an application at such time, in such manner, and containing—

(A) evidence that the applicant meets all criteria necessary to be designated an SBHC;

(B) evidence of local need for the services to be provided by the SBHC;

(C) an assurance that—

(i) SBHC services will be provided to those children and adolescents for whom parental or guardian consent has been obtained in cooperation with Federal, State, and local laws governing health care service provision to children and adolescents;

(ii) the SBHC has made and will continue to make every reasonable effort to establish and maintain collaborative relationships with other health care providers in the catchment area of the SBHC;

(iii) the SBHC will provide on-site access during the academic day when school is in session and 24-hour coverage through an on-call system and through its backup health providers to ensure access to services on a year-round basis when the school or the SBHC is closed;

(iv) the SBHC will be integrated into the school environment and will coordinate health services with school personnel, such as administrators, teachers, nurses, counselors, and support personnel, as well as with other community providers co-located at the school;

(v) the SBHC sponsoring facility assumes all responsibility for the SBHC administration, operations, and oversight; and

(vi) the SBHC will comply with Federal, State, and local laws concerning patient privacy and student records, including regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 and section 444 of the General Education Provisions Act; and

(D) such other information as the Secretary may require.

(d) PREFERENCES AND CONSIDERATION.—In reviewing applications:

(1) The Secretary may give preference to applicants who demonstrate an ability to serve the following:

(A) Communities that have evidenced barriers to primary health care and mental health and substance use disorder prevention services for children and adolescents.

(B) Communities with high per capita numbers of children and adolescents who are uninsured, underinsured, or enrolled in public health insurance programs.

(C) Populations of children and adolescents that have historically demonstrated difficulty in accessing health and mental health and substance use disorder prevention services.

(2) The Secretary may give consideration to whether an applicant has received a grant under subsection (a) of section 4101 of the Patient Protection and Affordable Care Act.

(e) WAIVER OF REQUIREMENTS.—The Secretary may—

(1) under appropriate circumstances, waive the application of all or part of the requirements of this subsection with respect to an SBHC for not to exceed 2 years; and

(2) upon a showing of good cause, waive the requirement that the SBHC provide all required comprehensive primary health services for a designated period of time to be determined by the Secretary.

(f) USE OF FUNDS.—

(1) FUNDS.—Funds awarded under a grant under this section—

(A) may be used for—

(i) acquiring and leasing equipment (including the costs of amortizing the principle of, and paying interest on, loans for such equipment);

(ii) providing training related to the provision of required comprehensive primary health services and additional health services;

(iii) the management and operation of health center programs;

(iv) the payment of salaries for physicians, nurses, and other personnel of the SBHC; and

(B) may not be used to provide abortions.

(2) CONSTRUCTION.—The Secretary may award grants which may be used to pay the costs associated with expanding and modernizing existing buildings for use as an SBHC, including the purchase of trailers or manufactured buildings to install on the school property.

(3) LIMITATIONS.—

(A) IN GENERAL.—Any provider of services that is determined by a State to be in violation of a State law described in subsection (a)(3)(B) with respect to activities carried out at a SBHC shall not be eligible to receive additional funding under this section.

(B) NO OVERLAPPING GRANT PERIOD.—No entity that has received funding under section 330 for a grant period shall be eligible for a grant under this section for with respect to the same grant period.

(g) MATCHING REQUIREMENT.—

(1) IN GENERAL.—Each eligible entity that receives a grant under this section shall provide, from non-Federal sources, an amount equal to 20 percent of the amount of the grant (which may be provided in cash or in-kind) to carry out the activities supported by the grant.

(2) WAIVER.—The Secretary may waive all or part of the matching requirement described in paragraph (1) for any fiscal year for the SBHC if the Secretary determines that applying the matching requirement to the SBHC would result in serious hardship or an inability to carry out the purposes of this section.

(h) SUPPLEMENT, NOT SUPPLANT.—Grant funds provided under this section shall be used to supplement, not supplant, other Federal or State funds.

(i) EVALUATION.—The Secretary shall develop and implement a plan for evaluating SBHCs and monitoring quality performance under the awards made under this section.

(j) AGE APPROPRIATE SERVICES.—An eligible entity receiving funds under this section shall only provide age appropriate services through a SBHC funded under this section to an individual.

(k) PARENTAL CONSENT.—An eligible entity receiving funds under this section shall not provide services through a SBHC funded under this section to an individual without the consent of the parent or guardian of such individual if such individual is considered a minor under applicable State law.

(l) AUTHORIZATION OF APPROPRIATIONS.—For purposes of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2010 through 2014.

PART R—PROGRAMS RELATING TO AUTISM

SEC. 399AA.[280i] DEVELOPMENTAL DISABILITIES SURVEILLANCE AND RESEARCH PROGRAM.

(a) AUTISM SPECTRUM DISORDER AND OTHER DEVELOPMENTAL DISABILITIES.—

(1) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may award grants or cooperative agreements to eligible entities for the collection, analysis, and reporting of State epidemiological data on autism spectrum disorder and other developmental disabilities. An eligible entity shall assist with the development and coordination of State autism spectrum disorder and other developmental disability surveillance efforts within a region. In making such awards, the Secretary may provide direct technical assistance in lieu of cash.

(2) DATA STANDARDS.—In submitting epidemiological data to the Secretary pursuant to paragraph (1), an eligible entity shall report data according to guidelines prescribed by the Director of the Centers for Disease Control and Prevention, after consultation with relevant State and local public health officials, private sector developmental disability researchers, and advocates for individuals with autism spectrum disorder or other developmental disabilities.

(3) ELIGIBILITY.—To be eligible to receive an award under paragraph (1), an entity shall be a public or nonprofit private entity (including a health department of a State or a political subdivision of a State, a university, or any other educational institution), and submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

(b) CENTERS OF EXCELLENCE IN AUTISM SPECTRUM DISORDER EPIDEMIOLOGY.—

(1) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall, subject to the availability of appropriations, award grants or cooperative agreements for the establishment of regional centers of excellence in autism spectrum disorder and other developmental disabilities epidemiology for the purpose of collecting and analyzing information on the number, incidence, correlates, and causes of autism spectrum disorder and other developmental disabilities.

(2) REQUIREMENTS.—To be eligible to receive a grant or cooperative agreement under paragraph (1), an entity shall submit to the Secretary an application containing such agreements and information as the Secretary may require, including an agreement that the center to be established under the grant or cooperative agreement shall operate in accordance with the following:

(A) The center will collect, analyze, and report autism spectrum disorder and other developmental disability data according to guidelines prescribed by the Director of the Centers for Disease Control and Prevention, after consultation with relevant State and local public health offi-

cials, private sector developmental disability researchers, and advocates for individuals with developmental disabilities.

(B) The center will develop or extend an area of special research expertise (including genetics, epigenetics, and epidemiological research related to environmental exposures), immunology, and other relevant research specialty areas.

(C) The center will identify eligible cases and controls through its surveillance system and conduct research into factors which may cause or increase the risk of autism spectrum disorder and other developmental disabilities.

(c) FEDERAL RESPONSE.—The Secretary shall coordinate the Federal response to requests for assistance from State health, mental health, and education department officials regarding potential or alleged autism spectrum disorder or developmental disability clusters.

(d) DEFINITIONS.—In this part:

(1) OTHER DEVELOPMENTAL DISABILITIES.—The term "other developmental disabilities" has the meaning given the term "developmental disability" in section 102(8) of the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (42 U.S.C. 15002(8)).

(2) STATE.—The term "State" means each of the several States, the District of Columbia, the Commonwealth of Puerto Rico, American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, the Virgin Islands, and the Trust Territory of the Pacific Islands.

(e) SUNSET.—This section shall not apply after September 30, 2014.

SEC. 399BB.[280i–1] AUTISM EDUCATION, EARLY DETECTION, AND INTERVENTION.

(a) PURPOSE.—It is the purpose of this section—

(1) to increase awareness, reduce barriers to screening and diagnosis, promote evidence-based interventions for individuals with autism spectrum disorder or other developmental disabilities, and train professionals to utilize valid and reliable screening tools to diagnose or rule out and provide evidence-based interventions for children with autism spectrum disorder and other developmental disabilities; and

(2) to conduct activities under this section with a focus on an interdisciplinary approach (as defined in programs developed under section 501(a)(2) of the Social Security Act) that will also focus on specific issues for children who are not receiving an early diagnosis and subsequent interventions.

(b) IN GENERAL.—The Secretary shall, subject to the availability of appropriations, establish and evaluate activities to—

(1) provide information and education on autism spectrum disorder and other developmental disabilities to increase public awareness of developmental milestones;

(2) promote research into the development and validation of reliable screening tools for autism spectrum disorder and other developmental disabilities and disseminate information regarding those screening tools;

(3) promote early screening of individuals at higher risk for autism spectrum disorder and other developmental disabilities as early as practicable, given evidence-based screening techniques and interventions;

(4) increase the number of individuals who are able to confirm or rule out a diagnosis of autism spectrum disorder and other developmental disabilities;

(5) increase the number of individuals able to provide evidence-based interventions for individuals diagnosed with autism spectrum disorder or other developmental disabilities; and

(6) promote the use of evidence-based interventions for individuals at higher risk for autism spectrum disorder and other developmental disabilities as early as practicable.

(c) INFORMATION AND EDUCATION.—

(1) IN GENERAL.—In carrying out subsection (b)(1), the Secretary, in collaboration with the Secretary of Education and the Secretary of Agriculture, shall, subject to the availability of appropriations, provide culturally competent information regarding autism spectrum disorder and other developmental disabilities, risk factors, characteristics, identification, diagnosis or rule out, and evidence-based interventions to meet the needs of individuals with autism spectrum disorder or other developmental disabilities and their families through—

(A) Federal programs, including—

(i) the Head Start program;

(ii) the Early Start program;

(iii) the Healthy Start program;

(iv) programs under the Child Care and Development Block Grant Act of 1990;

(v) programs under title XIX of the Social Security Act (particularly the Medicaid Early and Periodic Screening, Diagnosis and Treatment Program);

(vi) the program under title XXI of the Social Security Act (the State Children's Health Insurance Program);

(vii) the program under title V of the Social Security Act (the Maternal and Child Health Block Grant Program);

(viii) the program under parts B and C of the Individuals with Disabilities Education Act;

(ix) the special supplemental nutrition program for women, infants, and children established under section 17 of the Child Nutrition Act of 1966 (42 U.S.C. 1786); and

(x) the State grant program under the Rehabilitation Act of 1973.

(B) State licensed child care facilities; and

(C) other community-based organizations or points of entry for individuals with autism spectrum disorder and other developmental disabilities to receive services.

(2) LEAD AGENCY.—

(A) DESIGNATION.—As a condition on the provision of assistance or the conduct of activities under this section

with respect to a State, the Secretary may require the Governor of the State—

(i) to designate a public agency as a lead agency to coordinate the activities provided for under paragraph (1) in the State at the State level; and

(ii) acting through such lead agency, to make available to individuals and their family members, guardians, advocates, or authorized representatives; providers; and other appropriate individuals in the State, comprehensive culturally competent information about State and local resources regarding autism spectrum disorder and other developmental disabilities, risk factors, characteristics, identification, diagnosis or rule out, available services and supports, and evidence-based interventions.

(B) REQUIREMENTS OF AGENCY.—In designating the lead agency under subparagraph (A)(i), the Governor shall—

(i) select an agency that has demonstrated experience and expertise in—

(I) autism spectrum disorder and other developmental disability issues; and

(II) developing, implementing, conducting, and administering programs and delivering education, information, and referral services (including technology-based curriculum-development services) to individuals with developmental disabilities and their family members, guardians, advocates or authorized representatives, providers, and other appropriate individuals locally and across the State; and

(ii) consider input from individuals with developmental disabilities and their family members, guardians, advocates or authorized representatives, providers, and other appropriate individuals.

(C) INFORMATION.—Information under subparagraph (A)(ii) shall be provided through—

(i) toll-free telephone numbers;

(ii) Internet websites;

(iii) mailings; or

(iv) such other means as the Governor may require.

(d) TOOLS.—

(1) IN GENERAL.—To promote the use of valid and reliable screening tools for autism spectrum disorder and other developmental disabilities, the Secretary shall develop a curriculum for continuing education to assist individuals in recognizing the need for valid and reliable screening tools and the use of such tools.

(2) COLLECTION, STORAGE, COORDINATION, AND AVAILABILITY.—The Secretary, in collaboration with the Secretary of Education, shall provide for the collection, storage, coordination, and public availability of tools described in paragraph (1), educational materials and other products that are used by the

Federal programs referred to in subsection (c)(1)(A), as well as—

(A) programs authorized under the Developmental Disabilities Assistance and Bill of Rights Act of 2000;

(B) early intervention programs or interagency coordinating councils authorized under part C of the Individuals with Disabilities Education Act; and

(C) children with special health care needs programs authorized under title V of the Social Security Act.

(3) REQUIRED SHARING.—In establishing mechanisms and entities under this subsection, the Secretary, and the Secretary of Education, shall ensure the sharing of tools, materials, and products developed under this subsection among entities receiving funding under this section.

(e) DIAGNOSIS.—

(1) TRAINING.—The Secretary, in coordination with activities conducted under title V of the Social Security Act, shall, subject to the availability of appropriations, expand existing interdisciplinary training opportunities or opportunities to increase the number of sites able to diagnose or rule out individuals with autism spectrum disorder or other developmental disabilities and ensure that—

(A) competitive grants or cooperative agreements are awarded to public or nonprofit agencies, including institutions of higher education, to expand existing or develop new maternal and child health interdisciplinary leadership education in neurodevelopmental and related disabilities programs (similar to the programs developed under section 501(a)(2) of the Social Security Act) in States that do not have such a program;

(B) trainees under such training programs—

(i) receive an appropriate balance of academic, clinical, and community opportunities;

(ii) are culturally competent;

(iii) are ethnically diverse;

(iv) demonstrate a capacity to evaluate, diagnose or rule out, develop, and provide evidence-based interventions to individuals with autism spectrum disorder and other developmental disabilities; and

(v) demonstrate an ability to use a family-centered approach; and

(C) program sites provide culturally competent services.

(2) TECHNICAL ASSISTANCE.—The Secretary may award one or more grants under this section to provide technical assistance to the network of interdisciplinary training programs.

(3) BEST PRACTICES.—The Secretary shall promote research into additional valid and reliable tools for shortening the time required to confirm or rule out a diagnosis of autism spectrum disorder or other developmental disabilities and detecting individuals with autism spectrum disorder or other developmental disabilities at an earlier age.

(f) INTERVENTION.—The Secretary shall promote research, through grants or contracts, to determine the evidence-based prac-

tices for interventions for individuals with autism spectrum disorder or other developmental disabilities, develop guidelines for those interventions, and disseminate information related to such research and guidelines.

(g) SUNSET.—This section shall not apply after September 30, 2014.

SEC. 399CC.[280i–2] INTERAGENCY AUTISM COORDINATING COMMITTEE.

(a) ESTABLISHMENT.—The Secretary shall establish a committee, to be known as the "Interagency Autism Coordinating Committee" (in this section referred to as the "Committee"), to coordinate all efforts within the Department of Health and Human Services concerning autism spectrum disorder.

(b) RESPONSIBILITIES.—In carrying out its duties under this section, the Committee shall—

(1) develop and annually update a summary of advances in autism spectrum disorder research related to causes, prevention, treatment, early screening, diagnosis or rule out, intervention, and access to services and supports for individuals with autism spectrum disorder;

(2) monitor Federal activities with respect to autism spectrum disorder;

(3) make recommendations to the Secretary regarding any appropriate changes to such activities, including recommendations to the Director of NIH with respect to the strategic plan developed under paragraph (5);

(4) make recommendations to the Secretary regarding public participation in decisions relating to autism spectrum disorder;

(5) develop and annually update a strategic plan for the conduct of, and support for, autism spectrum disorder research, including proposed budgetary requirements; and

(6) submit to the Congress such strategic plan and any updates to such plan.

(c) MEMBERSHIP.—

(1) IN GENERAL.—The Committee shall be composed of—

(A) the Director of the Centers for Disease Control and Prevention;

(B) the Director of the National Institutes of Health, and the Directors of such national research institutes of the National Institutes of Health as the Secretary determines appropriate;

(C) the heads of such other agencies as the Secretary determines appropriate;

(D) representatives of other Federal Governmental agencies that serve individuals with autism spectrum disorder such as the Department of Education; and

(E) the additional members appointed under paragraph (2).

(2) ADDITIONAL MEMBERS.—Not fewer than 6 members of the Committee, or 1/3 of the total membership of the Committee, whichever is greater, shall be composed of non-Federal public members to be appointed by the Secretary, of which—

(A) at least one such member shall be an individual with a diagnosis of autism spectrum disorder;

(B) at least one such member shall be a parent or legal guardian of an individual with an autism spectrum disorder; and

(C) at least one such member shall be a representative of leading research, advocacy, and service organizations for individuals with autism spectrum disorder.

(d) ADMINISTRATIVE SUPPORT; TERMS OF SERVICE; OTHER PROVISIONS.—The following provisions shall apply with respect to the Committee:

(1) The Committee shall receive necessary and appropriate administrative support from the Secretary.

(2) Members of the Committee appointed under subsection (c)(2) shall serve for a term of 4 years, and may be reappointed for one or more additional 4 year term. Any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term. A member may serve after the expiration of the member's term until a successor has taken office.

(3) The Committee shall meet at the call of the chairperson or upon the request of the Secretary. The Committee shall meet not fewer than 2 times each year.

(4) All meetings of the Committee shall be public and shall include appropriate time periods for questions and presentations by the public.

(e) SUBCOMMITTEES; ESTABLISHMENT AND MEMBERSHIP.—In carrying out its functions, the Committee may establish subcommittees and convene workshops and conferences. Such subcommittees shall be composed of Committee members and may hold such meetings as are necessary to enable the subcommittees to carry out their duties.

(f) SUNSET.—This section shall not apply after September 30, 2014, and the Committee shall be terminated on such date.

SEC. 399DD.[280i–3] REPORT TO CONGRESS.

(a) IN GENERAL.—Not later than 2 years after the date of enactment of the Combating Autism Reauthorization Act of 2011, the Secretary, in coordination with the Secretary of Education, shall prepare and submit to the Health, Education, Labor, and Pensions Committee of the Senate and the Energy and Commerce Committee of the House of Representatives a progress report on activities related to autism spectrum disorder and other developmental disabilities.

(b) CONTENTS.—The report submitted under subsection (a) shall contain—

(1) a description of the progress made in implementing the provisions of the Combating Autism Act of 2006;

(2) a description of the amounts expended on the implementation of the particular provisions of Combating Autism Act of 2006;

(3) information on the incidence of autism spectrum disorder and trend data of such incidence since the date of enactment of the Combating Autism Act of 2006;

(4) information on the average age of diagnosis for children with autism spectrum disorder and other disabilities, including how that age may have changed over the 6-year period beginning on the date of enactment of the Combating Autism Act of 2006;

(5) information on the average age for intervention for individuals diagnosed with autism spectrum disorder and other developmental disabilities, including how that age may have changed over the 6-year period beginning on the date of enactment of the Combating Autism Act of 2006;

(6) information on the average time between initial screening and then diagnosis or rule out for individuals with autism spectrum disorder or other developmental disabilities, as well as information on the average time between diagnosis and evidence-based intervention for individuals with autism spectrum disorder or other developmental disabilities;

(7) information on the effectiveness and outcomes of interventions for individuals diagnosed with autism spectrum disorder, including by various subtypes, and other developmental disabilities and how the age of the child may affect such effectiveness;

(8) information on the effectiveness and outcomes of innovative and newly developed intervention strategies for individuals with autism spectrum disorder or other developmental disabilities; and

(9) information on services and supports provided to individuals with autism spectrum disorder and other developmental disabilities who have reached the age of majority (as defined for purposes of section 615(m) of the Individuals with Disabilities Education Act (20 U.S.C. 1415(m)).

SEC. 399EE.[280i–4] AUTHORIZATION OF APPROPRIATIONS.

(a) DEVELOPMENTAL DISABILITIES SURVEILLANCE AND RESEARCH PROGRAM.—To carry out section 399AA, there is authorized to be appropriated $22,000,000 for each of fiscal years 2012 through 2014.

(b) AUTISM EDUCATION, EARLY DETECTION, AND INTERVENTION.—To carry out section 399BB, there is authorized to be appropriated $48,000,000 for each of fiscal years 2011 through 2014.

(c) INTERAGENCY AUTISM COORDINATING COMMITTEE; CERTAIN OTHER PROGRAMS.—To carry out sections 399CC, 404H, and 409C, there is authorized to be appropriated $161,000,000 for each of fiscal years 2011 through 2014.

PART S—HEALTH CARE QUALITY PROGRAMS

Subpart I—National Strategy for Quality Improvement in Health Care

SEC. 399HH.[280j] NATIONAL STRATEGY FOR QUALITY IMPROVEMENT IN HEALTH CARE.

(a) ESTABLISHMENT OF NATIONAL STRATEGY AND PRIORITIES.—

(1) NATIONAL STRATEGY.—The Secretary, through a transparent collaborative process, shall establish a national strategy

to improve the delivery of health care services, patient health outcomes, and population health.

(2) IDENTIFICATION OF PRIORITIES.—

(A) IN GENERAL.—The Secretary shall identify national priorities for improvement in developing the strategy under paragraph (1).

(B) REQUIREMENTS.—The Secretary shall ensure that priorities identified under subparagraph (A) will—

(i) have the greatest potential for improving the health outcomes, efficiency, and patient-centeredness of health care for all populations, including children and vulnerable populations;

(ii) identify areas in the delivery of health care services that have the potential for rapid improvement in the quality and efficiency of patient care;

(iii) address gaps in quality, efficiency, comparative effectiveness information (taking into consideration the limitations set forth in subsections (c) and (d) of section 1182 of the Social Security Act), and health outcomes measures and data aggregation techniques;

(iv) improve Federal payment policy to emphasize quality and efficiency;

(v) enhance the use of health care data to improve quality, efficiency, transparency, and outcomes;

(vi) address the health care provided to patients with high-cost chronic diseases;

(vii) improve research and dissemination of strategies and best practices to improve patient safety and reduce medical errors, preventable admissions and readmissions, and health care-associated infections;

(viii) reduce health disparities across health disparity populations (as defined in section 485E) and geographic areas; and

(ix) address other areas as determined appropriate by the Secretary.

(C) CONSIDERATIONS.—In identifying priorities under subparagraph (A), the Secretary shall take into consideration the recommendations submitted by the entity with a contract under section 1890(a) of the Social Security Act and other stakeholders.

(D) COORDINATION WITH STATE AGENCIES.—The Secretary shall collaborate, coordinate, and consult with State agencies responsible for administering the Medicaid program under title XIX of the Social Security Act and the Children's Health Insurance Program under title XXI of such Act with respect to developing and disseminating strategies, goals, models, and timetables that are consistent with the national priorities identified under subparagraph (A).

(b) STRATEGIC PLAN.—

(1) IN GENERAL.—The national strategy shall include a comprehensive strategic plan to achieve the priorities described in subsection (a).

(2) REQUIREMENTS.—The strategic plan shall include provisions for addressing, at a minimum, the following:

(A) Coordination among agencies within the Department, which shall include steps to minimize duplication of efforts and utilization of common quality measures, where available. Such common quality measures shall be measures identified by the Secretary under section 1139A or 1139B of the Social Security Act or endorsed under section 1890 of such Act.

(B) Agency-specific strategic plans to achieve national priorities.

(C) Establishment of annual benchmarks for each relevant agency to achieve national priorities.

(D) A process for regular reporting by the agencies to the Secretary on the implementation of the strategic plan.

(E) Strategies to align public and private payers with regard to quality and patient safety efforts.

(F) Incorporating quality improvement and measurement in the strategic plan for health information technology required by the American Recovery and Reinvestment Act of 2009 (Public Law 111–5).

(c) PERIODIC UPDATE OF NATIONAL STRATEGY.—The Secretary shall update the national strategy not less than annually. Any such update shall include a review of short- and long-term goals.

(d) SUBMISSION AND AVAILABILITY OF NATIONAL STRATEGY AND UPDATES.—

(1) DEADLINE FOR INITIAL SUBMISSION OF NATIONAL STRATEGY.—Not later than January 1, 2011, the Secretary shall submit to the relevant committees of Congress the national strategy described in subsection (a).

(2) UPDATES.—

(A) IN GENERAL.—The Secretary shall submit to the relevant committees of Congress an annual update to the strategy described in paragraph (1).

(B) INFORMATION SUBMITTED.—Each update submitted under subparagraph (A) shall include—

(i) a review of the short- and long-term goals of the national strategy and any gaps in such strategy;

(ii) an analysis of the progress, or lack of progress, in meeting such goals and any barriers to such progress;

(iii) the information reported under section 1139A of the Social Security Act, consistent with the reporting requirements of such section; and

(iv) in the case of an update required to be submitted on or after January 1, 2014, the information reported under section 1139B(b)(4) of the Social Security Act, consistent with the reporting requirements of such section.

(C) SATISFACTION OF OTHER REPORTING REQUIREMENTS.—Compliance with the requirements of clauses (iii) and (iv) of subparagraph (B) shall satisfy the reporting requirements under sections 1139A(a)(6) and 1139B(b)(4), respectively, of the Social Security Act.

(e) HEALTH CARE QUALITY INTERNET WEBSITE.—Not later than January 1, 2011, the Secretary shall create an Internet website to make public information regarding—

(1) the national priorities for health care quality improvement established under subsection (a)(2);

(2) the agency-specific strategic plans for health care quality described in subsection (b)(2)(B); and

(3) other information, as the Secretary determines to be appropriate.

SEC. 399II.[280j–1] COLLECTION AND ANALYSIS OF DATA FOR QUALITY AND RESOURCE USE MEASURES.

(a) IN GENERAL.—

(1) ESTABLISHMENT OF STRATEGIC FRAMEWORK.—The Secretary shall establish and implement an overall strategic framework to carry out the public reporting of performance information, as described in section 399JJ. Such strategic framework may include methods and related timelines for implementing nationally consistent data collection, data aggregation, and analysis methods.

(2) COLLECTION AND AGGREGATION OF DATA.—The Secretary shall collect and aggregate consistent data on quality and resource use measures from information systems used to support health care delivery, and may award grants or contracts for this purpose. The Secretary shall align such collection and aggregation efforts with the requirements and assistance regarding the expansion of health information technology systems, the interoperability of such technology systems, and related standards that are in effect on the date of enactment of the Patient Protection and Affordable Care Act.

(3) SCOPE.—The Secretary shall ensure that the data collection, data aggregation, and analysis systems described in paragraph (1) involve an increasingly broad range of patient populations, providers, and geographic areas over time.

(b) GRANTS OR CONTRACTS FOR DATA COLLECTION.—

(1) IN GENERAL.—The Secretary may award grants or contracts to eligible entities to support new, or improve existing, efforts to collect and aggregate quality and resource use measures described under subsection (c).

(2) ELIGIBLE ENTITIES.—To be eligible for a grant or contract under this subsection, an entity shall—

(A) be—

(i) a multi-stakeholder entity that coordinates the development of methods and implementation plans for the consistent reporting of summary quality and cost information;

(ii) an entity capable of submitting such summary data for a particular population and providers, such as a disease registry, regional collaboration, health plan collaboration, or other population-wide source; or

(iii) a Federal Indian Health Service program or a health program operated by an Indian tribe (as defined in section 4 of the Indian Health Care Improvement Act);

(B) promote the use of the systems that provide data to improve and coordinate patient care;

(C) support the provision of timely, consistent quality and resource use information to health care providers, and other groups and organizations as appropriate, with an opportunity for providers to correct inaccurate measures; and

(D) agree to report, as determined by the Secretary, measures on quality and resource use to the public in accordance with the public reporting process established under section 399JJ.

(c) CONSISTENT DATA AGGREGATION.—The Secretary may award grants or contracts under this section only to entities that enable summary data that can be integrated and compared across multiple sources. The Secretary shall provide standards for the protection of the security and privacy of patient data.

(d) MATCHING FUNDS.—The Secretary may not award a grant or contract under this section to an entity unless the entity agrees that it will make available (directly or through contributions from other public or private entities) non-Federal contributions toward the activities to be carried out under the grant or contract in an amount equal to $1 for each $5 of Federal funds provided under the grant or contract. Such non-Federal matching funds may be provided directly or through donations from public or private entities and may be in cash or in-kind, fairly evaluated, including plant, equipment, or services.

(e) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated such sums as may be necessary for fiscal years 2010 through 2014.

SEC. 399JJ.[280j–2] PUBLIC REPORTING OF PERFORMANCE INFORMATION.

(a) DEVELOPMENT OF PERFORMANCE WEBSITES.—The Secretary shall make available to the public, through standardized Internet websites, performance information summarizing data on quality measures. Such information shall be tailored to respond to the differing needs of hospitals and other institutional health care providers, physicians and other clinicians, patients, consumers, researchers, policymakers, States, and other stakeholders, as the Secretary may specify.

(b) INFORMATION ON CONDITIONS.—The performance information made publicly available on an Internet website, as described in subsection (a), shall include information regarding clinical conditions to the extent such information is available, and the information shall, where appropriate, be provider-specific and sufficiently disaggregated and specific to meet the needs of patients with different clinical conditions.

(c) CONSULTATION.—

(1) IN GENERAL.—In carrying out this section, the Secretary shall consult with the entity with a contract under section 1890(a) of the Social Security Act, and other entities, as appropriate, to determine the type of information that is useful to stakeholders and the format that best facilitates use of the reports and of performance reporting Internet websites.

(2) CONSULTATION WITH STAKEHOLDERS.—The entity with a contract under section 1890(a) of the Social Security Act

shall convene multi-stakeholder groups, as described in such section, to review the design and format of each Internet website made available under subsection (a) and shall transmit to the Secretary the views of such multi-stakeholder groups with respect to each such design and format.

(d) COORDINATION.—Where appropriate, the Secretary shall coordinate the manner in which data are presented through Internet websites described in subsection (a) and for public reporting of other quality measures by the Secretary, including such quality measures under title XVIII of the Social Security Act.

(e) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated such sums as may be necessary for fiscal years 2010 through 2014.

SEC. 399KK.[280j–3] QUALITY IMPROVEMENT PROGRAM FOR HOSPITALS WITH A HIGH SEVERITY ADJUSTED READMISSION RATE.

(a) ESTABLISHMENT.—

(1) IN GENERAL.—Not later than 2 years after the date of enactment of this section, the Secretary shall make available a program for eligible hospitals to improve their readmission rates through the use of patient safety organizations (as defined in section 921(4)).

(2) ELIGIBLE HOSPITAL DEFINED.—In this subsection, the term "eligible hospital" means a hospital that the Secretary determines has a high rate of risk adjusted readmissions for the conditions described in section 1886(q)(8)(A) of the Social Security Act and has not taken appropriate steps to reduce such readmissions and improve patient safety as evidenced through historically high rates of readmissions, as determined by the Secretary.

(3) RISK ADJUSTMENT.—The Secretary shall utilize appropriate risk adjustment measures to determine eligible hospitals.

(b) REPORT TO THE SECRETARY.—As determined appropriate by the Secretary, eligible hospitals and patient safety organizations working with those hospitals shall report to the Secretary on the processes employed by the hospital to improve readmission rates and the impact of such processes on readmission rates.

PART T—ORAL HEALTHCARE PREVENTION ACTIVITIES

SEC. 399LL.[280k] ORAL HEALTHCARE PREVENTION EDUCATION CAMPAIGN.

(a) ESTABLISHMENT.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention and in consultation with professional oral health organizations, shall, subject to the availability of appropriations, establish a 5-year national, public education campaign (referred to in this section as the "campaign") that is focused on oral healthcare prevention and education, including prevention of oral disease such as early childhood and other caries, periodontal disease, and oral cancer.

(b) REQUIREMENTS.—In establishing the campaign, the Secretary shall—

(1) ensure that activities are targeted towards specific populations such as children, pregnant women, parents, the elderly, individuals with disabilities, and ethnic and racial minority populations, including Indians, Alaska Natives and Native Hawaiians (as defined in section 4(c) of the Indian Health Care Improvement Act) in a culturally and linguistically appropriate manner; and

(2) utilize science-based strategies to convey oral health prevention messages that include, but are not limited to, community water fluoridation and dental sealants.

(c) PLANNING AND IMPLEMENTATION.—Not later than 2 years after the date of enactment of this section, the Secretary shall begin implementing the 5-year campaign. During the 2-year period referred to in the previous sentence, the Secretary shall conduct planning activities with respect to the campaign.

SEC. 399LL–1.[280k–1] RESEARCH-BASED DENTAL CARIES DISEASE MANAGEMENT.

(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall award demonstration grants to eligible entities to demonstrate the effectiveness of research-based dental caries disease management activities.

(b) ELIGIBILITY.—To be eligible for a grant under this section, an entity shall—

(1) be a community-based provider of dental services (as defined by the Secretary), including a Federally-qualified health center, a clinic of a hospital owned or operated by a State (or by an instrumentality or a unit of government within a State), a State or local department of health, a dental program of the Indian Health Service, an Indian tribe or tribal organization, or an urban Indian organization (as such terms are defined in section 4 of the Indian Health Care Improvement Act), a health system provider, a private provider of dental services, medical, dental, public health, nursing, nutrition educational institutions, or national organizations involved in improving children's oral health; and

(2) submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

(c) USE OF FUNDS.—A grantee shall use amounts received under a grant under this section to demonstrate the effectiveness of research-based dental caries disease management activities.

(d) USE OF INFORMATION.—The Secretary shall utilize information generated from grantees under this section in planning and implementing the public education campaign under section 399LL.

SEC. 399LL–2.[280k–2] AUTHORIZATION OF APPROPRIATIONS.

There is authorized to be appropriated to carry out this part, such sums as may be necessary.

PART U—EMPLOYER-BASED WELLNESS PROGRAM

SEC. 399MM.[280l] TECHNICAL ASSISTANCE FOR EMPLOYER-BASED WELLNESS PROGRAMS.

In order to expand the utilization of evidence-based prevention and health promotion approaches in the workplace, the Director shall—

(1) provide employers (including small, medium, and large employers, as determined by the Director) with technical assistance, consultation, tools, and other resources in evaluating such employers' employer-based wellness programs, including—

(A) measuring the participation and methods to increase participation of employees in such programs;

(B) developing standardized measures that assess policy, environmental and systems changes necessary to have a positive health impact on employees' health behaviors, health outcomes, and health care expenditures; and

(C) evaluating such programs as they relate to changes in the health status of employees, the absenteeism of employees, the productivity of employees, the rate of workplace injury, and the medical costs incurred by employees; and

(2) build evaluation capacity among workplace staff by training employers on how to evaluate employer-based wellness programs and ensuring evaluation resources, technical assistance, and consultation are available to workplace staff as needed through such mechanisms as web portals, call centers, or other means.

SEC. 399MM–1.[280l–1] NATIONAL WORKSITE HEALTH POLICIES AND PROGRAMS STUDY.

(a) IN GENERAL.—In order to assess, analyze, and monitor over time data about workplace policies and programs, and to develop instruments to assess and evaluate comprehensive workplace chronic disease prevention and health promotion programs, policies and practices, not later than 2 years after the date of enactment of this part, and at regular intervals (to be determined by the Director) thereafter, the Director shall conduct a national worksite health policies and programs survey to assess employer-based health policies and programs.

(b) REPORT.—Upon the completion of each study under subsection (a), the Director shall submit to Congress a report that includes the recommendations of the Director for the implementation of effective employer-based health policies and programs.

SEC. 399MM–2.[280l–2] PRIORITIZATION OF EVALUATION BY SECRETARY.

The Secretary shall evaluate, in accordance with this part, all programs funded through the Centers for Disease Control and Prevention before conducting such an evaluation of privately funded programs unless an entity with a privately funded wellness program requests such an evaluation.

SEC. 399MM–3.[280l–3] PROHIBITION OF FEDERAL WORKPLACE WELLNESS REQUIREMENTS.

Notwithstanding any other provision of this part, any recommendations, data, or assessments carried out under this part shall not be used to mandate requirements for workplace wellness programs.

PART V—PROGRAMS RELATING TO BREAST HEALTH AND CANCER

SEC. 399NN.[280m] YOUNG WOMEN'S BREAST HEALTH AWARENESS AND SUPPORT OF YOUNG WOMEN DIAGNOSED WITH BREAST CANCER.

(a) PUBLIC EDUCATION CAMPAIGN.—

(1) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall conduct a national evidence-based education campaign to increase awareness of young women's knowledge regarding—

(A) breast health in young women of all racial, ethnic, and cultural backgrounds;

(B) breast awareness and good breast health habits;

(C) the occurrence of breast cancer and the general and specific risk factors in women who may be at high risk for breast cancer based on familial, racial, ethnic, and cultural backgrounds such as Ashkenazi Jewish populations;

(D) evidence-based information that would encourage young women and their health care professional to increase early detection of breast cancers; and

(E) the availability of health information and other resources for young women diagnosed with breast cancer.

(2) EVIDENCE-BASED, AGE APPROPRIATE MESSAGES.—The campaign shall provide evidence-based, age-appropriate messages and materials as developed by the Centers for Disease Control and Prevention and the Advisory Committee established under paragraph (4).

(3) MEDIA CAMPAIGN.—In conducting the education campaign under paragraph (1), the Secretary shall award grants to entities to establish national multimedia campaigns oriented to young women that may include advertising through television, radio, print media, billboards, posters, all forms of existing and especially emerging social networking media, other Internet media, and any other medium determined appropriate by the Secretary.

(4) ADVISORY COMMITTEE.—

(A) ESTABLISHMENT.—Not later than 60 days after the date of the enactment of this section, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish an advisory committee to assist in creating and conducting the education campaigns under paragraph (1) and subsection (b)(1).

(B) MEMBERSHIP.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall appoint to the advisory committee under subparagraph (A) such members as deemed necessary to prop-

erly advise the Secretary, and shall include organizations and individuals with expertise in breast cancer, disease prevention, early detection, diagnosis, public health, social marketing, genetic screening and counseling, treatment, rehabilitation, palliative care, and survivorship in young women.

(b) HEALTH CARE PROFESSIONAL EDUCATION CAMPAIGN.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, and in consultation with the Administrator of the Health Resources and Services Administration, shall conduct an education campaign among physicians and other health care professionals to increase awareness—

(1) of breast health, symptoms, and early diagnosis and treatment of breast cancer in young women, including specific risk factors such as family history of cancer and women that may be at high risk for breast cancer, such as Ashkenazi Jewish population;

(2) on how to provide counseling to young women about their breast health, including knowledge of their family cancer history and importance of providing regular clinical breast examinations;

(3) concerning the importance of discussing healthy behaviors, and increasing awareness of services and programs available to address overall health and wellness, and making patient referrals to address tobacco cessation, good nutrition, and physical activity;

(4) on when to refer patients to a health care provider with genetics expertise;

(5) on how to provide counseling that addresses long-term survivorship and health concerns of young women diagnosed with breast cancer; and

(6) on when to provide referrals to organizations and institutions that provide credible health information and substantive assistance and support to young women diagnosed with breast cancer.

(c) PREVENTION RESEARCH ACTIVITIES.—The Secretary, acting through—

(1) the Director of the Centers for Disease Control and Prevention, shall conduct prevention research on breast cancer in younger women, including—

(A) behavioral, survivorship studies, and other research on the impact of breast cancer diagnosis on young women;

(B) formative research to assist with the development of educational messages and information for the public, targeted populations, and their families about breast health, breast cancer, and healthy lifestyles;

(C) testing and evaluating existing and new social marketing strategies targeted at young women; and

(D) surveys of health care providers and the public regarding knowledge, attitudes, and practices related to breast health and breast cancer prevention and control in high-risk populations; and

(2) the Director of the National Institutes of Health, shall conduct research to develop and validate new screening tests and methods for prevention and early detection of breast cancer in young women.

(d) SUPPORT FOR YOUNG WOMEN DIAGNOSED WITH BREAST CANCER.—

(1) IN GENERAL.—The Secretary shall award grants to organizations and institutions to provide health information from credible sources and substantive assistance directed to young women diagnosed with breast cancer and pre-neoplastic breast diseases.

(2) PRIORITY.—In making grants under paragraph (1), the Secretary shall give priority to applicants that deal specifically with young women diagnosed with breast cancer and pre-neoplastic breast disease.

(e) NO DUPLICATION OF EFFORT.—In conducting an education campaign or other program under subsections (a), (b), (c), or (d), the Secretary shall avoid duplicating other existing Federal breast cancer education efforts.

(f) MEASUREMENT; REPORTING.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall—

(1) measure—

(A) young women's awareness regarding breast health, including knowledge of family cancer history, specific risk factors and early warning signs, and young women's proactive efforts at early detection;

(B) the number or percentage of young women utilizing information regarding lifestyle interventions that foster healthy behaviors;

(C) the number or percentage of young women receiving regular clinical breast exams; and

(D) the number or percentage of young women who perform breast self exams, and the frequency of such exams, before the implementation of this section;

(2) not less than every 3 years, measure the impact of such activities; and

(3) submit reports to the Congress on the results of such measurements.

(g) DEFINITION.—In this section, the term "young women" means women 15 to 44 years of age.

(h) AUTHORIZATION OF APPROPRIATIONS.—To carry out subsections (a), (b), (c)(1), and (d), there are authorized to be appropriated $9,000,000 for each of the fiscal years 2010 through 2014.

PUBLIC HEALTH SERVICE ACT

As Amended Through P.L. 113–5, Enacted March 13, 2013

TITLE IV—NATIONAL RESEARCH INSTITUTES

PART A—NATIONAL INSTITUTES OF HEALTH

SEC. 401.[281] ORGANIZATION OF NATIONAL INSTITUTES OF HEALTH.

(a) RELATION TO PUBLIC HEALTH SERVICE.—The National Institutes of Health is an agency of the Service. [1]

(b) NATIONAL RESEARCH INSTITUTES AND NATIONAL CENTERS.—The following agencies of the National Institutes of Health are national research institutes or national centers:

(1) The National Cancer Institute.

(2) The National Heart, Lung, and Blood Institute.

(3) The National Institute of Diabetes and Digestive and Kidney Diseases.

(4) The National Institute of Arthritis and Musculoskeletal and Skin Diseases.

(5) The National Institute on Aging.

(6) The National Institute of Allergy and Infectious Diseases.

(7) The Eunice Kennedy Shriver National Institute of Child Health and Human Development.

(8) The National Institute of Dental and Craniofacial Research. [2]

(9) The National Eye Institute.

(10) The National Institute of Neurological Disorders and Stroke.

(11) The National Institute on Deafness and Other Communication Disorders.

(12) The National Institute on Alcohol Abuse and Alcoholism.

(13) The National Institute on Drug Abuse.

(14) The National Institute of Mental Health.

(15) The National Institute of General Medical Sciences.

(16) The National Institute of Environmental Health Sciences.

(17) The National Institute of Nursing Research.

(18) The National Institute of Biomedical Imaging and Bioengineering.

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[1] See footnote for section 202.

[2] Section 212 of the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 1999 (as contained in section 101(f) of division A of Public Law 105–277; 112 Stat. 2681–359) amended subparagraph (H) to read as provided above, thereby indicating the intent of the Congress to change the designation of the Institute. (The former designation was the National Institute of Dental Research.) Conforming changes were not, however, made to section 453 or the related subpart heading, or to the reference in section 409A(a).

(19) The National Human Genome Research Institute.

(20) The National Library of Medicine.

(21) The National Center for Advancing Translational Sciences.

(22) The John E. Fogarty International Center for Advanced Study in the Health Sciences.

(23) The National Center for Complementary and Alternative Medicine.

(24) The National Institute on Minority Health and Health Disparities.

(25) Any other national center that, as an agency separate from any national research institute, was established within the National Institutes of Health as of the day before the date of the enactment of the National Institutes of Health Reform Act of 2006.

(c) DIVISION OF PROGRAM COORDINATION, PLANNING, AND STRATEGIC INITIATIVES.—

(1) IN GENERAL.—Within the Office of the Director of the National Institutes of Health, there shall be a Division of Program Coordination, Planning, and Strategic Initiatives (referred to in this subsection as the "Division").

(2) OFFICES WITHIN DIVISION.—

(A) OFFICES.—The following offices are within the Division: The Office of AIDS Research, the Office of Research on Women's Health, the Office of Behavioral and Social Sciences Research, the Office of Disease Prevention, the Office of Dietary Supplements, and any other office located within the Office of the Director of NIH as of the day before the date of the enactment of the National Institutes of Health Reform Act of 2006. In addition to such offices, the Director of NIH may establish within the Division such additional offices or other administrative units as the Director determines to be appropriate.

(B) AUTHORITIES.—Each office in the Division—

(i) shall continue to carry out the authorities that were in effect for the office before the date of enactment referred to in subparagraph (A); and

(ii) shall, as determined appropriate by the Director of NIH, support the Division with respect to the authorities described in section 402(b)(7).

(d) ORGANIZATION.—

(1) NUMBER OF INSTITUTES AND CENTERS.—In the National Institutes of Health, the number of national research institutes and national centers may not exceed a total of 27, including any such institutes or centers established under authority of paragraph (2) or under authority of this title as in effect on the day before the date of the enactment of the National Institutes of Health Reform Act of 2006.

(2) REORGANIZATION OF INSTITUTES.—

(A) IN GENERAL.—The Secretary may establish in the National Institutes of Health one or more additional national research institutes to conduct and support research, training, health information, and other programs with re-

spect to any particular disease or groups of diseases or any other aspect of human health if—

(i) the Secretary determines that an additional institute is necessary to carry out such activities; and

(ii) the additional institute is not established before the expiration of 180 days after the Secretary has provided the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate written notice of the determination made under clause (i) with respect to the institute.

(B) ADDITIONAL AUTHORITY.—The Secretary may reorganize the functions of any national research institute and may abolish any national research institute if the Secretary determines that the institute is no longer required. A reorganization or abolition may not take effect under this paragraph before the expiration of 180 days after the Secretary has provided the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate written notice of the reorganization or abolition.

(3) REORGANIZATION OF OFFICE OF DIRECTOR.—Notwithstanding subsection (c), the Director of NIH may, after a series of public hearings, and with the approval of the Secretary, reorganize the offices within the Office of the Director, including the addition, removal, or transfer of functions of such offices, and the establishment or termination of such offices, if the Director determines that the overall management and operation of programs and activities conducted or supported by such offices would be more efficiently carried out under such a reorganization.

(4) INTERNAL REORGANIZATION OF INSTITUTES AND CENTERS.—Notwithstanding any conflicting provisions of this title, the director of a national research institute or a national center may, after a series of public hearings and with the approval of the Director of NIH, reorganize the divisions, centers, or other administrative units within such institute or center, including the addition, removal, or transfer of functions of such units, and the establishment or termination of such units, if the director of such institute or center determines that the overall management and operation of programs and activities conducted or supported by such divisions, centers, or other units would be more efficiently carried out under such a reorganization.

(e) SCIENTIFIC MANAGEMENT REVIEW BOARD FOR PERIODIC ORGANIZATIONAL REVIEWS.—

(1) IN GENERAL.—Not later than 60 days after the date of the enactment of the National Institutes of Health Reform Act of 2006, the Secretary shall establish an advisory council within the National Institutes of Health to be known as the Scientific Management Review Board (referred to in this subsection as the "Board").

(2) DUTIES.—

(A) REPORTS ON ORGANIZATIONAL ISSUES.—The Board shall provide advice to the appropriate officials under subsection (d) regarding the use of the authorities established in paragraphs (2), (3), and (4) of such subsection to reorganize the National Institutes of Health (referred to in this subsection as "organizational authorities"). Not less frequently than once each 7 years, the Board shall—

(i) determine whether and to what extent the organizational authorities should be used; and

(ii) issue a report providing the recommendations of the Board regarding the use of the authorities and the reasons underlying the recommendations.

(B) CERTAIN RESPONSIBILITIES REGARDING REPORTS.—The activities of the Board with respect to a report under subparagraph (A) shall include the following:

(i) Reviewing the research portfolio of the National Institutes of Health (referred to in this subsection as "NIH") in order to determine the progress and effectiveness and value of the portfolio and the allocation among the portfolio activities of the resources of NIH.

(ii) Determining pending scientific opportunities, and public health needs, with respect to research within the jurisdiction of NIH.

(iii) For any proposal for organizational changes to which the Board gives significant consideration as a possible recommendation in such report—

(I) analyzing the budgetary and operational consequences of the proposed changes;

(II) taking into account historical funding and support for research activities at national research institutes and centers that have been established recently relative to national research institutes and centers that have been in existence for more than two decades;

(III) estimating the level of resources needed to implement the proposed changes;

(IV) assuming the proposed changes will be made and making a recommendation for the allocation of the resources of NIH among the national research institutes and national centers; and

(V) analyzing the consequences for the progress of research in the areas affected by the proposed changes.

(C) CONSULTATION.—In carrying out subparagraph (A), the Board shall consult with—

(i) the heads of national research institutes and national centers whose directors are not members of the Board;

(ii) other scientific leaders who are officers or employees of NIH and are not members of the Board;

(iii) advisory councils of the national research institutes and national centers;

(iv) organizations representing the scientific community; and

(v) organizations representing patients.

(3) COMPOSITION OF BOARD.—The Board shall consist of the Director of NIH, who shall be a permanent nonvoting member on an ex officio basis, and an odd number of additional members, not to exceed 21, all of whom shall be voting members. The voting members of the Board shall be the following:

(A) Not fewer than 9 officials who are directors of national research institutes or national centers. The Secretary shall designate such officials for membership and shall ensure that the group of officials so designated includes directors of—

(i) national research institutes whose budgets are substantial relative to a majority of the other institutes;

(ii) national research institutes whose budgets are small relative to a majority of the other institutes;

(iii) national research institutes that have been in existence for a substantial period of time without significant organizational change under subsection (d);

(iv) as applicable, national research institutes that have undergone significant organization changes under such subsection, or that have been established under such subsection, other than national research institutes for which such changes have been in place for a substantial period of time; and

(v) national centers.

(B) Members appointed by the Secretary from among individuals who are not officers or employees of the United States. Such members shall include—

(i) individuals representing the interests of public or private institutions of higher education that have historically received funds from NIH to conduct research; and

(ii) individuals representing the interests of private entities that have received funds from NIH to conduct research or that have broad expertise regarding how the National Institutes of Health functions, exclusive of private entities to which clause (i) applies.

(4) CHAIR.—The Chair of the Board shall be selected by the Secretary from among the members of the Board appointed under paragraph (3)(B). The term of office of the Chair shall be 2 years.

(5) MEETINGS.—

(A) IN GENERAL.—The Board shall meet at the call of the Chair or upon the request of the Director of NIH, but not fewer than 5 times with respect to issuing any particular report under paragraph (2)(A). The location of the meetings of the Board is subject to the approval of the Director of NIH.

(B) PARTICULAR FORUMS.—Of the meetings held under subparagraph (A) with respect to a report under paragraph (2)(A)—

(i) one or more shall be directed toward the scientific community to address scientific needs and opportunities related to proposals for organizational changes under subsection (d), or as the case may be, related to a proposal that no such changes be made; and

(ii) one or more shall be directed toward consumer organizations to address the needs and opportunities of patients and their families with respect to proposals referred to in clause (i).

(C) AVAILABILITY OF INFORMATION FROM FORUMS.—For each meeting under subparagraph (B), the Director of NIH shall post on the Internet site of the National Institutes of Health a summary of the proceedings.

(6) COMPENSATION; TERM OF OFFICE.—The provisions of subsections (b)(4) and (c) of section 406 apply with respect to the Board to the same extent and in the same manner as such provisions apply with respect to an advisory council referred to in such subsections, except that the reference in such subsection (c) to 4 years regarding the term of an appointed member is deemed to be a reference to 5 years.

(7) REPORTS.—

(A) RECOMMENDATIONS FOR CHANGES.—Each report under paragraph (2)(A) shall be submitted to—

(i) the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives;

(ii) the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate;

(iii) the Secretary; and

(iv) officials with organizational authorities, other than any such official who served as a member of the Board with respect to the report involved.

(B) AVAILABILITY TO PUBLIC.—The Director of NIH shall post each report under paragraph (2) on the Internet site of the National Institutes of Health.

(C) REPORT ON BOARD ACTIVITIES.—Not later than 18 months after the date of the enactment of the National Institutes of Health Reform Act of 2006, the Board shall submit to the committees specified in subparagraph (A) a report describing the activities of the Board.

(f) ORGANIZATIONAL CHANGES PER RECOMMENDATION OF SCIENTIFIC MANAGEMENT REVIEW BOARD.—

(1) IN GENERAL.—With respect to an official who has organizational authorities within the meaning of subsection (e)(2)(A), if a recommendation to the official for an organizational change is made in a report under such subsection, the official shall, except as provided in paragraphs (2), (3), and (4) of this subsection, make the change in accordance with the following:

(A) Not later than 100 days after the report is submitted under subsection (e)(7)(A), the official shall initiate

the applicable public process required in subsection (d) toward making the change.

(B) The change shall be fully implemented not later than the expiration of the 3-year period beginning on the date on which such process is initiated.

(2) INAPPLICABILITY TO CERTAIN REORGANIZATIONS.—Paragraph (1) does not apply to a recommendation made in a report under subsection (e)(2)(A) if the recommendation is for—

(A) an organizational change under subsection (d)(2) that constitutes the establishment, termination, or consolidation of one or more national research institutes or national centers; or

(B) an organizational change under subsection (d)(3).

(3) OBJECTION BY DIRECTOR OF NIH.—

(A) IN GENERAL.—Paragraph (1) does not apply to a recommendation for an organizational change made in a report under subsection (e)(2)(A) if, not later than 90 days after the report is submitted under subsection (e)(7)(A), the Director of NIH submits to the committees specified in such subsection a report providing that the Director objects to the change, which report includes the reasons underlying the objection.

(B) SCOPE OF OBJECTION.—For purposes of subparagraph (A), an objection by the Director of NIH may be made to the entirety of a recommended organizational change or to 1 or more aspects of the change. Any aspect of a change not objected to by the Director in a report under subparagraph (A) shall be implemented in accordance with paragraph (1).

(4) CONGRESSIONAL REVIEW.—An organizational change under subsection (d)(2) that is initiated pursuant to paragraph (1) shall be carried out by regulation in accordance with the procedures for substantive rules under section 553 of title 5, United States Code. A rule under the preceding sentence shall be considered a major rule for purposes of chapter 8 of such title (relating to congressional review of agency rulemaking).

(g) DEFINITIONS.—For purposes of this title:

(1) The term "Director of NIH" means the Director of the National Institutes of Health.

(2) The terms "national research institute" and "national center" mean an agency of the National Institutes of Health that is—

(A) listed in subsection (b) and not terminated under subsection (d)(2)(A); or

(B) established by the Director of NIH under such subsection.

(h) REFERENCES TO NIH.—For purposes of this title, a reference to the National Institutes of Health includes its agencies.

APPOINTMENT AND AUTHORITY OF DIRECTOR OF NIH.

SEC. 402.[282] (a) The National Institutes of Health shall be headed by the Director of NIH who shall be appointed by the President by and with the advice and consent of the Senate. The Direc-

tor of NIH shall perform functions as provided under subsection (b) and as the Secretary may otherwise prescribe.

(b) In carrying out the purposes of section 301, the Secretary, acting through the Director of NIH—

(1) shall carry out this title, including being responsible for the overall direction of the National Institutes of Health and for the establishment and implementation of general policies respecting the management and operation of programs and activities within the National Institutes of Health;

(2) shall coordinate and oversee the operation of the national research institutes, national centers, and administrative entities within the National Institutes of Health;

(3) shall, in consultation with the heads of the national research institutes and national centers, be responsible for program coordination across the national research institutes and national centers, including conducting priority-setting reviews, to ensure that the research portfolio of the National Institutes of Health is balanced and free of unnecessary duplication, and takes advantage of collaborative, cross-cutting research;

(4) shall assemble accurate data to be used to assess research priorities, including information to better evaluate scientific opportunity, public health burdens, and progress in reducing minority and other health disparities;

(5) shall ensure that scientifically based strategic planning is implemented in support of research priorities as determined by the agencies of the National Institutes of Health;

(6) shall ensure that the resources of the National Institutes of Health are sufficiently allocated for research projects identified in strategic plans;

(7)(A) shall, through the Division of Program Coordination, Planning, and Strategic Initiatives—

(i) identify research that represents important areas of emerging scientific opportunities, rising public health challenges, or knowledge gaps that deserve special emphasis and would benefit from conducting or supporting additional research that involves collaboration between 2 or more national research institutes or national centers, or would otherwise benefit from strategic coordination and planning;

(ii) include information on such research in reports under section 403; and

(iii) in the case of such research supported with funds referred to in subparagraph (B)—

(I) require as appropriate that proposals include milestones and goals for the research;

(II) require that the proposals include timeframes for funding of the research; and

(III) ensure appropriate consideration of proposals for which the principal investigator is an individual who has not previously served as the principal investigator of research conducted or supported by the National Institutes of Health;

(B) may, with respect to funds reserved under section 402A(c)(1) for the Common Fund, allocate such funds to the

national research institutes and national centers for conducting and supporting research that is identified under subparagraph (A); and

(C) may assign additional functions to the Division in support of responsibilities identified in subparagraph (A), as determined appropriate by the Director;

(8) shall, in coordination with the heads of the national research institutes and national centers, ensure that such institutes and centers—

(A) preserve an emphasis on investigator-initiated research project grants, including with respect to research involving collaboration between 2 or more such institutes or centers; and

(B) when appropriate, maximize investigator-initiated research project grants in their annual research portfolios;

(9) shall ensure that research conducted or supported by the National Institutes of Health is subject to review in accordance with section 492 and that, after such review, the research is reviewed in accordance with section 492A(a)(2) by the appropriate advisory council under section 406 before the research proposals are approved for funding;

(10) shall have authority to review and approve the establishment of all centers of excellence recommended by the national research institutes;

(11)(A) shall oversee research training for all of the national research institutes and National Research Service Awards in accordance with section 487; and

(B) may conduct and support research training—

(i) for which fellowship support is not provided under section 487; and

(ii) that does not consist of residency training of physicians or other health professionals;

(12) may, from funds appropriated under section 402A(b), reserve funds to provide for research on matters that have not received significant funding relative to other matters, to respond to new issues and scientific emergencies, and to act on research opportunities of high priority;

(13) may, subject to appropriations Acts, collect and retain registration fees obtained from third parties to defray expenses for scientific, educational, and research-related conferences;

(14) for the national research institutes and administrative entities within the National Institutes of Health—

(A) may acquire, construct, improve, repair, operate, and maintain, at the site of such institutes and entities, laboratories, and other research facilities, other facilities, equipment, and other real or personal property, and

(B) may acquire, without regard to the Act of March 3, 1877 (40 U.S.C. 34), by lease or otherwise through the Administrator of General Services, buildings or parts of buildings in the District of Columbia or communities located adjacent to the District of Columbia for use for a period not to exceed ten years;

(15) may secure resources for research conducted by or through the National Institutes of Health;

(16) may, without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates, establish such technical and scientific peer review groups and scientific program advisory committees as are needed to carry out the requirements of this title and appoint and pay the members of such groups, except that officers and employees of the United States shall not receive additional compensation for service as members of such groups;

(17) may secure for the National Institutes of Health consultation services and advice of persons from the United States or abroad;

(18) may use, with their consent, the services, equipment, personnel, information, and facilities of other Federal, State, or local public agencies, with or without reimbursement therefor;

(19) may, for purposes of study, admit and treat at facilities of the National Institutes of Health individuals not otherwise eligible for such treatment;

(20) may accept voluntary and uncompensated services;

(21) may perform such other administrative functions as the Secretary determines are needed to effectively carry out this title;

(22) may appoint physicians, dentists, and other health care professionals, subject to the provisions of title 5, United States Code, relating to appointments and classifications in the competitive service, and may compensate such professionals subject to the provisions of chapter 74 of title 38, United States Code;

(23) shall designate a contact point or office to help innovators and physicians identify sources of funding available for pediatric medical device development; and

(24) implement the Cures Acceleration Network described in section 480.

The Federal Advisory Committee Act shall not apply to the duration of a peer review group appointed under paragraph (16). The members of such a group shall be individuals who by virtue of their training or experience are eminently qualified to perform the review functions of such group. Not more than one-fourth of the members of any such group shall be officers or employees of the United States.

(c) The Director of NIH may make available to individuals and entities, for biomedical and behavioral research, substances and living organisms. Such substances and organisms shall be made available under such terms and conditions (including payment for them) as the Secretary determines appropriate.

(d)(1) The Director of NIH may obtain (in accordance with section 3109 of title 5, United States Code, but without regard to the limitation in such section on the period of service) the services of not more than 220 experts or consultants, with scientific or other professional qualifications, for the National Institutes of Health.

(2)(A) Except as provided in subparagraph (B), experts and consultants whose services are obtained under paragraph (1) shall

be paid or reimbursed, in accordance with title 5, United States Code, for their travel to and from their place of service and for other expenses associated with their assignment.

(B) Expenses specified in subparagraph (A) shall not be allowed in connection with the assignment of an expert or consultant whose services are obtained under paragraph (1) unless the expert or consultant has agreed in writing to complete the entire period of the assignment or one year of the assignment, whichever is shorter, unless separated or reassigned for reasons which are beyond the control of the expert or consultant and which are acceptable to the Secretary. If the expert or consultant violates the agreement, the money spent by the United States for such expenses is recoverable from the expert or consultant as a debt due the United States. The Secretary may waive in whole or in part a right of recovery under this subparagraph.

(e) The Director of NIH shall—

(1) advise the agencies of the National Institutes of Health on medical applications of research;

(2) coordinate, review, and facilitate the systematic identification and evaluation of, clinically relevant information from research conducted by or through the national research institutes;

(3) promote the effective transfer of the information described in paragraph (2) to the health care community and to entities that require such information;

(4) monitor the effectiveness of the activities described in paragraph (3); and

(5) ensure that, after January 1, 1994, all new or revised health education and promotion materials developed or funded by the National Institutes of Health and intended for the general public are in a form that does not exceed a level of functional literacy, as defined in the National Literacy Act of 1991 (Public Law 102–73)[3].

(f) There shall be in the National Institutes of Health an Associate Director for Prevention. The Director of NIH shall delegate to the Associate Director for Prevention the functions of the Director relating to the promotion of the disease prevention research programs of the national research institutes and the coordination of such programs among the national research institutes and between the national research institutes and other public and private entities, including elementary, secondary, and post-secondary schools. The Associate Director shall—

(1) annually review the efficacy of existing policies and techniques used by the national research institutes to disseminate the results of disease prevention and behavioral research programs; and

(2) recommend, coordinate, and oversee the modification or reconstruction of such policies and techniques to ensure maximum dissemination, using advanced technologies to the maximum extent practicable, of research results to such entities.

[3] So in law. That Act was repealed by section 251(a)(2) of Public Law 105–220 (112 Stat. 1079).

[(g) Transferred to section 461, redesignated as subsection (b) of such section, and amended (as so redesignated) by section 221(b)(5) of division F of Public Law 112–74.]

(h) The Secretary, acting through the Director of NIH and the Directors of the agencies of the National Institutes of Health, shall, in conducting and supporting programs for research, research training, recruitment, and other activities, provide for an increase in the number of women and individuals from disadvantaged backgrounds (including racial and ethnic minorities) in the fields of biomedical and behavioral research.

(i)(1)(A) The Secretary, acting through the Director of NIH, shall establish, maintain, and operate a data bank of information on clinical trials for drugs for serious or life-threatening diseases and conditions (in this subsection referred to as the "data bank"). The activities of the data bank shall be integrated and coordinated with related activities of other agencies of the Department of Health and Human Services, and to the extent practicable, coordinated with other data banks containing similar information.

(B) The Secretary shall establish the data bank after consultation with the Commissioner of Food and Drugs, the directors of the appropriate agencies of the National Institutes of Health (including the National Library of Medicine), and the Director of the Centers for Disease Control and Prevention.

(2) In carrying out paragraph (1), the Secretary shall collect, catalog, store, and disseminate the information described in such paragraph. The Secretary shall disseminate such information through information systems, which shall include toll-free telephone communications, available to individuals with serious or life-threatening diseases and conditions, to other members of the public, to health care providers, and to researchers.

(3) The data bank shall include the following:

(A) A registry of clinical trials (whether federally or privately funded) of experimental treatments for serious or life-threatening diseases and conditions under regulations promulgated pursuant to section 505(i) of the Federal Food, Drug, and Cosmetic Act, which provides a description of the purpose of each experimental drug, either with the consent of the protocol sponsor, or when a trial to test effectiveness begins. Information provided shall consist of eligibility criteria for participation in the clinical trials, a description of the location of trial sites, and a point of contact for those wanting to enroll in the trial, and shall be in a form that can be readily understood by members of the public.[4] Such information shall be forwarded to the data bank by the sponsor of the trial not later than 21 days after the approval of the protocol.

[4] Section 15(c)(2) of Public Law 107–109 (115 Stat. 1420) attempted to make amendments to the first sentence of subparagraph (A), but the amendments cannot be executed because the terms to be amended appear in the second sentence, not the first. The following shows the second sentence as it would appear if the amendments were executed to the second sentence: "Information provided shall consist of eligibility criteria for participation in the clinical trials, a description of the location of trial sites, a point of contact for those wanting to enroll in the trial, and a description of whether, and through what procedure, the manufacturer or sponsor of the investigation of a new drug will respond to requests for protocol exception, with appropriate safeguards, for single-patient and expanded protocol use of the new drug, particularly in children, and shall be in a form that can be readily understood by members of the public.".

(B) Information pertaining to experimental treatments for serious or life-threatening diseases and conditions that may be available—

(i) under a treatment investigational new drug application that has been submitted to the Secretary under section 561(c) of the Federal Food, Drug, and Cosmetic Act; or

(ii) as a Group C cancer drug (as defined by the National Cancer Institute).

The data bank may also include information pertaining to the results of clinical trials of such treatments, with the consent of the sponsor, including information concerning potential toxicities or adverse effects associated with the use or administration of such experimental treatments.

(4) The data bank shall not include information relating to an investigation if the sponsor has provided a detailed certification to the Secretary that disclosure of such information would substantially interfere with the timely enrollment of subjects in the investigation, unless the Secretary, after the receipt of the certification, provides the sponsor with a detailed written determination that such disclosure would not substantially interfere with such enrollment.

(5) Fees collected under section 736 of the Federal Food, Drug, and Cosmetic Act shall not be used in carrying out this subsection.

(j) EXPANDED CLINICAL TRIAL REGISTRY DATA BANK.—

(1) DEFINITIONS; REQUIREMENT.—

(A) DEFINITIONS.—In this subsection:

(i) APPLICABLE CLINICAL TRIAL.—The term "applicable clinical trial" means an applicable device clinical trial or an applicable drug clinical trial.

(ii) APPLICABLE DEVICE CLINICAL TRIAL.—The term "applicable device clinical trial" means—

(I) a prospective clinical study of health outcomes comparing an intervention with a device subject to section 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act against a control in human subjects (other than a small clinical trial to determine the feasibility of a device, or a clinical trial to test prototype devices where the primary outcome measure relates to feasibility and not to health outcomes); and

(II) a pediatric postmarket surveillance as required under section 522 of the Federal Food, Drug, and Cosmetic Act.

(iii) APPLICABLE DRUG CLINICAL TRIAL.—

(I) IN GENERAL.—The term "applicable drug clinical trial" means a controlled clinical investigation, other than a phase I clinical investigation, of a drug subject to section 505 of the Federal Food, Drug, and Cosmetic Act or to section 351 of this Act.

(II) CLINICAL INVESTIGATION.—For purposes of subclause (I), the term "clinical investigation" has the meaning given that term in section 312.3 of

title 21, Code of Federal Regulations (or any successor regulation).

(III) PHASE I.—For purposes of subclause (I), the term "phase I" has the meaning given that term in section 312.21 of title 21, Code of Federal Regulations (or any successor regulation).

(iv) CLINICAL TRIAL INFORMATION.—The term "clinical trial information" means, with respect to an applicable clinical trial, those data elements that the responsible party is required to submit under paragraph (2) or under paragraph (3).

(v) COMPLETION DATE.—The term "completion date" means, with respect to an applicable clinical trial, the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the prespecified protocol or was terminated.

(vi) DEVICE.—The term "device" means a device as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act.

(vii) DRUG.—The term "drug" means a drug as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act or a biological product as defined in section 351 of this Act.

(viii) ONGOING.—The term "ongoing" means, with respect to a clinical trial of a drug or a device and to a date, that—

(I) 1 or more patients is enrolled in the clinical trial; and

(II) the date is before the completion date of the clinical trial.

(ix) RESPONSIBLE PARTY.—The term "responsible party", with respect to a clinical trial of a drug or device, means—

(I) the sponsor of the clinical trial (as defined in section 50.3 of title 21, Code of Federal Regulations (or any successor regulation)); or

(II) the principal investigator of such clinical trial if so designated by a sponsor, grantee, contractor, or awardee, so long as the principal investigator is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial, and has the ability to meet all of the requirements under this subsection for the submission of clinical trial information.

(B) REQUIREMENT.—The Secretary shall develop a mechanism by which the responsible party for each applicable clinical trial shall submit the identity and contact information of such responsible party to the Secretary at the time of submission of clinical trial information under paragraph (2).

(2) EXPANSION OF CLINICAL TRIAL REGISTRY DATA BANK WITH RESPECT TO CLINICAL TRIAL INFORMATION.—

(A) IN GENERAL.—

(i) EXPANSION OF DATA BANK.—To enhance patient enrollment and provide a mechanism to track subsequent progress of clinical trials, the Secretary, acting through the Director of NIH, shall expand, in accordance with this subsection, the clinical trials registry of the data bank described under subsection (i)(1) (referred to in this subsection as the "registry data bank"). The Director of NIH shall ensure that the registry data bank is made publicly available through the Internet.

(ii) CONTENT.—The clinical trial information required to be submitted under this paragraph for an applicable clinical trial shall include—

(I) descriptive information, including—

(aa) a brief title, intended for the lay public;

(bb) a brief summary, intended for the lay public;

(cc) the primary purpose;

(dd) the study design;

(ee) for an applicable drug clinical trial, the study phase;

(ff) study type;

(gg) the primary disease or condition being studied, or the focus of the study;

(hh) the intervention name and intervention type;

(ii) the study start date;

(jj) the expected completion date;

(kk) the target number of subjects; and

(ll) outcomes, including primary and secondary outcome measures;

(II) recruitment information, including—

(aa) eligibility criteria;

(bb) gender;

(cc) age limits;

(dd) whether the trial accepts healthy volunteers;

(ee) overall recruitment status;

(ff) individual site status; and

(gg) in the case of an applicable drug clinical trial, if the drug is not approved under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of this Act, specify whether or not there is expanded access to the drug under section 561 of the Federal Food, Drug, and Cosmetic Act for those who do not qualify for enrollment in the clinical trial and how to obtain information about such access;

(III) location and contact information, including—

(aa) the name of the sponsor;

(bb) the responsible party, by official title; and

(cc) the facility name and facility contact information (including the city, State, and zip code for each clinical trial location, or a toll-free number through which such location information may be accessed); and

(IV) administrative data (which the Secretary may make publicly available as necessary), including—

(aa) the unique protocol identification number;

(bb) other protocol identification numbers, if any; and

(cc) the Food and Drug Administration IND/IDE protocol number and the record verification date.

(iii) MODIFICATIONS.—The Secretary may by regulation modify the requirements for clinical trial information under this paragraph, if the Secretary provides a rationale for why such a modification improves and does not reduce such clinical trial information.

(B) FORMAT AND STRUCTURE.—

(i) SEARCHABLE CATEGORIES.—The Director of NIH shall ensure that the public may, in addition to keyword searching, search the entries in the registry data bank by 1 or more of the following criteria:

(I) The disease or condition being studied in the clinical trial, using Medical Subject Headers (MeSH) descriptors.

(II) The name of the intervention, including any drug or device being studied in the clinical trial.

(III) The location of the clinical trial.

(IV) The age group studied in the clinical trial, including pediatric subpopulations.

(V) The study phase of the clinical trial.

(VI) The sponsor of the clinical trial, which may be the National Institutes of Health or another Federal agency, a private industry source, or a university or other organization.

(VII) The recruitment status of the clinical trial.

(VIII) The National Clinical Trial number or other study identification for the clinical trial.

(ii) ADDITIONAL SEARCHABLE CATEGORY.—Not later than 18 months after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, the Director of NIH shall ensure that the public may search the entries of the registry data bank by

the safety issue, if any, being studied in the clinical trial as a primary or secondary outcome.

(iii) OTHER ELEMENTS.—The Director of NIH shall also ensure that the public may search the entries of the registry data bank by such other elements as the Director deems necessary on an ongoing basis.

(iv) FORMAT.—The Director of the NIH shall ensure that the registry data bank is easily used by the public, and that entries are easily compared.

(C) DATA SUBMISSION.—The responsible party for an applicable clinical trial, including an applicable drug clinical trial for a serious or life-threatening disease or condition, that is initiated after, or is ongoing on the date that is 90 days after, the date of the enactment of the Food and Drug Administration Amendments Act of 2007, shall submit to the Director of NIH for inclusion in the registry data bank the clinical trial information described in of subparagraph (A)(ii) not later than the later of—

(i) 90 days after such date of enactment;

(ii) 21 days after the first patient is enrolled in such clinical trial; or

(iii) in the case of a clinical trial that is not for a serious or life-threatening disease or condition and that is ongoing on such date of enactment, 1 year after such date of enactment.

(D) POSTING OF DATA.—

(i) APPLICABLE DRUG CLINICAL TRIAL.—The Director of NIH shall ensure that clinical trial information for an applicable drug clinical trial submitted in accordance with this paragraph is posted in the registry data bank not later than 30 days after such submission.

(ii) APPLICABLE DEVICE CLINICAL TRIAL.—The Director of NIH shall ensure that clinical trial information for an applicable device clinical trial submitted in accordance with this paragraph is posted publicly in the registry data bank—

(I) not earlier than the date of clearance under section 510(k) of the Federal Food, Drug, and Cosmetic Act, or approval under section 515 or 520(m) of such Act, as applicable, for a device that was not previously cleared or approved, and not later than 30 days after such date; or

(II) for a device that was previously cleared or approved, not later than 30 days after the clinical trial information under paragraph (3)(C) is required to be posted by the Secretary.

(3) EXPANSION OF REGISTRY DATA BANK TO INCLUDE RESULTS OF CLINICAL TRIALS.—

(A) LINKING REGISTRY DATA BANK TO EXISTING RESULTS.—

(i) IN GENERAL.—Beginning not later than 90 days after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, for those

clinical trials that form the primary basis of an efficacy claim or are conducted after the drug involved is approved or after the device involved is cleared or approved, the Secretary shall ensure that the registry data bank includes links to results information as described in clause (ii) for such clinical trial—

(I) not earlier than 30 days after the date of the approval of the drug involved or clearance or approval of the device involved; or

(II) not later than 30 days after the results information described in clause (ii) becomes publicly available.

(ii) REQUIRED INFORMATION.—

(I) FDA INFORMATION.—The Secretary shall ensure that the registry data bank includes links to the following information:

(aa) If an advisory committee considered at a meeting an applicable clinical trial, any posted Food and Drug Administration summary document regarding such applicable clinical trial.

(bb) If an applicable drug clinical trial was conducted under section 505A or 505B of the Federal Food, Drug, and Cosmetic Act, a link to the posted Food and Drug Administration assessment of the results of such trial.

(cc) Food and Drug Administration public health advisories regarding the drug or device that is the subject of the applicable clinical trial, if any.

(dd) For an applicable drug clinical trial, the Food and Drug Administration action package for approval document required under section 505(l)(2) of the Federal Food, Drug, and Cosmetic Act.

(ee) For an applicable device clinical trial, in the case of a premarket application under section 515 of the Federal Food, Drug, and Cosmetic Act, the detailed summary of information respecting the safety and effectiveness of the device required under section 520(h)(1) of such Act, or, in the case of a report under section 510(k) of such Act, the section 510(k) summary of the safety and effectiveness data required under section 807.95(d) of title 21, Code of Federal Regulations (or any successor regulation).

(II) NIH INFORMATION.—The Secretary shall ensure that the registry data bank includes links to the following information:

(aa) Medline citations to any publications focused on the results of an applicable clinical trial.

(bb) The entry for the drug that is the subject of an applicable drug clinical trial in the National Library of Medicine database of structured product labels, if available.

(iii) RESULTS FOR EXISTING DATA BANK ENTRIES.—The Secretary may include the links described in clause (ii) for data bank entries for clinical trials submitted to the data bank prior to enactment of the Food and Drug Administration Amendments Act of 2007, as available.

(B) INCLUSION OF RESULTS.—The Secretary, acting through the Director of NIH, shall—

(i) expand the registry data bank to include the results of applicable clinical trials (referred to in this subsection as the "registry and results data bank");

(ii) ensure that such results are made publicly available through the Internet;

(iii) post publicly a glossary for the lay public explaining technical terms related to the results of clinical trials; and

(iv) in consultation with experts on risk communication, provide information with the information included under subparagraph (C) in the registry and results data bank to help ensure that such information does not mislead the patients or the public.

(C) BASIC RESULTS.—Not later than 1 year after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, the Secretary shall include in the registry and results data bank for each applicable clinical trial for a drug that is approved under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of this Act or a device that is cleared under section 510(k) of the Federal Food, Drug, and Cosmetic Act or approved under section 515 or 520(m) of such Act, the following elements:

(i) DEMOGRAPHIC AND BASELINE CHARACTERISTICS OF PATIENT SAMPLE.—A table of the demographic and baseline data collected overall and for each arm of the clinical trial to describe the patients who participated in the clinical trial, including the number of patients who dropped out of the clinical trial and the number of patients excluded from the analysis, if any.

(ii) PRIMARY AND SECONDARY OUTCOMES.—The primary and secondary outcome measures as submitted under paragraph (2)(A)(ii)(I)(ll), and a table of values for each of the primary and secondary outcome measures for each arm of the clinical trial, including the results of scientifically appropriate tests of the statistical significance of such outcome measures.

(iii) POINT OF CONTACT.—A point of contact for scientific information about the clinical trial results.

(iv) CERTAIN AGREEMENTS.—Whether there exists an agreement (other than an agreement solely to comply with applicable provisions of law protecting the

privacy of participants) between the sponsor or its agent and the principal investigator (unless the sponsor is an employer of the principal investigator) that restricts in any manner the ability of the principal investigator, after the completion date of the trial, to discuss the results of the trial at a scientific meeting or any other public or private forum, or to publish in a scientific or academic journal information concerning the results of the trial.

(D) EXPANDED REGISTRY AND RESULTS DATA BANK.—

(i) EXPANSION BY RULEMAKING.—To provide more complete results information and to enhance patient access to and understanding of the results of clinical trials, not later than 3 years after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, the Secretary shall by regulation expand the registry and results data bank as provided under this subparagraph.

(ii) CLINICAL TRIALS.—

(I) APPROVED PRODUCTS.—The regulations under this subparagraph shall require the inclusion of the results information described in clause (iii) for—

(aa) each applicable drug clinical trial for a drug that is approved under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of this Act; and

(bb) each applicable device clinical trial for a device that is cleared under section 510(k) of the Federal Food, Drug, and Cosmetic Act or approved under section 515 or 520(m) of such Act.

(II) UNAPPROVED PRODUCTS.—The regulations under this subparagraph shall establish whether or not the results information described in clause (iii) shall be required for—

(aa) an applicable drug clinical trial for a drug that is not approved under section 505 of the Federal Food, Drug, and Cosmetic Act and not licensed under section 351 of this Act (whether approval or licensure was sought or not); and

(bb) an applicable device clinical trial for a device that is not cleared under section 510(k) of the Federal Food, Drug, and Cosmetic Act and not approved under section 515 or section 520(m) of such Act (whether clearance or approval was sought or not).

(iii) REQUIRED ELEMENTS.—The regulations under this subparagraph shall require, in addition to the elements described in subparagraph (C), information within each of the following categories:

(I) A summary of the clinical trial and its results that is written in non-technical, understand-

able language for patients, if the Secretary determines that such types of summary can be included without being misleading or promotional.

(II) A summary of the clinical trial and its results that is technical in nature, if the Secretary determines that such types of summary can be included without being misleading or promotional.

(III) The full protocol or such information on the protocol for the trial as may be necessary to help to evaluate the results of the trial.

(IV) Such other categories as the Secretary determines appropriate.

(iv) RESULTS SUBMISSION.—The results information described in clause (iii) shall be submitted to the Director of NIH for inclusion in the registry and results data bank as provided by subparagraph (E), except that the Secretary shall by regulation determine—

(I) whether the 1-year period for submission of clinical trial information described in subparagraph (E)(i) should be increased from 1 year to a period not to exceed 18 months;

(II) whether the clinical trial information described in clause (iii) should be required to be submitted for an applicable clinical trial for which the clinical trial information described in subparagraph (C) is submitted to the registry and results data bank before the effective date of the regulations issued under this subparagraph; and

(III) in the case when the clinical trial information described in clause (iii) is required to be submitted for the applicable clinical trials described in clause (ii)(II), the date by which such clinical trial information shall be required to be submitted, taking into account—

(aa) the certification process under subparagraph (E)(iii) when approval, licensure, or clearance is sought; and

(bb) whether there should be a delay of submission when approval, licensure, or clearance will not be sought.

(v) ADDITIONAL PROVISIONS.—The regulations under this subparagraph shall also establish—

(I) a standard format for the submission of clinical trial information under this paragraph to the registry and results data bank;

(II) additional information on clinical trials and results that is written in nontechnical, understandable language for patients;

(III) considering the experience under the pilot quality control project described in paragraph (5)(C), procedures for quality control, including using representative samples, with respect to completeness and content of clinical trial infor-

mation under this subsection, to help ensure that data elements are not false or misleading and are non-promotional;

(IV) the appropriate timing and requirements for updates of clinical trial information, and whether and, if so, how such updates should be tracked;

(V) a statement to accompany the entry for an applicable clinical trial when the primary and secondary outcome measures for such clinical trial are submitted under paragraph (4)(A) after the date specified for the submission of such information in paragraph (2)(C); and

(VI) additions or modifications to the manner of reporting of the data elements established under subparagraph (C).

(vi) CONSIDERATION OF WORLD HEALTH ORGANIZATION DATA SET.—The Secretary shall consider the status of the consensus data elements set for reporting clinical trial results of the World Health Organization when issuing the regulations under this subparagraph.

(vii) PUBLIC MEETING.—The Secretary shall hold a public meeting no later than 18 months after the date of the enactment of the Food and Drug Administration Amendments Act of 2007 to provide an opportunity for input from interested parties with regard to the regulations to be issued under this subparagraph.

(E) SUBMISSION OF RESULTS INFORMATION.—

(i) IN GENERAL.—Except as provided in clauses (iii), (iv), (v), and (vi) the responsible party for an applicable clinical trial that is described in clause (ii) shall submit to the Director of NIH for inclusion in the registry and results data bank the clinical trial information described in subparagraph (C) not later than 1 year, or such other period as may be provided by regulation under subparagraph (D), after the earlier of—

(I) the estimated completion date of the trial as described in paragraph (2)(A)(ii)(I)(jj)); or

(II) the actual date of completion.

(ii) CLINICAL TRIALS DESCRIBED.—An applicable clinical trial described in this clause is an applicable clinical trial subject to—

(I) paragraph (2)(C); and

(II)(aa) subparagraph (C); or

(bb) the regulations issued under subparagraph (D).

(iii) DELAYED SUBMISSION OF RESULTS WITH CERTIFICATION.—If the responsible party for an applicable clinical trial submits a certification that clause (iv) or (v) applies to such clinical trial, the responsible party shall submit to the Director of NIH for inclusion in the registry and results data bank the clinical trial infor-

mation described in subparagraphs (C) and (D) as required under the applicable clause.

(iv) SEEKING INITIAL APPROVAL OF A DRUG OR DEVICE.—With respect to an applicable clinical trial that is completed before the drug is initially approved under section 505 of the Federal Food, Drug, and Cosmetic Act or initially licensed under section 351 of this Act, or the device is initially cleared under section 510(k) or initially approved under section 515 or 520(m) of the Federal Food, Drug, and Cosmetic Act, the responsible party shall submit to the Director of NIH for inclusion in the registry and results data bank the clinical trial information described in subparagraphs (C) and (D) not later than 30 days after the drug or device is approved under such section 505, licensed under such section 351, cleared under such section 510(k), or approved under such section 515 or 520(m), as applicable.

(v) SEEKING APPROVAL OF A NEW USE FOR THE DRUG OR DEVICE.—

(I) IN GENERAL.—With respect to an applicable clinical trial where the manufacturer of the drug or device is the sponsor of an applicable clinical trial, and such manufacturer has filed, or will file within 1 year, an application seeking approval under section 505 of the Federal Food, Drug, and Cosmetic Act, licensing under section 351 of this Act, or clearance under section 510(k), or approval under section 515 or 520(m), of the Federal Food, Drug, and Cosmetic Act for the use studied in such clinical trial (which use is not included in the labeling of the approved drug or device), then the responsible party shall submit to the Director of NIH for inclusion in the registry and results data bank the clinical trial information described in subparagraphs (C) and (D) on the earlier of the date that is 30 days after the date—

(aa) the new use of the drug or device is approved under such section 505, licensed under such section 351, cleared under such section 510(k), or approved under such section 515 or 520(m);

(bb) the Secretary issues a letter, such as a complete response letter, not approving the submission or not clearing the submission, a not approvable letter, or a not substantially equivalent letter for the new use of the drug or device under such section 505, 351, 510(k), 515, or 520(m); or

(cc) except as provided in subclause (III), the application or premarket notification under such section 505, 351, 510(k), 515, or 520(m) is withdrawn without resubmission for no less than 210 days.

(II) REQUIREMENT THAT EACH CLINICAL TRIAL IN APPLICATION BE TREATED THE SAME.—If a manufacturer makes a certification under clause (iii) that this clause applies with respect to a clinical trial, the manufacturer shall make such a certification with respect to each applicable clinical trial that is required to be submitted in an application or report for licensure, approval, or clearance (under section 351 of this Act or section 505, 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act, as applicable) of the use studied in the clinical trial.

(III) TWO-YEAR LIMITATION.—The responsible party shall submit to the Director of NIH for inclusion in the registry and results data bank the clinical trial information subject to subclause (I) on the date that is 2 years after the date a certification under clause (iii) was made to the Director of NIH, if an action referred to in item (aa), (bb), or (cc) of subclause (I) has not occurred by such date.

(vi) EXTENSIONS.—The Director of NIH may provide an extension of the deadline for submission of clinical trial information under clause (i) if the responsible party for the trial submits to the Director a written request that demonstrates good cause for the extension and provides an estimate of the date on which the information will be submitted. The Director of NIH may grant more than one such extension for a clinical trial.

(F) NOTICE TO DIRECTOR OF NIH.—The Commissioner of Food and Drugs shall notify the Director of NIH when there is an action described in subparagraph (E)(iv) or item (aa), (bb), or (cc) of subparagraph (E)(v)(I) with respect to an application or a report that includes a certification required under paragraph (5)(B) of such action not later than 30 days after such action.

(G) POSTING OF DATA.—The Director of NIH shall ensure that the clinical trial information described in subparagraphs (C) and (D) for an applicable clinical trial submitted in accordance with this paragraph is posted publicly in the registry and results database not later than 30 days after such submission.

(H) WAIVERS REGARDING CERTAIN CLINICAL TRIAL RESULTS.—The Secretary may waive any applicable requirements of this paragraph for an applicable clinical trial, upon a written request from the responsible party, if the Secretary determines that extraordinary circumstances justify the waiver and that providing the waiver is consistent with the protection of public health, or in the interest of national security. Not later than 30 days after any part of a waiver is granted, the Secretary shall notify, in writing, the appropriate committees of Congress of the

waiver and provide an explanation for why the waiver was granted.

(I) ADVERSE EVENTS.—

(i) REGULATIONS.—Not later than 18 months after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, the Secretary shall by regulation determine the best method for including in the registry and results data bank appropriate results information on serious adverse and frequent adverse events for applicable clinical trials described in subparagraph (C) in a manner and form that is useful and not misleading to patients, physicians, and scientists.

(ii) DEFAULT.—If the Secretary fails to issue the regulation required by clause (i) by the date that is 24 months after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, clause (iii) shall take effect.

(iii) ADDITIONAL ELEMENTS.—Upon the application of clause (ii), the Secretary shall include in the registry and results data bank for applicable clinical trials described in subparagraph (C), in addition to the clinical trial information described in subparagraph (C), the following elements:

(I) SERIOUS ADVERSE EVENTS.—A table of anticipated and unanticipated serious adverse events grouped by organ system, with number and frequency of such event in each arm of the clinical trial.

(II) FREQUENT ADVERSE EVENTS.—A table of anticipated and unanticipated adverse events that are not included in the table described in subclause (I) that exceed a frequency of 5 percent within any arm of the clinical trial, grouped by organ system, with number and frequency of such event in each arm of the clinical trial.

(iv) POSTING OF OTHER INFORMATION.—In carrying out clause (iii), the Secretary shall, in consultation with experts in risk communication, post with the tables information to enhance patient understanding and to ensure such tables do not mislead patients or the lay public.

(v) RELATION TO SUBPARAGRAPH (C).—Clinical trial information included in the registry and results data bank pursuant to this subparagraph is deemed to be clinical trial information included in such data bank pursuant to subparagraph (C).

(4) ADDITIONAL SUBMISSIONS OF CLINICAL TRIAL INFORMATION.—

(A) VOLUNTARY SUBMISSIONS.—A responsible party for a clinical trial that is not an applicable clinical trial, or that is an applicable clinical trial that is not subject to paragraph (2)(C), may submit complete clinical trial information described in paragraph (2) or paragraph (3) pro-

vided the responsible party submits clinical trial information for each applicable clinical trial that is required to be submitted under section 351 or under section 505, 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act in an application or report for licensure, approval, or clearance of the drug or device for the use studied in the clinical trial.

(B) REQUIRED SUBMISSIONS.—

(i) IN GENERAL.—Notwithstanding paragraphs (2) and (3) and subparagraph (A), in any case in which the Secretary determines for a specific clinical trial described in clause (ii) that posting in the registry and results data bank of clinical trial information for such clinical trial is necessary to protect the public health—

(I) the Secretary may require by notification that such information be submitted to the Secretary in accordance with paragraphs (2) and (3) except with regard to timing of submission;

(II) unless the responsible party submits a certification under paragraph (3)(E)(iii), such information shall be submitted not later than 30 days after the date specified by the Secretary in the notification; and

(III) failure to comply with the requirements under subclauses (I) and (II) shall be treated as a violation of the corresponding requirement of such paragraphs.

(ii) CLINICAL TRIALS DESCRIBED.—A clinical trial described in this clause is—

(I) an applicable clinical trial for a drug that is approved under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of this Act or for a device that is cleared under section 510(k) of the Federal Food, Drug, and Cosmetic Act or approved under section 515 or section 520(m) of such Act, whose completion date is on or after the date 10 years before the date of the enactment of the Food and Drug Administration Amendments Act of 2007; or

(II) an applicable clinical trial that is described by both by paragraph (2)(C) and paragraph (3)(D)(ii)(II)).

(C) UPDATES TO CLINICAL TRIAL DATA BANK.—

(i) SUBMISSION OF UPDATES.—The responsible party for an applicable clinical trial shall submit to the Director of NIH for inclusion in the registry and results data bank updates to reflect changes to the clinical trial information submitted under paragraph (2). Such updates—

(I) shall be provided not less than once every 12 months, unless there were no changes to the clinical trial information during the preceding 12-month period;

(II) shall include identification of the dates of any such changes;

(III) not later than 30 days after the recruitment status of such clinical trial changes, shall include an update of the recruitment status; and

(IV) not later than 30 days after the completion date of the clinical trial, shall include notification to the Director that such clinical trial is complete.

(ii) PUBLIC AVAILABILITY OF UPDATES.—The Director of NIH shall make updates submitted under clause (i) publicly available in the registry data bank. Except with regard to overall recruitment status, individual site status, location, and contact information, the Director of NIH shall ensure that updates to elements required under subclauses (I) to (V) of paragraph (2)(A)(ii) do not result in the removal of any information from the original submissions or any preceding updates, and information in such databases is presented in a manner that enables users to readily access each original element submission and to track the changes made by the updates. The Director of NIH shall provide a link from the table of primary and secondary outcomes required under paragraph (3)(C)(ii) to the tracked history required under this clause of the primary and secondary outcome measures submitted under paragraph (2)(A)(ii)(I)(ll).

(5) COORDINATION AND COMPLIANCE.—

(A) CLINICAL TRIALS SUPPORTED BY GRANTS FROM FEDERAL AGENCIES.—

(i) GRANTS FROM CERTAIN FEDERAL AGENCIES.—If an applicable clinical trial is funded in whole or in part by a grant from any agency of the Department of Health and Human Services, including the Food and Drug Administration, the National Institutes of Health, or the Agency for Healthcare Research and Quality, any grant or progress report forms required under such grant shall include a certification that the responsible party has made all required submissions to the Director of NIH under paragraphs (2) and (3).

(ii) VERIFICATION BY FEDERAL AGENCIES.—The heads of the agencies referred to in clause (i), as applicable, shall verify that the clinical trial information for each applicable clinical trial for which a grantee is the responsible party has been submitted under paragraphs (2) and (3) before releasing any remaining funding for a grant or funding for a future grant to such grantee.

(iii) NOTICE AND OPPORTUNITY TO REMEDY.—If the head of an agency referred to in clause (i), as applicable, verifies that a grantee has not submitted clinical trial information as described in clause (ii), such agency head shall provide notice to such grantee of such non-compliance and allow such grantee 30 days to cor-

rect such non-compliance and submit the required clinical trial information.

(iv) CONSULTATION WITH OTHER FEDERAL AGENCIES.—The Secretary shall—

(I) consult with other agencies that conduct research involving human subjects in accordance with any section of part 46 of title 45, Code of Federal Regulations (or any successor regulations), to determine if any such research is an applicable clinical trial; and

(II) develop with such agencies procedures comparable to those described in clauses (i), (ii), and (iii) to ensure that clinical trial information for such applicable clinical trial is submitted under paragraphs (2) and (3).

(B) CERTIFICATION TO ACCOMPANY DRUG, BIOLOGICAL PRODUCT, AND DEVICE SUBMISSIONS.—At the time of submission of an application under section 505 of the Federal Food, Drug, and Cosmetic Act, section 515 of such Act, section 520(m) of such Act, or section 351 of this Act, or submission of a report under section 510(k) of such Act, such application or submission shall be accompanied by a certification that all applicable requirements of this subsection have been met. Where available, such certification shall include the appropriate National Clinical Trial control numbers.

(C) QUALITY CONTROL.—

(i) PILOT QUALITY CONTROL PROJECT.—Until the effective date of the regulations issued under paragraph (3)(D), the Secretary, acting through the Director of NIH and the Commissioner of Food and Drugs, shall conduct a pilot project to determine the optimal method of verification to help to ensure that the clinical trial information submitted under paragraph (3)(C) is non-promotional and is not false or misleading in any particular under subparagraph (D). The Secretary shall use the publicly available information described in paragraph (3)(A) and any other information available to the Secretary about applicable clinical trials to verify the accuracy of the clinical trial information submitted under paragraph (3)(C).

(ii) NOTICE OF COMPLIANCE.—If the Secretary determines that any clinical trial information was not submitted as required under this subsection, or was submitted but is false or misleading in any particular, the Secretary shall notify the responsible party and give such party an opportunity to remedy such non-compliance by submitting the required revised clinical trial information not later than 30 days after such notification.

(D) TRUTHFUL CLINICAL TRIAL INFORMATION.—

(i) IN GENERAL.—The clinical trial information submitted by a responsible party under this subsection shall not be false or misleading in any particular.

(ii) EFFECT.—Clause (i) shall not have the effect of—

(I) requiring clinical trial information with respect to an applicable clinical trial to include information from any source other than such clinical trial involved; or

(II) requiring clinical trial information described in paragraph (3)(D) to be submitted for purposes of paragraph (3)(C).

(E) PUBLIC NOTICES.—

(i) NOTICE OF VIOLATIONS.—If the responsible party for an applicable clinical trial fails to submit clinical trial information for such clinical trial as required under paragraphs (2) or (3), the Director of NIH shall include in the registry and results data bank entry for such clinical trial a notice—

(I) that the responsible party is not in compliance with this Act by—

(aa) failing to submit required clinical trial information; or

(bb) submitting false or misleading clinical trial information;

(II) of the penalties imposed for the violation, if any; and

(III) whether the responsible party has corrected the clinical trial information in the registry and results data bank.

(ii) NOTICE OF FAILURE TO SUBMIT PRIMARY AND SECONDARY OUTCOMES.—If the responsible party for an applicable clinical trial fails to submit the primary and secondary outcomes as required under section 2(A)(ii)(I)(ll), the Director of NIH shall include in the registry and results data bank entry for such clinical trial a notice that the responsible party is not in compliance by failing to register the primary and secondary outcomes in accordance with this act, and that the primary and secondary outcomes were not publicly disclosed in the database before conducting the clinical trial.

(iii) FAILURE TO SUBMIT STATEMENT.—The notice under clause (i) for a violation described in clause (i)(I)(aa) shall include the following statement: "The entry for this clinical trial was not complete at the time of submission, as required by law. This may or may not have any bearing on the accuracy of the information in the entry.".

(iv) SUBMISSION OF FALSE INFORMATION STATEMENT.—The notice under clause (i) for a violation described in clause (i)(I)(bb) shall include the following statement: "The entry for this clinical trial was found to be false or misleading and therefore not in compliance with the law.".

(v) NON-SUBMISSION OF STATEMENT.—The notice under clause (ii) for a violation described in clause (ii)

shall include the following statement: "The entry for this clinical trial did not contain information on the primary and secondary outcomes at the time of submission, as required by law. This may or may not have any bearing on the accuracy of the information in the entry.".

(vi) COMPLIANCE SEARCHES.—The Director of NIH shall provide that the public may easily search the registry and results data bank for entries that include notices required under this subparagraph.

(6) LIMITATION ON DISCLOSURE OF CLINICAL TRIAL INFORMATION.—

(A) IN GENERAL.—Nothing in this subsection (or under section 552 of title 5, United States Code) shall require the Secretary to publicly disclose, by any means other than the registry and results data bank, information described in subparagraph (B).

(B) INFORMATION DESCRIBED.—Information described in this subparagraph is—

(i) information submitted to the Director of NIH under this subsection, or information of the same general nature as (or integrally associated with) the information so submitted; and

(ii) information not otherwise publicly available, including because it is protected from disclosure under section 552 of title 5, United States Code.

(7) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this subsection $10,000,000 for each fiscal year.

(k)(1) The Director of NIH may establish a program to provide day care services for the employees of the National Institutes of Health similar to those services provided by other Federal agencies (including the availability of day care service on a 24-hour-a-day basis).

(2) Any day care provider at the National Institutes of Health shall establish a sliding scale of fees that takes into consideration the income and needs of the employee.

(3) For purposes regarding the provision of day care services, the Director of NIH may enter into rental or lease purchase agreements.

(l) COUNCIL OF COUNCILS.—

(1) ESTABLISHMENT.—Not later than 90 days after the date of the enactment of the National Institutes of Health Reform Act of 2006, the Director of NIH shall establish within the Office of the Director an advisory council to be known as the "Council of Councils" (referred to in this subsection as the "Council") for the purpose of advising the Director on matters related to the policies and activities of the Division of Program Coordination, Planning, and Strategic Initiatives, including making recommendations with respect to the conduct and support of research described in subsection (b)(7).

(2) MEMBERSHIP.—

(A) IN GENERAL.—The Council shall be composed of 27 members selected by the Director of NIH with approval

from the Secretary from among the list of nominees under subparagraph (C).

(B) CERTAIN REQUIREMENTS.—In selecting the members of the Council, the Director of NIH shall ensure—

(i) the representation of a broad range of disciplines and perspectives; and

(ii) the ongoing inclusion of at least 1 representative from each national research institute whose budget is substantial relative to a majority of the other institutes.

(C) NOMINATION.—The Director of NIH shall maintain an updated list of individuals who have been nominated to serve on the Council, which list shall consist of the following:

(i) For each national research institute and national center, 3 individuals nominated by the head of such institute or center from among the members of the advisory council of the institute or center, of which—

(I) two shall be scientists; and

(II) one shall be from the general public or shall be a leader in the field of public policy, law, health policy, economics, or management.

(ii) For each office within the Division of Program Coordination, Planning, and Strategic Initiatives, 1 individual nominated by the head of such office.

(iii) Members of the Council of Public Representatives.

(3) TERMS.—

(A) IN GENERAL.—The term of service for a member of the Council shall be 6 years, except as provided in subparagraphs (B) and (C).

(B) TERMS OF INITIAL APPOINTEES.—Of the initial members selected for the Council, the Director of NIH shall designate—

(i) nine for a term of 6 years;

(ii) nine for a term of 4 years; and

(iii) nine for a term of 2 years.

(C) VACANCIES.—Any member appointed to fill a vacancy occurring before the expiration of the term for which the member's predecessor was appointed shall be appointed only for the remainder of that term. A member may serve after the expiration of that member's term until a successor has taken office.

SEC. 402A.[282a] AUTHORIZATION OF APPROPRIATIONS.

(a) IN GENERAL.—For the purpose of carrying out this title, there are authorized to be appropriated—

(1) $30,331,309,000 for fiscal year 2007;

(2) $32,831,309,000 for fiscal year 2008; and

(3) such sums as may be necessary for fiscal year 2009.

(b) OFFICE OF THE DIRECTOR.—Of the amount authorized to be appropriated under subsection (a) for a fiscal year, there are authorized to be appropriated for programs and activities under this

title carried out through the Office of the Director of NIH such sums as may be necessary for each of the fiscal years 2007 through 2009.

(c) TRANS-NIH RESEARCH.—

(1) COMMON FUND.—

(A) ACCOUNT.—For the purpose of allocations under section 402(b)(7)(B) (relating to research identified by the Division of Program Coordination, Planning, and Strategic Initiatives), there is established an account to be known as the Common Fund.

(B) RESERVATION.—

(i) IN GENERAL.—Of the total amount appropriated under subsection (a) for fiscal year 2007 or any subsequent fiscal year, the Director of NIH shall reserve an amount for the Common Fund, subject to any applicable provisions in appropriations Acts.

(ii) MINIMUM AMOUNT.—For each fiscal year, the percentage constituted by the amount reserved under clause (i) relative to the total amount appropriated under subsection (a) for such year may not be less than the percentage constituted by the amount so reserved for the preceding fiscal year relative to the total amount appropriated under subsection (a) for such preceding fiscal year, subject to any applicable provisions in appropriations Acts.

(C) COMMON FUND STRATEGIC PLANNING REPORT.—Not later than June 1, 2007, and every 2 years thereafter, the Secretary, acting through the Director of NIH, shall submit a report to the Congress containing a strategic plan for funding research described in section 402(b)(7)(A)(i) (including personnel needs) through the Common Fund. Each such plan shall include the following:

(i) An estimate of the amounts determined by the Director of NIH to be appropriate for maximizing the potential of such research.

(ii) An estimate of the amounts determined by the Director of NIH to be sufficient only for continuing to fund research activities previously identified by the Division of Program Coordination, Planning, and Strategic Initiatives.

(iii) An estimate of the amounts determined by the Director of NIH to be necessary to fund research described in section 402(b)(7)(A)(i)—

(I) that is in addition to the research activities described in clause (ii); and

(II) for which there is the most substantial need.

(D) EVALUATION.—During the 6-month period following the end of the first fiscal year for which the total amount reserved under subparagraph (B) is equal to 5 percent of the total amount appropriated under subsection (a) for such fiscal year, the Secretary, acting through the Director of NIH, in consultation with the advisory council established under section 402(k), shall submit recommenda-

tions to the Congress for changes regarding amounts for the Common Fund.

(2) TRANS-NIH RESEARCH REPORTING.—

(A) LIMITATION.—With respect to the total amount appropriated under subsection (a) for fiscal year 2008 or any subsequent fiscal year, if the head of a national research institute or national center fails to submit the report required by subparagraph (B) for the preceding fiscal year, the amount made available for the institute or center for the fiscal year involved may not exceed the amount made available for the institute or center for fiscal year 2006.

(B) REPORTING.—Not later than January 1, 2008, and each January 1st thereafter—

(i) the head of each national research institute or national center shall submit to the Director of NIH a report on the amount made available by the institute or center for conducting or supporting research that involves collaboration between the institute or center and 1 or more other national research institutes or national centers; and

(ii) the Secretary shall submit a report to the Congress identifying the percentage of funds made available by each national research institute and national center with respect to such fiscal year for conducting or supporting research described in clause (i).

(C) DETERMINATION.—For purposes of determining the amount or percentage of funds to be reported under subparagraph (B), any amounts made available to an institute or center under section 402(b)(7)(B) shall be included.

(D) VERIFICATION OF AMOUNTS.—Upon receipt of each report submitted under subparagraph (B)(i), the Director of NIH shall review and, in cases of discrepancy, verify the accuracy of the amounts specified in the report.

(E) WAIVER.—At the request of any national research institute or national center, the Director of NIH may waive the application of this paragraph to such institute or center if the Director finds that the conduct or support of research described in subparagraph (B)(i) is inconsistent with the mission of such institute or center.

(d) TRANSFER AUTHORITY.—Of the total amount appropriated under subsection (a) for a fiscal year, the Director of NIH may (in addition to the reservation under subsection (c)(1) for such year) transfer not more than 1 percent for programs or activities that are authorized in this title and identified by the Director to receive funds pursuant to this subsection. In making such transfers, the Director may not decrease any appropriation account under subsection (a) by more than 1 percent.

(e) RULE OF CONSTRUCTION.—This section may not be construed as affecting the authorities of the Director of NIH under section 401.

SEC. 402B.[282b] ELECTRONIC CODING OF GRANTS AND ACTIVITIES.

The Secretary, acting through the Director of NIH, shall establish an electronic system to uniformly code research grants and ac-

tivities of the Office of the Director and of all the national research institutes and national centers. The electronic system shall be searchable by a variety of codes, such as the type of research grant, the research entity managing the grant, and the public health area of interest. When permissible, the Secretary, acting through the Director of NIH, shall provide information on relevant literature and patents that are associated with research activities of the National Institutes of Health.

SEC. 403.[283] BIENNIAL REPORTS OF DIRECTOR OF NIH.

(a) IN GENERAL.—The Director of NIH shall submit to the Congress on a biennial basis a report in accordance with this section. The first report shall be submitted not later than 1 year after the date of the enactment of the National Institutes of Health Reform Act of 2006. Each such report shall include the following information:

(1) An assessment of the state of biomedical and behavioral research.

(2) A description of the activities conducted or supported by the agencies of the National Institutes of Health and policies respecting the programs of such agencies.

(3) Classification and justification for the priorities established by the agencies, including a strategic plan and recommendations for future research initiatives to be carried out under section 402(b)(7) through the Division of Program Coordination, Planning, and Strategic Initiatives.

(4) A catalog of all the research activities of the agencies, prepared in accordance with the following:

(A) The catalog shall, for each such activity—

(i) identify the agency or agencies involved;

(ii) state whether the activity was carried out directly by the agencies or was supported by the agencies and describe to what extent the agency was involved; and

(iii) identify whether the activity was carried out through a center of excellence.

(B) In the case of clinical research, the catalog shall, as appropriate, identify study populations by demographic variables and other variables that contribute to research on minority health and health disparities.

(C) Research activities listed in the catalog shall include, where applicable, the following:

(i) Epidemiological studies and longitudinal studies.

(ii) Disease registries, information clearinghouses, and other data systems.

(iii) Public education and information campaigns.

(iv) Training activities, including—

(I) National Research Service Awards and Clinical Transformation Science Awards;

(II) graduate medical education programs, including information on the number and type of graduate degrees awarded during the period in

which the programs received funding under this title;

(III) investigator-initiated awards for postdoctoral training and postdoctoral training funded through research grants;

(IV) a breakdown by demographic variables and other appropriate categories; and

(V) an evaluation and comparison of outcomes and effectiveness of various training programs.

(v) Clinical trials, including a breakdown of participation by study populations and demographic variables and such other information as may be necessary to demonstrate compliance with section 492B (regarding inclusion of women and minorities in clinical research).

(vi) Translational research activities with other agencies of the Public Health Service.

(5) A summary of the research activities throughout the agencies, which summary shall be organized by the following categories, where applicable:

(A) Cancer.

(B) Neurosciences.

(C) Life stages, human development, and rehabilitation.

(D) Organ systems.

(E) Autoimmune diseases.

(F) Genomics.

(G) Molecular biology and basic science.

(H) Technology development.

(I) Chronic diseases, including pain and palliative care.

(J) Infectious diseases and bioterrorism.

(K) Minority health and health disparities.

(L) Such additional categories as the Director determines to be appropriate.

(6) A review of each entity receiving funding under this title in its capacity as a center of excellence (in this paragraph referred to as a "center of excellence"), including the following:

(A) An evaluation of the performance and research outcomes of each center of excellence.

(B) Recommendations for promoting coordination of information among the centers of excellence.

(C) Recommendations for improving the effectiveness, efficiency, and outcomes of the centers of excellence.

(D) If no additional centers of excellence have been funded under this title since the previous report under this section, an explanation of the reasons for not funding any additional centers.

(b) REQUIREMENT REGARDING DISEASE-SPECIFIC RESEARCH ACTIVITIES.—In a report under subsection (a), the Director of NIH, when reporting on research activities relating to a specific disease, disorder, or other adverse health condition, shall—

(1) present information in a standardized format;

(2) identify the actual dollar amounts obligated for such activities; and

(3) include a plan for research on the specific disease, disorder, or other adverse health condition, including a statement of objectives regarding the research, the means for achieving the objectives, a date by which the objectives are expected to be achieved, and justifications for revisions to the plan.

(c) ADDITIONAL REPORTS.—In addition to reports required by subsections (a) and (b), the Director of NIH or the head of a national research institute or national center may submit to the Congress such additional reports as the Director or the head of such institute or center determines to be appropriate.

SEC. 403A.[283a] ANNUAL REPORTING TO INCREASE INTERAGENCY COLLABORATION AND COORDINATION.

(a) COLLABORATION WITH OTHER HHS AGENCIES.—On an annual basis, the Director of NIH shall submit to the Secretary a report on the activities of the National Institutes of Health involving collaboration with other agencies of the Department of Health and Human Services.

(b) CLINICAL TRIALS.—Each calendar year, the Director of NIH shall submit to the Commissioner of Food and Drugs a report that identifies each clinical trial that is registered during such calendar year in the databank of information established under section 402(i).

(c) HUMAN TISSUE SAMPLES.—On an annual basis, the Director of NIH shall submit to the Congress a report that describes how the National Institutes of Health and its agencies store and track human tissue samples.

(d) FIRST REPORT.—The first report under subsections (a), (b), and (c) shall be submitted not later than 1 year after the date of the enactment of the National Institutes of Health Reform Act of 2006.

SEC. 403B.[283a–1] ANNUAL REPORTING TO PREVENT FRAUD AND ABUSE.

(a) WHISTLEBLOWER COMPLAINTS.—

(1) IN GENERAL.—On an annual basis, the Director of NIH shall submit to the Inspector General of the Department of Health and Human Services, the Secretary, the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate a report summarizing the activities of the National Institutes of Health relating to whistleblower complaints.

(2) CONTENTS.—For each whistleblower complaint pending during the year for which a report is submitted under this subsection, the report shall identify the following:

(A) Each agency of the National Institutes of Health involved.

(B) The status of the complaint.

(C) The resolution of the complaint to date.

(b) EXPERTS AND CONSULTANTS.—On an annual basis, the Director of NIH shall submit to the Inspector General of the Depart-

ment of Health and Human Services, the Secretary, the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate a report that—

(1) identifies the number of experts and consultants, including any special consultants, whose services are obtained by the National Institutes of Health or its agencies;

(2) specifies whether such services were obtained under section 207(f), section 402(d), or other authority;

(3) describes the qualifications of such experts and consultants;

(4) describes the need for hiring such experts and consultants; and

(5) if such experts and consultants make financial disclosures to the National Institutes of Health or any of its agencies, specifies the income, gifts, assets, and liabilities so disclosed.

(c) FIRST REPORT.—The first report under subsections (a) and (b) shall be submitted not later than 1 year after the date of the enactment of the National Institutes of Health Reform Act of 2006.

SEC. 403C.[283a–2] ANNUAL REPORTING REGARDING TRAINING OF GRADUATE STUDENTS FOR DOCTORAL DEGREES.

(a) IN GENERAL.—Each institution receiving an award under this title for the training of graduate students for doctoral degrees shall annually report to the Director of NIH, with respect to graduate students supported by the National Institutes of Health at such institution—

(1) the percentage of such students admitted for study who successfully attain a doctoral degree; and

(2) for students described in paragraph (1), the average time (not including any leaves of absence) between the beginning of graduate study and the receipt of a doctoral degree.

(3)[5] PROVISION OF INFORMATION TO APPLICANTS.—Each institution described in subsection (a) shall provide to each student submitting an application for a program of graduate study at such institution the information described in paragraphs (1) and (2) of such subsection with respect to the program or programs to which such student has applied.

DES.

SEC. 403D.[283a–3] (a) The Director of NIH shall establish a program for the conduct and support of research and training, the dissemination of health information, and other programs with respect to the diagnosis and treatment of conditions associated with exposure to the drug diethylstilbestrol (in this section referred to as "DES").

(b) In carrying out subsection (a), the Director of NIH, after consultation with nonprofit private entities representing individuals who have been exposed to DES, shall conduct or support programs to educate health professionals and the public on the drug,

[5] So in law. Paragraph (3) probably should be subsection (b).

including the importance of identifying and treating individuals who have been exposed to the drug.

(c) After consultation with the Office of Research on Women's Health, the Director of NIH, acting through the appropriate national research institutes, shall in carrying out subsection (a) conduct or support one or more longitudinal studies to determine the incidence of the following diseases or disorders in the indicated populations and the relationship of DES to the diseases or disorders:

(1) In the case of women to whom (on or after January 1, 1938) DES was administered while the women were pregnant, the incidence of all diseases and disorders (including breast cancer, gynecological cancers, and impairments of the immune system, including autoimmune disease).

(2) In the case of women exposed to DES in utero, the incidence of clear cell cancer (including recurrences), the long-term health effects of such cancer, and the effects of treatments for such cancer.

(3) In the case of men and women exposed to DES in utero, the incidence of all diseases and disorders (including impairments of the reproductive and autoimmune systems).

(4) In the case of children of men or women exposed to DES in utero, the incidence of all diseases and disorders.

(d) For purposes of this section, an individual shall be considered to have been exposed to DES in utero if, during the pregnancy that resulted in the birth of such individual, DES was (on or after January 1, 1938) administered to the biological mother of the individual.

OFFICE OF BEHAVIORAL AND SOCIAL SCIENCES RESEARCH.

SEC. 404A.[6] **[**283c**]** (a) There is established within the Office of the Director of NIH an office to be known as the Office of Behavioral and Social Sciences Research (in this section referred to as the "Office"). The Office shall be headed by a director, who shall be appointed by the Director of NIH.

(b)(1) With respect to research on the relationship between human behavior and the development, treatment, and prevention of medical conditions, the Director of the Office shall—

(A) coordinate research conducted or supported by the agencies of the National Institutes of Health; and

(B) identify projects of behavioral and social sciences research that should be conducted or supported by the national research institutes, and develop such projects in cooperation with such institutes.

(2) Research authorized under paragraph (1) includes research on teen pregnancy, infant mortality, violent behavior, suicide, and homelessness. Such research does not include neurobiological research, or research in which the behavior of an organism is observed for the purpose of determining activity at the cellular or molecular level.

[6] Section 404 was struck by section 101(b)(2) of Public Law 106–525 (114 Stat. 2501).

CHILDREN'S VACCINE INITIATIVE.

SEC. 404B.[283d] (a) DEVELOPMENT OF NEW VACCINES.—The Secretary, in consultation with the Director of the National Vaccine Program under title XXI and acting through the Directors of the National Institute for Allergy and Infectious Diseases, the Eunice Kennedy Shriver National Institute of Child Health and Human Development, the National Institute for Aging, and other public and private programs, shall carry out activities, which shall be consistent with the global Children's Vaccine Initiative, to develop affordable new and improved vaccines to be used in the United States and in the developing world that will increase the efficacy and efficiency of the prevention of infectious diseases. In carrying out such activities, the Secretary shall, to the extent practicable, develop and make available vaccines that require fewer contacts to deliver, that can be given early in life, that provide long lasting protection, that obviate refrigeration, needles and syringes, and that protect against a larger number of diseases.

(b) REPORT.—In the report required in section 2104[7], the Secretary, acting through the Director of the National Vaccine Program under title XXI, shall include information with respect to activities and the progress made in implementing the provisions of this section and achieving its goals.

PLAN FOR USE OF ANIMALS IN RESEARCH.

SEC. 404C.[283e] (a) The Director of NIH, after consultation with the committee established under subsection (e), shall prepare a plan—

(1) for the National Institutes of Health to conduct or support research into—

(A) methods of biomedical research and experimentation that do not require the use of animals;

(B) methods of such research and experimentation that reduce the number of animals used in such research;

(C) methods of such research and experimentation that produce less pain and distress in such animals; and

(D) methods of such research and experimentation that involve the use of marine life (other than marine mammals);

(2) for establishing the validity and reliability of the methods described in paragraph (1);

(3) for encouraging the acceptance by the scientific community of such methods that have been found to be valid and reliable; and

(4) for training scientists in the use of such methods that have been found to be valid and reliable.

(b) Not later than October 1, 1993, the Director of NIH shall submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, the plan required in subsection (a) and shall begin implementation of the plan.

[7] Section 2104 was repealed by section 601(a)(1)(H) of Public Law 105–362 (112 Stat. 3285).

(c) The Director of NIH shall periodically review, and as appropriate, make revisions in the plan required under subsection (a). A description of any revision made in the plan shall be included in the first biennial report under section 403 that is submitted after the revision is made.

(d) The Director of NIH shall take such actions as may be appropriate to convey to scientists and others who use animals in biomedical or behavioral research or experimentation information respecting the methods found to be valid and reliable under subsection (a)(2).

(e)(1) The Director of NIH shall establish within the National Institutes of Health a committee to be known as the Interagency Coordinating Committee on the Use of Animals in Research (in this subsection referred to as the "Committee").

(2) The Committee shall provide advice to the Director of NIH on the preparation of the plan required in subsection (a).

(3) The Committee shall be composed of—

(A) the Directors of each of the national research institutes (or the designees of such Directors); and

(B) representatives of the Environmental Protection Agency, the Food and Drug Administration, the Consumer Product Safety Commission, the National Science Foundation, and such additional agencies as the Director of NIH determines to be appropriate, which representatives shall include not less than one veterinarian with expertise in laboratory-animal medicine.

REQUIREMENTS REGARDING SURVEYS OF SEXUAL BEHAVIOR.

SEC. 404D.[283f] With respect to any survey of human sexual behavior proposed to be conducted or supported through the National Institutes of Health, the survey may not be carried out unless—

(1) the proposal has undergone review in accordance with any applicable requirements of sections 491 and 492; and

(2) the Secretary, in accordance with section 492A, makes a determination that the information expected to be obtained through the survey will assist—

(A) in reducing the incidence of sexually transmitted diseases, the incidence of infection with the human immunodeficiency virus, or the incidence of any other infectious disease; or

(B) in improving reproductive health or other conditions of health.

SEC. 404E.[283g] MUSCULAR DYSTROPHY; INITIATIVE THROUGH DIRECTOR OF NATIONAL INSTITUTES OF HEALTH.

(a) EXPANSION, INTENSIFICATION, AND COORDINATION OF ACTIVITIES.—

(1) IN GENERAL.—The Director of NIH, in coordination with the Directors of the National Institute of Neurological Disorders and Stroke, the National Institute of Arthritis and Muscoskeletal and Skin Diseases, the Eunice Kennedy Shriver National Institute of Child Health and Human Development, the National Heart, Lung, and Blood Institute, and the other national research institutes as appropriate, shall expand and

intensify programs of such Institutes with respect to research and related activities concerning various forms of muscular dystrophy, including Duchenne, myotonic, facioscapulohumeral muscular dystrophy (referred to in this section as "FSHD") and other forms of muscular dystrophy.

(2) COORDINATION.—The Directors referred to in paragraph (1) shall jointly coordinate the programs referred to in such paragraph and consult with the Muscular Dystrophy Interagency Coordinating Committee established under section 6 of the MD–CARE Act.

(3) ALLOCATIONS BY DIRECTOR OF NIH.—The Director of NIH shall allocate the amounts appropriated to carry out this section for each fiscal year among the national research institutes referred to in paragraph (1).

(b) CENTERS OF EXCELLENCE.—

(1) IN GENERAL.—The Director of NIH shall award grants and contracts under subsection (a)(1) to public or nonprofit private entities to pay all or part of the cost of planning, establishing, improving, and providing basic operating support for centers of excellence regarding research on various forms of muscular dystrophy. Such centers of excellence shall be known as the "Paul D. Wellstone Muscular Dystrophy Cooperative Research Centers".

(2) RESEARCH.—Each center under paragraph (1) shall supplement but not replace the establishment of a comprehensive research portfolio in all the muscular dystrophies. As a whole, the centers shall conduct basic and clinical research in all forms of muscular dystrophy including early detection, diagnosis, prevention, and treatment, including the fields of muscle biology, genetics, noninvasive imaging, genetics, pharmacological and other therapies.

(3) COORDINATION OF CENTERS.—The Director of NIH shall, as appropriate, provide for the coordination of information among centers under paragraph (1) and ensure regular communication between such centers.

(4) ORGANIZATION OF CENTERS.—Each center under paragraph (1) shall use the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such requirements as may be prescribed by the Director of NIH.

(5) DURATION OF SUPPORT.—Support for a center established under paragraph (1) may be provided under this section for a period of not to exceed 5 years. Such period may be extended for 1 or more additional periods not exceeding 5 years if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director of NIH and if such group has recommended to the Director that such period should be extended.

(c) FACILITATION OF RESEARCH.—The Director of NIH shall provide for a program under subsection (a)(1) under which samples of tissues and genetic materials that are of use in research on muscular dystrophy are donated, collected, preserved, and made available for such research. The program shall be carried out in accord-

ance with accepted scientific and medical standards for the donation, collection, and preservation of such samples.

(d) COORDINATING COMMITTEE.—

(1) IN GENERAL.—The Secretary shall establish the Muscular Dystrophy Coordinating Committee (referred to in this section as the "Coordinating Committee") to coordinate activities across the National Institutes and with other Federal health programs and activities relating to the various forms of muscular dystrophy.

(2) COMPOSITION.—The Coordinating Committee shall consist of not more than 15 members to be appointed by the Secretary, of which—

(A) ⅔ of such members shall represent governmental agencies, including the directors or their designees of each of the national research institutes involved in research with respect to muscular dystrophy and representatives of all other Federal departments and agencies whose programs involve health functions or responsibilities relevant to such diseases, including the Centers for Disease Control and Prevention, the Health Resources and Services Administration and the Food and Drug Administration and representatives of other governmental agencies that serve children with muscular dystrophy, such as the Department of Education; and

(B) ⅓ of such members shall be public members, including a broad cross section of persons affected with muscular dystrophies including parents or legal guardians, affected individuals, researchers, and clinicians.

Members appointed under subparagraph (B) shall serve for a term of 3 years, and may serve for an unlimited number of terms if reappointed.

(3) CHAIR.—

(A) IN GENERAL.—With respect to muscular dystrophy, the Chair of the Coordinating Committee shall serve as the principal advisor to the Secretary, the Assistant Secretary for Health, and the Director of NIH, and shall provide advice to the Director of the Centers for Disease Control and Prevention, the Commissioner of Food and Drugs, and to the heads of other relevant agencies. The Coordinating Committee shall select the Chair for a term not to exceed 2 years.

(B) APPOINTMENT.—The Chair of the Committee shall be appointed by and be directly responsible to the Secretary.

(4) ADMINISTRATIVE SUPPORT; TERMS OF SERVICE; OTHER PROVISIONS.—The following shall apply with respect to the Coordinating Committee:

(A) The Coordinating Committee shall receive necessary and appropriate administrative support from the Department of Health and Human Services.

(B) The Coordinating Committee shall meet as appropriate as determined by the Secretary, in consultation with the chair.

(e) PLAN FOR HHS ACTIVITIES.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this section, the Coordinating Committee shall develop a plan for conducting and supporting research and education on muscular dystrophy through the national research institutes and shall periodically review and revise the plan. The plan shall—

(A) provide for a broad range of research and education activities relating to biomedical, epidemiological, psychosocial, and rehabilitative issues, including studies of the impact of such diseases in rural and underserved communities;

(B) identify priorities among the programs and activities of the National Institutes of Health regarding such diseases; and

(C) reflect input from a broad range of scientists, patients, and advocacy groups.

(2) CERTAIN ELEMENTS OF PLAN.—The plan under paragraph (1) shall, with respect to each form of muscular dystrophy, provide for the following as appropriate:

(A) Research to determine the reasons underlying the incidence and prevalence of various forms of muscular dystrophy.

(B) Basic research concerning the etiology and genetic links of the disease and potential causes of mutations.

(C) The development of improved screening techniques.

(D) Basic and clinical research for the development and evaluation of new treatments, including new biological agents.

(E) Information and education programs for health care professionals and the public.

(f) PUBLIC INPUT.—The Secretary shall, under subsection (a)(1), provide for a means through which the public can obtain information on the existing and planned programs and activities of the Department of Health and Human Services with respect to various forms of muscular dystrophy and through which the Secretary can receive comments from the public regarding such programs and activities.

(g) CLINICAL RESEARCH.—The Coordinating Committee may evaluate the potential need to enhance the clinical research infrastructure required to test emerging therapies for the various forms of muscular dystrophy by prioritizing the achievement of the goals related to this topic in the plan under subsection (e)(1).

SEC. 404H.[283j] REVIEW OF CENTERS OF EXCELLENCE.

(a) IN GENERAL.—Not later than April 1, 2008, and periodically thereafter, the Secretary, acting through the Director of NIH, shall conduct a review and submit a report to the appropriate committees of the Congress on the centers of excellence.

(b) REPORT CONTENTS.—Each report under subsection (a) shall include the following:

(1) Evaluation of the performance and research outcomes of each center of excellence.

(2) Recommendations for promoting coordination of information among centers of excellence.

(3) Recommendations for improving the effectiveness, efficiency, and outcomes of the centers of excellence.

(c) DEFINITION.—In this section, the term "center of excellence" means an entity receiving funding under this title in its capacity as a center of excellence.

SEC. 404I.[283k] BIOMEDICAL AND BEHAVIORAL RESEARCH FACILITIES.

(a) MODERNIZATION AND CONSTRUCTION OF FACILITIES.—

(1) IN GENERAL.—The Director of NIH, acting through the Office of the Director of NIH or the Director of the National Institute of Allergy and Infectious Diseases, may make grants or contracts to public and nonprofit private entities to expand, remodel, renovate, or alter existing research facilities or construct new research facilities, subject to the provisions of this section.

(2) CONSTRUCTION AND COST OF CONSTRUCTION.—For purposes of this section, the terms "construction" and "cost of construction" include the construction of new buildings and the expansion, renovation, remodeling, and alteration of existing buildings, including architects' fees, but do not include the cost of acquisition of land or off-site improvements.

(b) SCIENTIFIC AND TECHNICAL REVIEW BOARDS FOR MERIT-BASED REVIEW OF PROPOSALS.—

(1) IN GENERAL: APPROVAL AS PRECONDITION TO GRANTS.—

(A) ESTABLISHMENT.—There is established a Scientific and Technical Review Board on Biomedical and Behavioral Research Facilities (referred to in this section as the "Board").

(B) REQUIREMENT.—The Director of NIH, acting through the Office of the Director of NIH, may approve an application for a grant under subsection (a) only if the Board has under paragraph (2) recommended the application for approval.

(2) DUTIES.—

(A) ADVICE.—The Board shall provide advice to the Director of NIH and the Council of Councils established under section 402(l) (in this section referred to as the "Council") in carrying out this section.

(B) DETERMINATION OF MERIT.—In carrying out subparagraph (A), the Board shall make a determination of the merit of each application submitted for a grant under subsection (a), after consideration of the requirements established in subsection (c), and shall report the results of the determination to the Director of NIH and the Council. Such determinations shall be conducted in a manner consistent with procedures established under section 492.

(C) AMOUNT.—In carrying out subparagraph (A), the Board shall, in the case of applications recommended for approval, make recommendations to the Director and the Council on the amount that should be provided under the grant.

(D) ANNUAL REPORT.—In carrying out subparagraph (A), the Board shall prepare an annual report for the Director of NIH and the Council describing the activities of the Board in the fiscal year for which the report is made. Each such report shall be available to the public, and shall—

(i) summarize and analyze expenditures made under this section;

(ii) provide a summary of the types, numbers, and amounts of applications that were recommended for grants under subsection (a) but that were not approved by the Director of NIH; and

(iii) contain the recommendations of the Board for any changes in the administration of this section.

(3) MEMBERSHIP.—

(A) IN GENERAL.—Subject to subparagraph (B), the Board shall be composed of 15 members to be appointed by the Director of NIH, acting through the Office of the Director of NIH, and such ad-hoc or temporary members as the Director of NIH, acting through the Office of the Director of NIH, determines to be appropriate. All members of the Board, including temporary and ad-hoc members, shall be voting members.

(B) LIMITATION.—Not more than three individuals who are officers or employees of the Federal Government may serve as members of the Board.

(4) CERTAIN REQUIREMENTS REGARDING MEMBERSHIP.—In selecting individuals for membership on the Board, the Director of NIH, acting through the Office of the Director of NIH, shall ensure that the members are individuals who, by virtue of their training or experience, are eminently qualified to perform peer review functions. In selecting such individuals for such membership, the Director of NIH, acting through the Office of the Director of NIH, shall ensure that the members of the Board collectively—

(A) are experienced in the planning, construction, financing, and administration of entities that conduct biomedical or behavioral research sciences;

(B) are knowledgeable in making determinations of the need of entities for biomedical or behavioral research facilities, including such facilities for the dentistry, nursing, pharmacy, and allied health professions;

(C) are knowledgeable in evaluating the relative priorities for applications for grants under subsection (a) in view of the overall research needs of the United States; and

(D) are experienced with emerging centers of excellence, as described in subsection (c)(2).

(5) CERTAIN AUTHORITIES.—

(A) WORKSHOPS AND CONFERENCES.—In carrying out paragraph (2), the Board may convene workshops and conferences, and collect data as the Board considers appropriate.

(B) SUBCOMMITTEES.—In carrying out paragraph (2), the Board may establish subcommittees within the Board. Such subcommittees may hold meetings as determined necessary to enable the subcommittee to carry out its duties.

(6) TERMS.—

(A) IN GENERAL.—Except as provided in subparagraph (B), each appointed member of the Board shall hold office for a term of 4 years. Any member appointed to fill a vacancy occurring prior to the expiration of the term for which such member's predecessor was appointed shall be appointed for the remainder of the term of the predecessor.

(B) STAGGERED TERMS.—Members appointed to the Board shall serve staggered terms as specified by the Director of NIH, acting through the Office of the Director of NIH, when making the appointments.

(C) REAPPOINTMENT.—No member of the Board shall be eligible for reappointment to the Board until 1 year has elapsed after the end of the most recent term of the member.

(7) COMPENSATION.—Members of the Board who are not officers or employees of the United States shall receive for each day the members are engaged in the performance of the functions of the Board compensation at the same rate received by members of other national advisory councils established under this title.

(c) REQUIREMENTS FOR GRANTS.—

(1) IN GENERAL.—The Director of NIH, acting through the Office of the Director of NIH or the National Institute of Allergy and Infectious Diseases, may make a grant under subsection (a) only if the applicant for the grant meets the following conditions:

(A) The applicant is determined by such Director to be competent to engage in the type of research for which the proposed facility is to be constructed.

(B) The applicant provides assurances satisfactory to the Director that—

(i) for not less than 20 years after completion of the construction involved, the facility will be used for the purposes of the research for which it is to be constructed;

(ii) sufficient funds will be available to meet the non-Federal share of the cost of constructing the facility;

(iii) sufficient funds will be available, when construction is completed, for the effective use of the facility for the research for which it is being constructed; and

(iv) the proposed construction will expand the applicant's capacity for research, or is necessary to improve or maintain the quality of the applicant's research.

(C) The applicant meets reasonable qualifications established by the Director with respect to—

(i) the relative scientific and technical merit of the applications, and the relative effectiveness of the proposed facilities, in expanding the capacity for biomedical or behavioral research and in improving the quality of such research;

(ii) the quality of the research or training, or both, to be carried out in the facilities involved;

(iii) the congruence of the research activities to be carried out within the facility with the research and investigator manpower needs of the United States; and

(iv) the age and condition of existing research facilities.

(D) The applicant has demonstrated a commitment to enhancing and expanding the research productivity of the applicant.

(2) INSTITUTIONS OF EMERGING EXCELLENCE.—From the amount appropriated to carry out this section for a fiscal year up to $50,000,000, the Director of NIH, acting through the Office of the Director of NIH, shall make available 25 percent of such amount, and from the amount appropriated to carry out this section for a fiscal year that is over $50,000,000, the Director of NIH, acting through the Office of the Director of NIH, shall make available up to 25 percent of such amount, for grants under subsection (a) to applicants that in addition to meeting the requirements established in paragraph (1), have demonstrated emerging excellence in biomedical or behavioral research, as follows:

(A) The applicant has a plan for research or training advancement and possesses the ability to carry out the plan.

(B) The applicant carries out research and research training programs that have a special relevance to a problem, concern, or unmet health need of the United States.

(C) The applicant has been productive in research or research development and training.

(D) The applicant—

(i) has been designated as a center of excellence under section 739;

(ii) is located in a geographic area whose population includes a significant number of individuals with health status deficit, and the applicant provides health services to such individuals; or

(iii) is located in a geographic area in which a deficit in health care technology, services, or research resources may adversely affect the health status of the population of the area in the future, and the applicant is carrying out activities with respect to protecting the health status of such population.

(d) REQUIREMENT OF APPLICATION.—The Director of NIH, acting through the Office of the Director of NIH or the National Institute of Allergy and Infectious Diseases, may make a grant under subsection (a) only if an application for the grant is submitted to the Director and the application is in such form, is made in such

manner, and contains such agreements, assurances, and information as the Director determines to be necessary to carry out this section.

(e) AMOUNT OF GRANT; PAYMENTS.—

(1) AMOUNT.—The amount of any grant awarded under subsection (a) shall be determined by the Director of NIH, acting through the Office of the Director of NIH or the National Institute of Allergy and Infectious Diseases,,[8] except that such amount shall not exceed—

(A) 50 percent (or, in the case of the Institute, 75 percent) of the necessary cost of the construction of a proposed facility as determined by the Director; or

(B) in the case of a multipurpose facility, 40 percent (or, in the case of the Institute, 75 percent) of that part of the necessary cost of construction that the Director determines to be proportionate to the contemplated use of the facility.

(2) RESERVATION OF AMOUNTS.—On the approval of any application for a grant under subsection (a), the Director of NIH, acting through the Office of the Director of NIH or the National Institute of Allergy and Infectious Diseases, shall reserve, from any appropriation available for such grants, the amount of such grant, and shall pay such amount, in advance or by way of reimbursement, and in such installments consistent with the construction progress, as the Director may determine appropriate. The reservation of any amount by the Director under this paragraph may be amended by the Director, either on the approval of an amendment of the application or on the revision of the estimated cost of construction of the facility.

(3) EXCLUSION OF CERTAIN COSTS.—In determining the amount of any grant under subsection (a), there shall be excluded from the cost of construction an amount equal to the sum of—

(A) the amount of any other Federal grant that the applicant has obtained, or is assured of obtaining, with respect to construction that is to be financed in part by a grant authorized under this section; and

(B) the amount of any non-Federal funds required to be expended as a condition of such other Federal grant.

(4) WAIVER OF LIMITATIONS.—The limitations imposed under paragraph (1) may be waived at the discretion of the Director of NIH, acting through the Office of the Director of NIH or the National Institute of Allergy and Infectious Diseases, for applicants meeting the conditions described in subsection (c).

(f) RECAPTURE OF PAYMENTS.—If, not later than 20 years after the completion of construction for which a grant has been awarded under subsection (a)—

(1) in the case of an award by the Director of NIH, acting through the Office of the Director of NIH, the applicant or

[8] Two commas in subsection (e)(1) so in law. See amendment made by section 221(b)(1)(B)(ii) of division F of Public Law 112–74.

other owner of the facility shall cease to be a public or non profit private entity; or

(2) the facility shall cease to be used for the research purposes for which it was constructed (unless the Director of NIH, acting through the Office of the Director of NIH or the National Institute of Allergy and Infectious Diseases, determines, in accordance with regulations, that there is good cause for releasing the applicant or other owner from obligation to do so),

the United States shall be entitled to recover from the applicant or other owner of the facility the amount bearing the same ratio to the current value (as determined by an agreement between the parties or by action brought in the United States District Court for the district in which such facility is situated) of the facility as the amount of the Federal participation bore to the cost of the construction of such facility.

(g) GUIDELINES.—Not later than 6 months after the date of the enactment of this section, the Director of NIH, acting through the Office of the Director of NIH, after consultation with the Council, shall issue guidelines with respect to grants under subsection (a).

CONSTRUCTION OF REGIONAL CENTERS FOR RESEARCH ON PRIMATES.

SEC. 404J.[283l] (a) With respect to activities carried out by the Director of NIH, acting through the Office of the Director of NIH, to support regional centers for research on primates, the Director of NIH may, for each of the fiscal years 1994 through 1996[9], reserve from the amounts appropriated to carry out section 404I up to $2,500,000 for the purpose of making awards of grants and contracts to public or nonprofit private entities to construct, renovate, or otherwise improve such regional centers. The reservation of such amounts for any fiscal year is subject to the availability of qualified applicants for such awards.

(b) The Director of NIH may not make a grant or enter into a contract under subsection (a) unless the applicant for such assistance agrees, with respect to the costs to be incurred by the applicant in carrying out the purpose described in such subsection, to make available (directly or through donations from public or private entities) non-Federal contributions in cash toward such costs in an amount equal to not less than $1 for each $4 of Federal funds provided in such assistance.

SEC. 404K.[283m] SANCTUARY SYSTEM FOR SURPLUS CHIMPANZEES.

(a) IN GENERAL.—The Secretary shall provide for the establishment and operation in accordance with this section of a system to provide for the lifetime care of chimpanzees that have been used, or were bred or purchased for use, in research conducted or supported by the National Institutes of Health, the Food and Drug Administration, or other agencies of the Federal Government, and with respect to which it has been determined by the Secretary that

[9] The probable intent of the Congress is that the authorization of appropriations be for fiscals year 2000 through 2002. Section 304 of Public Law 106–505 (114 Stat. 2335) provided that section 481B(a) "is amended by striking '1994' and all that follows through '$5,000,000' and inserting '2000 through 2002, reserve from the amounts appropriated under section 481A(i) such sums as necessary'". The amendment cannot be executed because a term referenced in the instructions, "$5,000,000", does not appear in section 481B(a). The term "2,500,000" probably should have been referenced.

the chimpanzees are not needed for such research (in this section referred to as "surplus chimpanzees").

(b) ADMINISTRATION OF SANCTUARY SYSTEM.—The Secretary shall carry out this section, including the establishment of regulations under subsection (d), in consultation with the board of directors of the nonprofit private entity that receives the contract under subsection (e) (relating to the operation of the sanctuary system).

(c) ACCEPTANCE OF CHIMPANZEES INTO SYSTEM.—All surplus chimpanzees owned by the Federal Government shall be accepted into the sanctuary system. Subject to standards under subsection (d)(4), any chimpanzee that is not owned by the Federal Government can be accepted into the system if the owner transfers to the sanctuary system title to the chimpanzee.

(d) STANDARDS FOR PERMANENT RETIREMENT OF SURPLUS CHIMPANZEES.—

(1) IN GENERAL.—Not later than 180 days after the date of the enactment of this section, the Secretary shall by regulation establish standards for operating the sanctuary system to provide for the permanent retirement of surplus chimpanzees. In establishing the standards, the Secretary shall consider the recommendations of the board of directors of the nonprofit private entity that receives the contract under subsection (e), and shall consider the recommendations of the National Research Council applicable to surplus chimpanzees that are made in the report published in 1997 and entitled "Chimpanzees in Research—Strategies for Their Ethical Care, Management, and Use".

(2) CHIMPANZEES ACCEPTED INTO SYSTEM.—With respect to chimpanzees that are accepted into the sanctuary system, standards under paragraph (1) shall include the following:

(A) A prohibition that the chimpanzees may not be used for research, except as authorized under paragraph (3).

(B) Provisions regarding the housing of the chimpanzees.

(C) Provisions regarding the behavioral well-being of the chimpanzees.

(D) A requirement that the chimpanzees be cared for in accordance with the Animal Welfare Act.

(E) A requirement that the chimpanzees be prevented from breeding.

(F) A requirement that complete histories be maintained on the health and use in research of the chimpanzees.

(G) A requirement that the chimpanzees be monitored for the purpose of promptly detecting the presence in the chimpanzees of any condition that may be a threat to the public health or the health of other chimpanzees.

(H) A requirement that chimpanzees posing such a threat be contained in accordance with applicable recommendations of the Director of the Centers for Disease Control and Prevention.

(I) A prohibition that none of the chimpanzees may be subjected to euthanasia, except as in the best interests of

the chimpanzee involved, as determined by the system and an attending veterinarian.

(J) A prohibition that the chimpanzees may not be discharged from the system.

(K) A provision that the Secretary may, in the discretion of the Secretary, accept into the system chimpanzees that are not surplus chimpanzees.

(L) Such additional standards as the Secretary determines to be appropriate.

(3) RESTRICTIONS REGARDING RESEARCH.—

(A) IN GENERAL.—For purposes of paragraph (2)(A), standards under paragraph (1) shall provide that a chimpanzee accepted into the sanctuary system may not be used for studies or research, except that the chimpanzee may be used for noninvasive behavioral studies or medical studies based on information collected during the course of normal veterinary care that is provided for the benefit of the chimpanzee, provided that any such study involves minimal physical and mental harm, pain, distress, and disturbance to the chimpanzee and the social group in which the chimpanzee lives.

(B) ADDITIONAL RESTRICTION.—For purposes of paragraph (2)(A), a condition for the use in studies or research of a chimpanzee accepted into the sanctuary system is (in addition to conditions under subparagraph (A) of this paragraph) that the applicant for such use has not been fined for, or signed a consent decree for, any violation of the Animal Welfare Act.

(4) NON-FEDERAL CHIMPANZEES OFFERED FOR ACCEPTANCE INTO SYSTEM.—With respect to a chimpanzee that is not owned by the Federal Government and is offered for acceptance into the sanctuary system, standards under paragraph (1) shall include the following:

(A) A provision that the Secretary may authorize the imposition of a fee for accepting such chimpanzee into the system, except as follows:

(i) Such a fee may not be imposed for accepting the chimpanzee if, on the day before the date of the enactment of this section, the chimpanzee was owned by the nonprofit private entity that receives the contract under subsection (e) or by any individual sanctuary facility receiving a subcontract or grant under subsection (e)(1).

(ii) Such a fee may not be imposed for accepting the chimpanzee if the chimpanzee is owned by an entity that operates a primate center, and if the chimpanzee is housed in the primate center pursuant to the program for regional centers for research on primates that is carried out by the Director of NIH, acting through the Office of the Director of NIH,.[10]

[10] A period followed by a comma in clause (ii) so in law. See amendment made by section 221(b)(3)(B) of division F of Public Law 112–74.

Any fees collected under this subparagraph are available to the Secretary for the costs of operating the system. Any other fees received by the Secretary for the long-term care of chimpanzees (including any Federal fees that are collected for such purpose and are identified in the report under section 3 of the Chimpanzee Health Improvement, Maintenance, and Protection Act) are available for operating the system, in addition to availability for such other purposes as may be authorized for the use of the fees.

(B) A provision that the Secretary may deny such chimpanzee acceptance into the system if the capacity of the system is not sufficient to accept the chimpanzee, taking into account the physical capacity of the system; the financial resources of the system; the number of individuals serving as the staff of the system, including the number of professional staff; the necessity of providing for the safety of the staff and of the public; the necessity of caring for accepted chimpanzees in accordance with the standards under paragraph (1); and such other factors as may be appropriate.

(C) A provision that the Secretary may deny such chimpanzee acceptance into the system if a complete history of the health and use in research of the chimpanzee is not available to the Secretary.

(D) Such additional standards as the Secretary determines to be appropriate.

(e) AWARD OF CONTRACT FOR OPERATION OF SYSTEM.—

(1) IN GENERAL.—Subject to the availability of funds pursuant to subsection (g), the Secretary shall make an award of a contract to a nonprofit private entity under which the entity has the responsibility of operating (and establishing, as applicable) the sanctuary system and awarding subcontracts or grants to individual sanctuary facilities that meet the standards under subsection (d).

(2) REQUIREMENTS.—The Secretary may make an award under paragraph (1) to a nonprofit private entity only if the entity meets the following requirements:

(A) The entity has a governing board of directors that is composed and appointed in accordance with paragraph (3) and is satisfactory to the Secretary.

(B) The terms of service for members of such board are in accordance with paragraph (3).

(C) The members of the board serve without compensation. The members may be reimbursed for travel, subsistence, and other necessary expenses incurred in carrying out the duties of the board.

(D) The entity has an executive director meeting such requirements as the Secretary determines to be appropriate.

(E) The entity makes the agreement described in paragraph (4) (relating to non-Federal contributions).

(F) The entity agrees to comply with standards under subsection (d).

(G) The entity agrees to make necropsy reports on chimpanzees in the sanctuary system available on a reasonable basis to persons who conduct biomedical or behavioral research, with priority given to such persons who are Federal employees or who receive financial support from the Federal Government for research.

(H) Such other requirements as the Secretary determines to be appropriate.

(3) BOARD OF DIRECTORS.—For purposes of subparagraphs (A) and (B) of paragraph (2):

(A) The governing board of directors of the nonprofit private entity involved is composed and appointed in accordance with this paragraph if the following conditions are met:

(i) Such board is composed of not more than 13 voting members.

(ii) Such members include individuals with expertise and experience in the science of managing captive chimpanzees (including primate veterinary care), appointed from among individuals endorsed by organizations that represent individuals in such field.

(iii) Such members include individuals with expertise and experience in the field of animal protection, appointed from among individuals endorsed by organizations that represent individuals in such field.

(iv) Such members include individuals with expertise and experience in the zoological field (including behavioral primatology), appointed from among individuals endorsed by organizations that represent individuals in such field.

(v) Such members include individuals with expertise and experience in the field of the business and management of nonprofit organizations, appointed from among individuals endorsed by organizations that represent individuals in such field.

(vi) Such members include representatives from entities that provide accreditation in the field of laboratory animal medicine.

(vii) Such members include individuals with expertise and experience in the field of containing biohazards.

(viii) Such members include an additional member who serves as the chair of the board, appointed from among individuals who have been endorsed for purposes of clause (ii), (iii), (iv), or (v).

(ix) None of the members of the board has been fined for, or signed a consent decree for, any violation of the Animal Welfare Act.

(B) The terms of service for members of the board of directors are in accordance with this paragraph if the following conditions are met:

(i) The term of the chair of the board is 3 years.

(ii) The initial members of the board select, by a random method, one member from each of the six

fields specified in subparagraph (A) to serve a term of 2 years and (in addition to the chair) one member from each of such fields to serve a term of 3 years.

(iii) After the initial terms under clause (ii) expire, each member of the board (other than the chair) is appointed to serve a term of 2 years.

(iv) An individual whose term of service expires may be reappointed to the board.

(v) A vacancy in the membership of the board is filled in the manner in which the original appointment was made.

(vi) If a member of the board does not serve the full term applicable to the member, the individual appointed to fill the resulting vacancy is appointed for the remainder of the term of the predecessor member.

(4) REQUIREMENT OF MATCHING FUNDS.—The agreement required in paragraph (2)(E) for a nonprofit private entity (relating to the award of the contract under paragraph (1)) is an agreement that, with respect to the costs to be incurred by the entity in establishing and operating the sanctuary system, the entity will make available (directly or through donations from public or private entities) non-Federal contributions toward such costs, in cash or in kind, in an amount not less than the following, as applicable:

(A) For expenses associated with establishing the sanctuary system (as determined by the Secretary), 10 percent of such costs ($1 for each $9 of Federal funds provided under the contract under paragraph (1)).

(B) For expenses associated with operating the sanctuary system (as determined by the Secretary), 25 percent of such costs ($1 for each $3 of Federal funds provided under such contract).

(5) ESTABLISHMENT OF CONTRACT ENTITY.—If the Secretary determines that an entity meeting the requirements of paragraph (2) does not exist, not later than 60 days after the date of the enactment of this section, the Secretary shall, for purposes of paragraph (1), make a grant for the establishment of such an entity, including paying the cost of incorporating the entity under the law of one of the States.

(f) DEFINITIONS.—For purposes of this section:

(1) PERMANENT RETIREMENT.—The term "permanent retirement", with respect to a chimpanzee that has been accepted into the sanctuary system, means that under subsection (a) the system provides for the lifetime care of the chimpanzee, that under subsection (d)(2) the system does not permit the chimpanzee to be used in research (except as authorized under subsection (d)(3)) or to be euthanized (except as provided in subsection (d)(2)(I)), that under subsection (d)(2) the system will not discharge the chimpanzee from the system, and that under such subsection the system otherwise cares for the chimpanzee.

(2) SANCTUARY SYSTEM.—The term "sanctuary system" means the system described in subsection (a).

(3) SECRETARY.—The term "Secretary" means the Secretary of Health and Human Services.

(4) SURPLUS CHIMPANZEES.—The term "surplus chimpanzees" has the meaning given that term in subsection (a).

(g) FUNDING.—

(1) IN GENERAL.—Of the amount appropriated under this Act for fiscal year 2001 and each subsequent fiscal year, the Secretary, subject to paragraph (2), shall reserve a portion for purposes of the operation (and establishment, as applicable) of the sanctuary system and for purposes of paragraph (3), except that the Secretary may not for such purposes reserve any further funds from such amount after the aggregate total of the funds so reserved for such fiscal years reaches $30,000,000. The purposes for which funds reserved under the preceding sentence may be expended include the construction and renovation of facilities for the sanctuary system.

(2) LIMITATION.—Funds may not be reserved for a fiscal year under paragraph (1) unless the amount appropriated under this Act for such year equals or exceeds the amount appropriated under this Act for fiscal year 1999.

(3) USE OF FUNDS FOR OTHER COMPLIANT FACILITIES.—With respect to amounts reserved under paragraph (1) for a fiscal year, the Secretary may use a portion of such amounts to make awards of grants or contracts to public or private entities operating facilities that, as determined by the board of directors of the nonprofit private entity that receives the contract under subsection (e), provide for the retirement of chimpanzees in accordance with the same standards that apply to the sanctuary system pursuant to regulations under subsection (d). Such an award may be expended for the expenses of operating the facilities involved.

SEC. 404L.[283n] SHARED INSTRUMENTATION GRANT PROGRAM.

(a) REQUIREMENTS FOR GRANTS.—In determining whether to award a grant to an applicant under the Shared Instrumentation Grant Program, the Director of NIH, acting through the Office of the Director of NIH, shall consider—

(1) the extent to which an award for the specific instrument involved would meet the scientific needs and enhance the planned research endeavors of the major users by providing an instrument that is unavailable or to which availability is highly limited;

(2) with respect to the instrument involved, the availability and commitment of the appropriate technical expertise within the major user group or the applicant institution for use of the instrumentation;

(3) the adequacy of the organizational plan for the use of the instrument involved and the internal advisory committee for oversight of the applicant, including sharing arrangements if any;

(4) the applicant's commitment for continued support of the utilization and maintenance of the instrument; and

(5) the extent to which the specified instrument will be shared and the benefit of the proposed instrument to the overall research community to be served.

(b) PEER REVIEW.—In awarding grants under the program described in subsection (a), the Director of NIH, acting through the Office of the Director of NIH, shall comply with the peer review requirements in section 492.

PART B—GENERAL PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES

APPOINTMENT AND AUTHORITY OF THE DIRECTORS OF THE NATIONAL RESEARCH INSTITUTES.

SEC. 405.[284] (a) The Director of the National Cancer Institute shall be appointed by the President and the Directors of the other national research institutes shall be appointed by the Secretary. Each Director of a national research institute shall report directly to the Director of NIH.

(b)(1) In carrying out the purposes of section 301 with respect to human diseases or disorders or other aspects of human health for which the national research institutes were established, the Secretary, acting through the Director of each national research institute—

(A) shall encourage and support research, investigations, experiments, demonstrations, and studies in the health sciences related to—

(i) the maintenance of health,

(ii) the detection, diagnosis, treatment, and prevention of human diseases and disorders,

(iii) the rehabilitation of individuals with human diseases, disorders, and disabilities, and

(iv) the expansion of knowledge of the processes underlying human diseases, disorders, and disabilities, the processes underlying the normal and pathological functioning of the body and its organ systems, and the processes underlying the interactions between the human organism and the environment;

(B) may, subject to the peer review prescribed under section 492(b) and any advisory council review under section 406(a)(3)(A)(i), conduct the research, investigations, experiments, demonstrations, and studies referred to in subparagraph (A);

(C) may conduct and support research training (i) for which fellowship support is not provided under section 487, and (ii) which is not residency training of physicians or other health professionals;

(D) may develop, implement, and support demonstrations and programs for the application of the results of the activities of the institute to clinical practice and disease prevention activities;

(E) may develop, conduct, and support public and professional education and information programs;

(F) may secure, develop and maintain, distribute, and support the development and maintenance of resources needed for research;

(G) may make available the facilities of the institute to appropriate entities and individuals engaged in research activi-

ties and cooperate with and assist Federal and State agencies charged with protecting the public health;

(H) may accept unconditional gifts made to the institute for its activities, and, in the case of gifts of a value in excess of $50,000, establish suitable memorials to the donor;

(I) may secure for the institute consultation services and advice of persons from the United States or abroad;

(J) may use, with their consent, the services, equipment, personnel, information, and facilities of other Federal, State, or local public agencies, with or without reimbursement therefor;

(K) may accept voluntary and uncompensated services; and

(L) may perform such other functions as the Secretary determines are needed to carry out effectively the purposes of the institute.

The indemnification provisions of section 2354, title 10, United States Code, shall apply with respect to contracts entered into under this subsection and section 402(b).

(2) Support for an activity or program under this subsection may be provided through grants, contracts, and cooperative agreements. The Secretary, acting through the Director of each national research institute—

(A) may enter into a contract for research, training, or demonstrations only if the contract has been recommended after technical and scientific peer review required by regulations under section 492;

(B) may make grants and cooperative agreements under paragraph (1) for research, training, or demonstrations, except that—

(i) if the direct cost of the grant or cooperative agreement to be made does not exceed $50,000, such grant or cooperative agreement may be made only if such grant or cooperative agreement has been recommended after technical and scientific peer review required by regulations under section 492, and

(ii) if the direct cost of the grant or cooperative agreement to be made exceeds $50,000, such grant or cooperative agreement may be made only if such grant or cooperative agreement has been recommended after technical and scientific peer review required by regulations under section 492 and is recommended under section 406(a)(3)(A)(ii) by the advisory council for the national research institute involved; and

(C) shall, subject to section 2353(d)(2), receive from the President and the Office of Management and Budget directly all funds appropriated by the Congress for obligation and expenditure by the Institute.

(c) In carrying out subsection (b), each Director of a national research institute—

(1) shall coordinate, as appropriate, the activities of the institute with similar programs of other public and private entities;

(2) shall cooperate with the Directors of the other national research institutes in the development and support of multi-

disciplinary research and research that involves more than one institute;

(3) may, in consultation with the advisory council for the Institute and with the approval of the Director of NIH—

(A) establish technical and scientific peer review groups in addition to those appointed under section 402(b)(16); and

(B) appoint the members of peer review groups established under subparagraph (A); and

(4) may publish, or arrange for the publication of, information with respect to the purpose of the Institute without regard to section 501 of title 44, United States Code.

The Federal Advisory Committee Act shall not apply to the duration of a peer review group appointed under paragraph (3).

ADVISORY COUNCILS.

SEC. 406.[284a] (a)(1) Except as provided in subsection (h), the Secretary shall appoint an advisory council for each national research institute which (A) shall advise, assist, consult with, and make recommendations to the Secretary and the Director of such institute on matters related to the activities carried out by and through the institute and the policies respecting such activities, and (B) shall carry out the special functions prescribed by part C.

(2) Each advisory council for a national research institute may recommend to the Secretary acceptance, in accordance with section 231, of conditional gifts for study, investigation, or research respecting the diseases, disorders, or other aspect of human health with respect to which the institute was established, for the acquisition of grounds, or for the construction, equipping, or maintenance of facilities for the institute.

(3) Each advisory council for a national research institute—

(A)(i) may on the basis of the materials provided under section 492(b)(2) respecting research conducted at the institute, make recommendations to the Director of the institute respecting such research,

(ii) may review applications for grants and cooperative agreements for research or training and for which advisory council approval is required under section 405(b)(2) and recommend for approval applications for projects which show promise of making valuable contributions to human knowledge, and

(iii) may review any grant, contract, or cooperative agreement proposed to be made or entered into by the institute;

(B) may collect, by correspondence or by personal investigation, information as to studies which are being carried on in the United States or any other country as to the diseases, disorders, or other aspect of human health with respect to which the institute was established and with the approval of the Director of the institute make available such information through appropriate publications for the benefit of public and private health entities and health professions personnel and scientists and for the information of the general public; and

(C) may appoint subcommittees and convene workshops and conferences.

(b)(1) Each advisory council shall consist of ex officio members and not more than eighteen members appointed by the Secretary. The ex officio members shall be nonvoting members.

(2) The ex officio members of an advisory council shall consist of—

(A) the Secretary, the Director of NIH, the Director of the national research institute for which the council is established, the Chief Medical Director of the Department of Veterans Affairs or the Chief Dental Director of the Department of Veterans Affairs, and the Assistant Secretary of Defense for Health Affairs (or the designees of such officers), and

(B) such additional officers or employees of the United States as the Secretary determines necessary for the advisory council to effectively carry out its functions.

(3) The members of an advisory council who are not ex officio members shall be appointed as follows:

(A) Two-thirds of the members shall be appointed by the Secretary from among the leading representatives of the health and scientific disciplines (including not less than two individuals who are leaders in the fields of public health and the behavioral or social sciences) relevant to the activities of the national research institute for which the advisory council is established.

(B) One-third of the members shall be appointed by the Secretary from the general public and shall include leaders in fields of public policy, law, health policy, economics, and management.

(4) Members of an advisory council who are officers or employees of the United States shall not receive any compensation for service on the advisory council. The other members of an advisory council shall receive, for each day (including traveltime) they are engaged in the performance of the functions of the advisory council, compensation at rates not to exceed the daily equivalent of the annual rate in effect for grade GS–18 of the General Schedule.

(c) The term of office of an appointed member of an advisory council is four years, except that any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term and the Secretary shall make appointments to an advisory council in such a manner as to ensure that the terms of the members do not all expire in the same year. A member may serve after the expiration of the member's term for 180 days after the date of such expiration. A member who has been appointed for a term of four years may not be reappointed to an advisory council before two years from the date of expiration of such term of office. If a vacancy occurs in the advisory council among the appointed members, the Secretary shall make an appointment to fill the vacancy within 90 days from the date the vacancy occurs.

(d) The chairman of an advisory council shall be selected by the Secretary from among the appointed members, except that the Secretary may select the Director of the national research institute for which the advisory council is established to be the chairman of

the advisory council. The term of office of the chairman shall be two years.

(e) The advisory council shall meet at the call of the chairman or upon the request of the Director of the national research institute for which it was established, but at least three times each fiscal year. The location of the meetings of each advisory council is subject to the approval of the Director of the national research institute for which the advisory council was established.

(f) The Director of the national research institute for which an advisory council is established shall designate a member of the staff of the institute to serve as the executive secretary of the advisory council. The Director of such institute shall make available to the advisory council such staff, information, and other assistance as it may require to carry out its functions. The Director of such institute shall provide orientation and training for new members of the advisory council to provide them with such information and training as may be appropriate for their effective participation in the functions of the advisory council.

(g) Each advisory council may prepare, for inclusion in the biennial report made under section 407, (1) comments respecting the activities of the advisory council in the fiscal years respecting which the report is prepared, (2) comments on the progress of the national research institute for which it was established in meeting its objectives, and (3) recommendations respecting the future directions and program and policy emphasis of the institute. Each advisory council may prepare such additional reports as it may determine appropriate.

(h)(1) Except as provided in paragraph (2), this section does not terminate the membership of any advisory council for a national research institute which was in existence on the date of enactment of the Health Research Extension Act of 1985. After such date—

(A) the Secretary shall make appointments to each such advisory council in such a manner as to bring about as soon as practicable the composition for such council prescribed by this section;

(B) each advisory council shall organize itself in accordance with this section and exercise the functions prescribed by this section; and

(C) the Director of each national research institute shall perform for such advisory council the functions prescribed by this section.

(2)(A) The National Cancer Advisory Board shall be the advisory council for the National Cancer Institute. This section applies to the National Cancer Advisory Board, except that—

(i) appointments to such Board shall be made by the President;

(ii) the term of office of an appointed member shall be 6 years;

(iii) of the members appointed to the Board not less than five members shall be individuals knowledgeable in environmental carcinogenesis (including carcinogenesis involving occupational and dietary factors);

(iv) the chairman of the Board shall be selected by the President from the appointed members and shall serve as chairman for a term of two years;

(v) the ex officio members of the Board shall be nonvoting members and shall be the Secretary, the Director of the Office of Science and Technology Policy, the Director of NIH, the Chief Medical Director of the Department of Veterans Affairs, the Director of the National Institute for Occupational Safety and Health, the Director of the National Institute of Environmental Health Sciences, the Secretary of Labor, the Commissioner of the Food and Drug Administration, the Administrator of the Environmental Protection Agency, the Chairman of the Consumer Product Safety Commission, the Assistant Secretary of Defense for Health Affairs, and the Director of the Office of Science of the Department of Energy (or the designees of such officers); and

(vi) the Board shall meet at least four times each fiscal year.

(B) This section applies to the advisory council to the National Heart, Lung, and Blood Institute, except that the advisory council shall meet at least four times each fiscal year.[11]

CERTAIN USES OF FUNDS.

SEC. 408.[284c] (a)(1) Except as provided in paragraph (2), the sum of the amounts obligated in any fiscal year for administrative expenses of the National Institutes of Health may not exceed an amount which is 5.5 percent of the total amount appropriated for such fiscal year for the National Institutes of Health.

(2) Paragraph (1) does not apply to the National Library of Medicine, the National Center for Nursing Research,[12] the John E. Fogarty International Center for Advanced Study in the Health Sciences, the Warren G. Magnuson Clinical Center, and the Office of Medical Applications of Research.

(3) For purposes of paragraph (1), the term "administrative expenses" means expenses incurred for the support of activities relevant to the award of grants, contracts, and cooperative agreements and expenses incurred for general administration of the scientific programs and activities of the National Institutes of Health.

(b) For fiscal year 1989 and subsequent fiscal years, amounts made available to the National Institutes of Health shall be available for payment of nurses and allied health professionals in accordance with payment authorities, scheduling options, benefits, and other authorities provided under chapter 73 of title 38, United States Code, for nurses of the Department of Veterans Affairs.

DEFINITIONS.

SEC. 409.[284d] (a) HEALTH SERVICE RESEARCH.—For purposes of this title, the term "health services research" means research endeavors that study the impact of the organization, financing and management of health services on the quality, cost, access

[11] Section 407 of the Public Health Service Act was repealed by section 104(b)(1)(C) of Public Law 109–482 (120 Stat. 3693).

[12] See footnote 2 for section 403(5).

to and outcomes of care. Such term does not include research on the efficacy of services to prevent, diagnose, or treat medical conditions.

(b) CLINICAL RESEARCH.—As used in this title, the term "clinical research" means patient oriented clinical research conducted with human subjects, or research on the causes and consequences of disease in human populations involving material of human origin (such as tissue specimens and cognitive phenomena) for which an investigator or colleague directly interacts with human subjects in an outpatient or inpatient setting to clarify a problem in human physiology, pathophysiology or disease, or epidemiologic or behavioral studies, outcomes research or health services research, or developing new technologies, therapeutic interventions, or clinical trials.

RESEARCH ON OSTEOPOROSIS, PAGET'S DISEASE, AND RELATED BONE DISORDERS.

SEC. 409A.[284e] (a) ESTABLISHMENT.—The Directors of the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the National Institute on Aging, the National Institute of Dental Research,[13] and the National Institute of Diabetes and Digestive and Kidney Diseases, shall expand and intensify the programs of such Institutes with respect to research and related activities concerning osteoporosis, Paget's disease, and related bone disorders.

(b) COORDINATION.—The Directors referred to in subsection (a) shall jointly coordinate the programs referred to in such subsection and consult with the Arthritis and Musculoskeletal Diseases Interagency Coordinating Committee and the Interagency Task Force on Aging Research.

(c) INFORMATION CLEARINGHOUSE.—

(1) IN GENERAL.—In order to assist in carrying out the purpose described in subsection (a), the Director of NIH shall provide for the establishment of an information clearinghouse on osteoporosis and related bone disorders to facilitate and enhance knowledge and understanding on the part of health professionals, patients, and the public through the effective dissemination of information.

(2) ESTABLISHMENT THROUGH GRANT OR CONTRACT.—For the purpose of carrying out paragraph (1), the Director of NIH shall enter into a grant, cooperative agreement, or contract with a nonprofit private entity involved in activities regarding the prevention and control of osteoporosis and related bone disorders.

PARKINSON'S DISEASE.

SEC. 409B.[42 U.S.C. 284f] (a) IN GENERAL.—The Director of NIH shall establish a program for the conduct and support of research and training with respect to Parkinson's disease (subject to the extent of amounts appropriated to carry out this section).

(b) INTER-INSTITUTE COORDINATION.—

[13] See footnote for section 401(b)(1)(H).

(1) IN GENERAL.—The Director of NIH shall provide for the coordination of the program established under subsection (a) among all of the national research institutes conducting Parkinson's disease research.

(2) CONFERENCE.—Coordination under paragraph (1) shall include the convening of a research planning conference not less frequently than once every 2 years. Each such conference shall prepare and submit to the Committee on Appropriations and the Committee on Labor and Human Resources of the Senate and the Committee on Appropriations and the Committee on Commerce of the House of Representatives a report concerning the conference.

(c) MORRIS K. UDALL RESEARCH CENTERS.—

(1) IN GENERAL.—The Director of NIH is authorized to award Core Center Grants to encourage the development of innovative multidisciplinary research and provide training concerning Parkinson's disease. The Director is authorized to award not more than 10 Core Center Grants and designate each center funded under such grants as a Morris K. Udall Center for Research on Parkinson's Disease.

(2) REQUIREMENTS.—

(A) IN GENERAL.—With respect to Parkinson's disease, each center assisted under this subsection shall—

(i) use the facilities of a single institution or a consortium of cooperating institutions, and meet such qualifications as may be prescribed by the Director of the NIH; and

(ii) conduct basic and clinical research.

(B) DISCRETIONARY REQUIREMENTS.—With respect to Parkinson's disease, each center assisted under this subsection may—

(i) conduct training programs for scientists and health professionals;

(ii) conduct programs to provide information and continuing education to health professionals;

(iii) conduct programs for the dissemination of information to the public;

(iv) separately or in collaboration with other centers, establish a nationwide data system derived from patient populations with Parkinson's disease, and where possible, comparing relevant data involving general populations;

(v) separately or in collaboration with other centers, establish a Parkinson's Disease Information Clearinghouse to facilitate and enhance knowledge and understanding of Parkinson's disease; and

(vi) separately or in collaboration with other centers, establish a national education program that fosters a national focus on Parkinson's disease and the care of those with Parkinson's disease.

(3) STIPENDS REGARDING TRAINING PROGRAMS.—A center may use funds provided under paragraph (1) to provide stipends for scientists and health professionals enrolled in training programs under paragraph (2)(B).

(4) DURATION OF SUPPORT.—Support of a center under this subsection may be for a period not exceeding five years. Such period may be extended by the Director of NIH for one or more additional periods of not more than five years if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

(d) MORRIS K. UDALL AWARDS FOR EXCELLENCE IN PARKINSON'S DISEASE RESEARCH.—The Director of NIH is authorized to establish a grant program to support investigators with a proven record of excellence and innovation in Parkinson's disease research and who demonstrate potential for significant future breakthroughs in the understanding of the pathogensis, diagnosis, and treatment of Parkinson's disease. Grants under this subsection shall be available for a period of not to exceed 5 years.

EXPANSION, INTENSIFICATION, AND COORDINATION OF ACTIVITIES OF NATIONAL INSTITUTES OF HEALTH WITH RESPECT TO RESEARCH ON AUTISM SPECTRUM DISORDER [14].

SEC. 409C.[284g] (a) IN GENERAL.—

(1) EXPANSION OF ACTIVITIES.—The Director of NIH (in this section referred to as the "Director") shall, subject to the availability of appropriations, expand, intensify, and coordinate the activities of the National Institutes of Health with respect to research on autism spectrum disorder, including basic and clinical research in fields including pathology, developmental neurobiology, genetics, epigenetics, pharmacology, nutrition, immunology, neuroimmunology, neurobehavioral development, endocrinology, gastroenterology, and toxicology. Such research shall investigate the cause (including possible environmental causes), diagnosis or rule out, early detection, prevention, services, supports, intervention, and treatment of autism spectrum disorder.

(2) CONSOLIDATION.—The Director may consolidate program activities under this section if such consolidation would improve program efficiencies and outcomes.

(3) ADMINISTRATION OF PROGRAM; COLLABORATION AMONG AGENCIES.—The Director shall carry out this section acting through the Director of the National Institute of Mental Health and in collaboration with any other agencies that the Director determines appropriate.

(b) CENTERS OF EXCELLENCE.—

(1) IN GENERAL.—The Director shall under subsection (a)(1) make awards of grants and contracts to public or nonprofit private entities to pay all or part of the cost of planning, establishing, improving, and providing basic operating support for centers of excellence regarding research on autism spectrum disorder.

[14] Title I of Public Law 106–310 (114 Stat. 1105) established several programs regarding autism, including the program under section 409C above. Section 105 of the Public Law requires annual reports to the Congress on the implementation of such title I and the amendments made by the title.

(2) RESEARCH.—Each center under paragraph (1) shall conduct basic and clinical research into autism spectrum disorder. Such research should include investigations into the cause, diagnosis, early detection, prevention, control, and treatment of autism spectrum disorder. The centers, as a group, shall conduct research including the fields of developmental neurobiology, genetics, and psychopharmacology.

(3) SERVICES FOR PATIENTS.—

(A) IN GENERAL.—A center under paragraph (1) may expend amounts provided under such paragraph to carry out a program to make individuals aware of opportunities to participate as subjects in research conducted by the centers.

(B) REFERRALS AND COSTS.—A program under subparagraph (A) may, in accordance with such criteria as the Director may establish, provide to the subjects described in such subparagraph, referrals for health and other services, and such patient care costs as are required for research.

(C) AVAILABILITY AND ACCESS.—The extent to which a center can demonstrate availability and access to clinical services shall be considered by the Director in decisions about awarding grants to applicants which meet the scientific criteria for funding under this section.

(4) ORGANIZATION OF CENTERS.—Each center under paragraph (1) shall use the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such requirements as may be prescribed by the Director.

(5) NUMBER OF CENTERS; DURATION OF SUPPORT.—

(A) IN GENERAL.—The Director shall provide for the establishment of not less than five centers under paragraph (1).

(B) DURATION.—Support for a center established under paragraph (1) may be provided under this section for a period of not to exceed 5 years. Such period may be extended for one or more additional periods not exceeding 5 years if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

(c) FACILITATION OF RESEARCH.—The Director shall under subsection (a)(1) provide for a program under which samples of tissues and genetic materials that are of use in research on autism spectrum disorder are donated, collected, preserved, and made available for such research. The program shall be carried out in accordance with accepted scientific and medical standards for the donation, collection, and preservation of such samples.

(d) PUBLIC INPUT.—The Director shall under subsection (a)(1) provide for means through which the public can obtain information on the existing and planned programs and activities of the National Institutes of Health with respect to autism spectrum disorder and through which the Director can receive comments from the public regarding such programs and activities.

PEDIATRIC RESEARCH INITIATIVE.

SEC. 409D.[284h] (a) ESTABLISHMENT.—The Secretary shall establish within the Office of the Director of NIH a Pediatric Research Initiative (referred to in this section as the "Initiative") to conduct and support research that is directly related to diseases, disorders, and other conditions in children. The Initiative shall be headed by the Director of NIH.

(b) PURPOSE.—The purpose of the Initiative is to provide funds to enable the Director of NIH—

(1) to increase support for pediatric biomedical research within the National Institutes of Health to realize the expanding opportunities for advancement in scientific investigations and care for children;

(2) to enhance collaborative efforts among the Institutes to conduct and support multidisciplinary research in the areas that the Director deems most promising; and

(3) in coordination with the Food and Drug Administration, to increase the development of adequate pediatric clinical trials and pediatric use information to promote the safer and more effective use of prescription drugs in the pediatric population.

(c) DUTIES.—In carrying out subsection (b), the Director of NIH shall—

(1) consult with the Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development and the other national research institutes, in considering their requests for new or expanded pediatric research efforts, and consult with the Administrator of the Health Resources and Services Administration and other advisors as the Director determines to be appropriate;

(2) have broad discretion in the allocation of any Initiative assistance among the Institutes, among types of grants, and between basic and clinical research so long as the assistance is directly related to the illnesses and conditions of children; and

(3) be responsible for the oversight of any newly appropriated Initiative funds and annually report to Congress and the public on the extent of the total funds obligated to conduct or support pediatric research across the National Institutes of Health, including the specific support and research awards allocated through the Initiative.

(d) TRANSFER OF FUNDS.—The Director of NIH may transfer amounts appropriated under this section to any of the Institutes for a fiscal year to carry out the purposes of the Initiative under this section.

SEC. 409E.[284i] AUTOIMMUNE DISEASES.

(a) EXPANSION, INTENSIFICATION, AND COORDINATION OF ACTIVITIES.—

(1) IN GENERAL.—The Director of NIH shall expand, intensify, and coordinate research and other activities of the National Institutes of Health with respect to autoimmune diseases.

(2) ALLOCATIONS BY DIRECTOR OF NIH.—With respect to amounts appropriated to carry out this section for a fiscal year, the Director of NIH shall allocate the amounts among the national research institutes that are carrying out paragraph (1).

(3) DEFINITION.—The term "autoimmune disease" includes, for purposes of this section such diseases or disorders with evidence of autoimmune pathogensis as the Secretary determines to be appropriate.

(b) COORDINATING COMMITTEE.—

(1) IN GENERAL.—The Secretary shall ensure that the Autoimmune Diseases Coordinating Committee (referred to in this section as the "Coordinating Committee") coordinates activities across the National Institutes and with other Federal health programs and activities relating to such diseases.

(2) COMPOSITION.—The Coordinating Committee shall be composed of the directors or their designees of each of the national research institutes involved in research with respect to autoimmune diseases and representatives of all other Federal departments and agencies whose programs involve health functions or responsibilities relevant to such diseases, including the Centers for Disease Control and Prevention and the Food and Drug Administration.

(3) CHAIR.—

(A) IN GENERAL.—With respect to autoimmune diseases, the Chair of the Committee shall serve as the principal advisor to the Secretary, the Assistant Secretary for Health, and the Director of NIH, and shall provide advice to the Director of the Centers for Disease Control and Prevention, the Commissioner of Food and Drugs, and other relevant agencies.

(B) DIRECTOR OF NIH.—The Chair of the Committee shall be directly responsible to the Director of NIH.

(c) PLAN FOR NIH ACTIVITIES.—

(1) IN GENERAL.—Not later than 1 year after the date of the enactment of this section, the Coordinating Committee shall develop a plan for conducting and supporting research and education on autoimmune diseases through the national research institutes and shall periodically review and revise the plan. The plan shall—

(A) provide for a broad range of research and education activities relating to biomedical, psychosocial, and rehabilitative issues, including studies of the disproportionate impact of such diseases on women;

(B) identify priorities among the programs and activities of the National Institutes of Health regarding such diseases; and

(C) reflect input from a broad range of scientists, patients, and advocacy groups.

(2) CERTAIN ELEMENTS OF PLAN.—The plan under paragraph (1) shall, with respect to autoimmune diseases, provide for the following as appropriate:

(A) Research to determine the reasons underlying the incidence and prevalence of the diseases.

(B) Basic research concerning the etiology and causes of the diseases.

(C) Epidemiological studies to address the frequency and natural history of the diseases, including any differences among the sexes and among racial and ethnic groups.

(D) The development of improved screening techniques.

(E) Clinical research for the development and evaluation of new treatments, including new biological agents.

(F) Information and education programs for health care professionals and the public.

(3) IMPLEMENTATION OF PLAN.—The Director of NIH shall ensure that programs and activities of the National Institutes of Health regarding autoimmune diseases are implemented in accordance with the plan under paragraph (1).

MUSCULAR DYSTROPHY RESEARCH.

SEC. 409F.[284j] (a) COORDINATION OF ACTIVITIES.—The Director of NIH shall expand and increase coordination in the activities of the National Institutes of Health with respect to research on muscular dystrophies, including Duchenne muscular dystrophy.

(b) ADMINISTRATION OF PROGRAM; COLLABORATION AMONG AGENCIES.—The Director of NIH shall carry out this section through the appropriate institutes, including the National Institute of Neurological Disorders and Stroke and in collaboration with any other agencies that the Director determines appropriate.

SEC. 409G.[284k] CLINICAL RESEARCH.

(a) IN GENERAL.—The Director of National Institutes of Health shall undertake activities to support and expand the involvement of the National Institutes of Health in clinical research.

(b) REQUIREMENTS.—In carrying out subsection (a), the Director of National Institutes of Health shall—

(1) consider the recommendations of the Division of Research Grants Clinical Research Study Group and other recommendations for enhancing clinical research; and

(2) establish intramural and extramural clinical research fellowship programs directed specifically at medical and dental students and a continuing education clinical research training program at the National Institutes of Health.

(c) SUPPORT FOR THE DIVERSE NEEDS OF CLINICAL RESEARCH.—The Director of National Institutes of Health, in cooperation with the Directors of the Institutes, Centers, and Divisions of the National Institutes of Health, shall support and expand the resources available for the diverse needs of the clinical research community, including inpatient, outpatient, and critical care clinical research.

(d) PEER REVIEW.—The Director of National Institutes of Health shall establish peer review mechanisms to evaluate applications for the awards and fellowships provided for in subsection (b)(2) and section 409D. Such review mechanisms shall include individuals who are exceptionally qualified to appraise the merits of potential clinical research training and research grant proposals.

SEC. 409H.[284l] ENHANCEMENT AWARDS.

(a) MENTORED PATIENT-ORIENTED RESEARCH CAREER DEVELOPMENT AWARDS.—

(1) GRANTS.—

(A) IN GENERAL.—The Director of the National Institutes of Health shall make grants (to be referred to as "Mentored Patient-Oriented Research Career Development Awards") to support individual careers in clinical research at general clinical research centers or at other institutions that have the infrastructure and resources deemed appropriate for conducting patient-oriented clinical research.

(B) USE.—Grants under subparagraph (A) shall be used to support clinical investigators in the early phases of their independent careers by providing salary and such other support for a period of supervised study.

(2) APPLICATIONS.—An application for a grant under this subsection shall be submitted by an individual scientist at such time as the Director may require.

(b) MID-CAREER INVESTIGATOR AWARDS IN PATIENT-ORIENTED RESEARCH.—

(1) GRANTS.—

(A) IN GENERAL.—The Director of the National Institutes of Health shall make grants (to be referred to as "Mid-Career Investigator Awards in Patient-Oriented Research") to support individual clinical research projects at general clinical research centers or at other institutions that have the infrastructure and resources deemed appropriate for conducting patient-oriented clinical research.

(B) USE.—Grants under subparagraph (A) shall be used to provide support for mid-career level clinicians to allow such clinicians to devote time to clinical research and to act as mentors for beginning clinical investigators.

(2) APPLICATIONS.—An application for a grant under this subsection shall be submitted by an individual scientist at such time as the Director requires.

(c) GRADUATE TRAINING IN CLINICAL INVESTIGATION AWARD.—

(1) IN GENERAL.—The Director of the National Institutes of Health shall make grants (to be referred to as "Graduate Training in Clinical Investigation Awards") to support individuals pursuing master's or doctoral degrees in clinical investigation.

(2) APPLICATIONS.—An application for a grant under this subsection shall be submitted by an individual scientist at such time as the Director may require.

(3) LIMITATIONS.—Grants under this subsection shall be for terms of 2 years or more and shall provide stipend, tuition, and institutional support for individual advanced degree programs in clinical investigation.

(4) DEFINITION.—As used in this subsection, the term "advanced degree programs in clinical investigation" means programs that award a master's or Ph.D. degree in clinical investigation after 2 or more years of training in areas such as the following:

(A) Analytical methods, biostatistics, and study design.

(B) Principles of clinical pharmacology and pharmacokinetics.

(C) Clinical epidemiology.

(D) Computer data management and medical informatics.

(E) Ethical and regulatory issues.

(F) Biomedical writing.

(d) CLINICAL RESEARCH CURRICULUM AWARDS.—

(1) IN GENERAL.—The Director of the National Institutes of Health shall make grants (to be referred to as "Clinical Research Curriculum Awards") to institutions for the development and support of programs of core curricula for training clinical investigators, including medical students. Such core curricula may include training in areas such as the following:

(A) Analytical methods, biostatistics, and study design.

(B) Principles of clinical pharmacology and pharmacokinetics.

(C) Clinical epidemiology.

(D) Computer data management and medical informatics.

(E) Ethical and regulatory issues.

(F) Biomedical writing.

(2) APPLICATIONS.—An application for a grant under this subsection shall be submitted by an individual institution or a consortium of institutions at such time as the Director may require. An institution may submit only one such application.

(3) LIMITATIONS.—Grants under this subsection shall be for terms of up to 5 years and may be renewable.

SEC. 409I.[284m] PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.[15].

(a) LIST OF PRIORITY ISSUES IN PEDIATRIC THERAPEUTICS.—

(1) IN GENERAL.—Not later than one year after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, the Secretary, acting through the Director of the National Institutes of Health and in consultation with the Commissioner of Food and Drugs and experts in pediatric research, shall develop and publish a priority list of needs in pediatric therapeutics, including drugs, biological products, or indications that require study. The list shall be revised every three years.

(2) CONSIDERATION OF AVAILABLE INFORMATION.—In developing and prioritizing the list under paragraph (1), the Secretary—

(A) shall consider—

(i) therapeutic gaps in pediatrics that may include developmental pharmacology, pharmacogenetic determinants of drug response, metabolism of drugs and biologics in children, and pediatric clinical trials;

(ii) particular pediatric diseases, disorders or conditions where more complete knowledge and testing of

[15] Section 16 of Public Law 107–109 (115 Stat. 1421) requires the Comptroller General of the United States, in consultation with the Secretary of Health and Human Services, to submit to Congress a report that relates to section 409I and to section 505A of the Federal Food, Drug, and Cosmetic Act. The report is required to be submitted not later than October 1, 2006.

therapeutics, including drugs and biologics, may be beneficial in pediatric populations; and

(iii) the adequacy of necessary infrastructure to conduct pediatric pharmacological research, including research networks and trained pediatric investigators; and

(B) may consider the availability of qualified countermeasures (as defined in section 319F–1), security countermeasures (as defined in section 319F–2), and qualified pandemic or epidemic products (as defined in section 319F–3) to address the needs of pediatric populations, in consultation with the Assistant Secretary for Preparedness and Response, consistent with the purposes of this section.

(b) PEDIATRIC STUDIES AND RESEARCH.—The Secretary, acting through the National Institutes of Health, shall award funds to entities that have the expertise to conduct pediatric clinical trials or other research (including qualified universities, hospitals, laboratories, contract research organizations, practice groups, federally funded programs such as pediatric pharmacology research units, other public or private institutions, or individuals) to enable the entities to conduct the drug studies or other research on the issues described in paragraphs (1) and (2)(A) of subsection (a). The Secretary may use contracts, grants, or other appropriate funding mechanisms to award funds under this subsection.

(c) PROCESS FOR PROPOSED PEDIATRIC STUDY REQUESTS AND LABELING CHANGES.—

(1) SUBMISSION OF PROPOSED PEDIATRIC STUDY REQUEST.—The Director of the National Institutes of Health shall, as appropriate, submit proposed pediatric study requests for consideration by the Commissioner of Food and Drugs for pediatric studies of a specific pediatric indication identified under subsection (a). Such a proposed pediatric study request shall be made in a manner equivalent to a written request made under subsection (b) or (c) of section 505A of the Federal Food, Drug, and Cosmetic Act, or section 351(m) of this Act, including with respect to the information provided on the pediatric studies to be conducted pursuant to the request. The Director of the National Institutes of Health may submit a proposed pediatric study request for a drug for which—

(A)(i) there is an approved application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or section 351(k) of this Act; or

(ii) there is a submitted application that could be approved under the criteria of such section; and

(B) there remains no patent listed pursuant to section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act, and every three-year and five-year period referred to in subsection (c)(3)(E)(ii), (c)(3)(E)(iii), (c)(3)(E)(iv), (j)(5)(F)(ii), (j)(5)(F)(iii), or (j)(5)(F)(iv) of section 505 of the Federal Food, Drug, and Cosmetic Act, or applicable twelve-year period referred to in section 351(k)(7) of this Act, and any seven-year period referred to in section 527 of the Federal Food, Drug, and Cosmetic Act has ended for at least one form of the drug; and

(C) additional studies are needed to assess the safety and effectiveness of the use of the drug in the pediatric population.

(2) WRITTEN REQUEST TO HOLDERS OF APPROVED APPLICATIONS.—The Commissioner of Food and Drugs, in consultation with the Director of the National Institutes of Health, may issue a written request based on the proposed pediatric study request for the indication or indications submitted pursuant to paragraph (1) (which shall include a timeframe for negotiations for an agreement) for pediatric studies concerning a drug identified under subsection (a) to all holders of an approved application for the drug. Such a written request shall be made in a manner equivalent to the manner in which a written request is made under subsection (b) or (c) of section 505A of the Federal Food, Drug, and Cosmetic Act or section 351(m) of this Act, including with respect to information provided on the pediatric studies to be conducted pursuant to the request and using appropriate formulations for each age group for which the study is requested.

(3) REQUESTS FOR PROPOSALS.—If the Commissioner of Food and Drugs does not receive a response to a written request issued under paragraph (2) not later than 30 days after the date on which a request was issued, the Secretary, acting through the Director of the National Institutes of Health and in consultation with the Commissioner of Food and Drugs, shall publish a request for proposals to conduct the pediatric studies described in the written request in accordance with subsection (b).

(4) DISQUALIFICATION.—A holder that receives a first right of refusal shall not be entitled to respond to a request for proposals under paragraph (3).

(5) CONTRACTS, GRANTS, OR OTHER FUNDING MECHANISMS.—A contract, grant, or other funding may be awarded under this section only if a proposal is submitted to the Secretary in such form and manner, and containing such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(6) REPORTING OF STUDIES.—

(A) IN GENERAL.—On completion of a pediatric study in accordance with an award under this section, a report concerning the study shall be submitted to the Director of the National Institutes of Health and the Commissioner of Food and Drugs. The report shall include all data generated in connection with the study, including a written request if issued.

(B) AVAILABILITY OF REPORTS.—Each report submitted under subparagraph (A) shall be considered to be in the public domain (subject to section 505A(d)(4) of the Federal Food, Drug, and Cosmetic Act) and shall be assigned a docket number by the Commissioner of Food and Drugs. An interested person may submit written comments concerning such pediatric studies to the Commissioner of Food and Drugs, and the written comments shall become part of the docket file with respect to each of the drugs.

(C) ACTION BY COMMISSIONER.—The Commissioner of Food and Drugs shall take appropriate action in response to the reports submitted under subparagraph (A) in accordance with paragraph (7).

(7) REQUESTS FOR LABELING CHANGE.—During the 180-day period after the date on which a report is submitted under paragraph (6)(A), the Commissioner of Food and Drugs shall—

(A) review the report and such other data as are available concerning the safe and effective use in the pediatric population of the drug studied;

(B) negotiate with the holders of approved applications for the drug studied for any labeling changes that the Commissioner of Food and Drugs determines to be appropriate and requests the holders to make; and

(C)(i) place in the public docket file a copy of the report and of any requested labeling changes; and

(ii) publish in the Federal Register and through a posting on the Web site of the Food and Drug Administration a summary of the report and a copy of any requested labeling changes.

(8) DISPUTE RESOLUTION.—

(A) REFERRAL TO PEDIATRIC ADVISORY COMMITTEE.—If, not later than the end of the 180-day period specified in paragraph (7), the holder of an approved application for the drug involved does not agree to any labeling change requested by the Commissioner of Food and Drugs under that paragraph, the Commissioner of Food and Drugs shall refer the request to the Pediatric Advisory Committee.

(B) ACTION BY THE PEDIATRIC ADVISORY COMMITTEE.—Not later than 90 days after receiving a referral under subparagraph (A), the Pediatric Advisory Committee shall—

(i) review the available information on the safe and effective use of the drug in the pediatric population, including study reports submitted under this section; and

(ii) make a recommendation to the Commissioner of Food and Drugs as to appropriate labeling changes, if any.

(9) FDA DETERMINATION.—Not later than 30 days after receiving a recommendation from the Pediatric Advisory Committee under paragraph (8)(B)(ii) with respect to a drug, the Commissioner of Food and Drugs shall consider the recommendation and, if appropriate, make a request to the holders of approved applications for the drug to make any labeling change that the Commissioner of Food and Drugs determines to be appropriate.

(10) FAILURE TO AGREE.—If a holder of an approved application for a drug, within 30 days after receiving a request to make a labeling change under paragraph (9), does not agree to make a requested labeling change, the Commissioner of Food and Drugs may deem the drug to be misbranded under the Federal Food, Drug, and Cosmetic Act.

(11) NO EFFECT ON AUTHORITY.—Nothing in this subsection limits the authority of the United States to bring an enforcement action under the Federal Food, Drug, and Cosmetic Act when a drug lacks appropriate pediatric labeling. Neither course of action (the Pediatric Advisory Committee process or an enforcement action referred to in the preceding sentence) shall preclude, delay, or serve as the basis to stay the other course of action.

(d) DISSEMINATION OF PEDIATRIC INFORMATION.—Not later than one year after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, the Secretary, acting through the Director of the National Institutes of Health, shall study the feasibility of establishing a compilation of information on pediatric drug use and report the findings to Congress.

(e) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—There are authorized to be appropriated to carry out this section, $25,000,000 for each of fiscal years 2013 through 2017.

(2) AVAILABILITY.—Any amount appropriated under paragraph (1) shall remain available to carry out this section until expended.

SEC. 409J.[284q] PAIN RESEARCH.

(a) RESEARCH INITIATIVES.—

(1) IN GENERAL.—The Director of NIH is encouraged to continue and expand, through the Pain Consortium, an aggressive program of basic and clinical research on the causes of and potential treatments for pain.

(2) ANNUAL RECOMMENDATIONS.—Not less than annually, the Pain Consortium, in consultation with the Division of Program Coordination, Planning, and Strategic Initiatives, shall develop and submit to the Director of NIH recommendations on appropriate pain research initiatives that could be undertaken with funds reserved under section 402A(c)(1) for the Common Fund or otherwise available for such initiatives.

(3) DEFINITION.—In this subsection, the term "Pain Consortium" means the Pain Consortium of the National Institutes of Health or a similar trans-National Institutes of Health coordinating entity designated by the Secretary for purposes of this subsection.

(b) INTERAGENCY PAIN RESEARCH COORDINATING COMMITTEE.—

(1) ESTABLISHMENT.—The Secretary shall establish not later than 1 year after the date of the enactment of this section and as necessary maintain a committee, to be known as the Interagency Pain Research Coordinating Committee (in this section referred to as the "Committee"), to coordinate all efforts within the Department of Health and Human Services and other Federal agencies that relate to pain research.

(2) MEMBERSHIP.—

(A) IN GENERAL.—The Committee shall be composed of the following voting members:

(i) Not more than 7 voting Federal representatives appoint by the Secretary from agencies that conduct pain care research and treatment.

(ii) 12 additional voting members appointed under subparagraph (B).

(B) ADDITIONAL MEMBERS.—The Committee shall include additional voting members appointed by the Secretary as follows:

(i) 6 non-Federal members shall be appointed from among scientists, physicians, and other health professionals.

(ii) 6 members shall be appointed from members of the general public, who are representatives of leading research, advocacy, and service organizations for individuals with pain-related conditions.

(C) NONVOTING MEMBERS.—The Committee shall include such nonvoting members as the Secretary determines to be appropriate.

(3) CHAIRPERSON.—The voting members of the Committee shall select a chairperson from among such members. The selection of a chairperson shall be subject to the approval of the Director of NIH.

(4) MEETINGS.—The Committee shall meet at the call of the chairperson of the Committee or upon the request of the Director of NIH, but in no case less often than once each year.

(5) DUTIES.—The Committee shall—

(A) develop a summary of advances in pain care research supported or conducted by the Federal agencies relevant to the diagnosis, prevention, and treatment of pain and diseases and disorders associated with pain;

(B) identify critical gaps in basic and clinical research on the symptoms and causes of pain;

(C) make recommendations to ensure that the activities of the National Institutes of Health and other Federal agencies are free of unnecessary duplication of effort;

(D) make recommendations on how best to disseminate information on pain care; and

(E) make recommendations on how to expand partnerships between public entities and private entities to expand collaborative, cross-cutting research.

(6) REVIEW.—The Secretary shall review the necessity of the Committee at least once every 2 years.

PART C—SPECIFIC PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES

Subpart 1—National Cancer Institute

PURPOSE OF INSTITUTE.

SEC. 410.[285] The general purpose of the National Cancer Institute (hereafter in this subpart referred to as the "Institute") is the conduct and support of research, training, health information dissemination, and other programs with respect to the cause, diagnosis, prevention, and treatment of cancer, rehabilitation from cancer, and the continuing care of cancer patients and the families of cancer patients.

NATIONAL CANCER PROGRAM.

SEC. 411.[285a] The National Cancer Program shall consist of (1) an expanded, intensified, and coordinated cancer research program encompassing the research programs conducted and supported by the Institute and the related research programs of the other national research institutes, including an expanded and intensified research program for the prevention of cancer caused by occupational or environmental exposure to carcinogens, and (2) the other programs and activities of the Institute.

CANCER CONTROL PROGRAMS.

SEC. 412.[285a–1] The Director of the Institute shall establish and support demonstration, education, and other programs for the detection, diagnosis, prevention, and treatment of cancer and for rehabilitation and counseling respecting cancer. Programs established and supported under this section shall include—

(1) locally initiated education and demonstration programs (and regional networks of such programs) to transmit research results and to disseminate information respecting—

(A) the detection, diagnosis, prevention, and treatment of cancer,

(B) the continuing care of cancer patients and the families of cancer patients, and

(C) rehabilitation and counseling respecting cancer,

to physicians and other health professionals who provide care to individuals who have cancer;

(2) the demonstration of and the education of students of the health professions and health professionals in—

(A) effective methods for the prevention and early detection of cancer and the identification of individuals with a high risk of developing cancer, and

(B) improved methods of patient referral to appropriate centers for early diagnosis and treatment of cancer; and

(3) the demonstration of new methods for the dissemination of information to the general public concerning the prevention, early detection, diagnosis, and treatment and control of cancer and information concerning unapproved and ineffective methods, drugs, and devices for the diagnosis, prevention, treatment, and control of cancer.

SPECIAL AUTHORITIES OF THE DIRECTOR.

SEC. 413.[285a–2] (a)(1) The Director of the Institute shall establish an information and education program to collect, identify, analyze, and disseminate on a timely basis, through publications and other appropriate means, to cancer patients and their families, physicians and other health professionals, and the general public, information on cancer research, diagnosis, prevention, and treatment (including information respecting nutrition programs for cancer patients and the relationship between nutrition and cancer). The Director of the Institute may take such action as may be necessary to insure that all channels for the dissemination and ex-

change of scientific knowledge and information are maintained between the Institute and the public and between the Institute and other scientific, medical, and biomedical disciplines and organizations nationally and internationally.

(2) In carrying out paragraph (1), the Director of the Institute shall—

(A) provide public and patient information and education programs, providing information that will help individuals take personal steps to reduce their risk of cancer, to make them aware of early detection techniques and to motivate appropriate utilization of those techniques, to help individuals deal with cancer if it strikes, and to provide information to improve long-term survival;

(B) continue and expand programs to provide physicians and the public with state-of-the-art information on the treatment of particular forms of cancers, and to identify those clinical trials that might benefit patients while advancing knowledge of cancer treatment;

(C) assess the incorporation of state-of-the-art cancer treatments into clinical practice and the extent to which cancer patients receive such treatments and include the results of such assessments in the biennial reports required under section 407;

(D) maintain and operate the International Cancer Research Data Bank, which shall collect, catalog, store, and disseminate insofar as feasible the results of cancer research and treatment undertaken in any country for the use of any person involved in cancer research and treatment in any country; and

(E) to the extent practicable, in disseminating the results of such cancer research and treatment, utilize information systems available to the public.

(b) The Director of the Institute in carrying out the National Cancer Program—

(1) shall establish or support the large-scale production or distribution of specialized biological materials and other therapeutic substances for cancer research and set standards of safety and care for persons using such materials;

(2) shall, in consultation with the advisory council for the Institute, support (A) research in the cancer field outside the United States by highly qualified foreign nationals which can be expected to benefit the American people, (B) collaborative research involving American and foreign participants, and (C) the training of American scientists abroad and foreign scientists in the United States;

(3) shall, in consultation with the advisory council for the Institute, support appropriate programs of education and training (including continuing education and laboratory and clinical research training);

(4) shall encourage and coordinate cancer research by industrial concerns where such concerns evidence a particular capability for such research;

(5) may obtain (after consultation with the advisory council for the Institute and in accordance with section 3109 of title 5, United States Code, but without regard to the limitation in such section on the period of service) the services of not more

than one hundred and fifty-one experts or consultants who have scientific or professional qualifications;

(6)(A) may, in consultation with the advisory council for the Institute, acquire, construct, improve, repair, operate, and maintain laboratories, other research facilities, equipment, and such other real or personal property as the Director determines necessary;

(B) may, in consultation with the advisory council for the Institute, make grants for construction or renovation of facilities; and

(C) may, in consultation with the advisory council for the Institute, acquire, without regard to the Act of March 3, 1877 (40 U.S.C. 34), by lease or otherwise through the Administrator of General Services, buildings or parts of buildings in the District of Columbia or communities located adjacent to the District of Columbia for the use of the Institute for a period not to exceed ten years;

(7) may, in consultation with the advisory council for the Institute, appoint one or more advisory committees composed of such private citizens and officials of Federal, State, and local governments to advise the Director with respect to the Director's functions;

(8) may, subject to section 405(b)(2) and without regard to section 3324 of title 31, United States Code, and section 3709 of the Revised Statutes (41 U.S.C. 5), enter into such contracts, leases, cooperative agreements, as may be necessary in the conduct of functions of the Director, with any public agency, or with any person, firm, association, corporation, or educational institution; and

(9) shall, notwithstanding section 405(a), prepare and submit, directly to the President for review and transmittal to Congress, an annual budget estimate (including an estimate of the number and type of personnel needs for the Institute) for the National Cancer Program, after reasonable opportunity for comment (but without change) by the Secretary, the Director of NIH, and the Institute's advisory council.

Except as otherwise provided, experts and consultants whose services are obtained under paragraph (5) shall be paid or reimbursed, in accordance with title 5, United States Code, for their travel to and from their place of service and for other expenses associated with their assignment. Such expenses shall not be allowed in connection with the assignment of an expert or consultant whose services are obtained under paragraph (5) unless the expert or consultant has agreed in writing to complete the entire period of the assignment or one year of the assignment, whichever is shorter, unless separated or reassigned for reasons which are beyond the control of the expert or consultant and which are acceptable to the Director of the Institute. If the expert or consultant violates the agreement, the money spent by the United States for such expenses is recoverable from the expert or consultant as a debt due the United States. The Secretary may waive in whole or in part a right of recovery under the preceding sentence.

(c) PRE-CLINICAL MODELS TO EVALUATE PROMISING PEDIATRIC CANCER THERAPIES.—

(1) EXPANSION AND COORDINATION OF ACTIVITIES.—The Director of the National Cancer Institute shall expand, intensify, and coordinate the activities of the Institute with respect to research on the development of preclinical models to evaluate which therapies are likely to be effective for treating pediatric cancer.

(2) COORDINATION WITH OTHER INSTITUTES.—The Director of the Institute shall coordinate the activities under paragraph (1) with similar activities conducted by other national research institutes and agencies of the National Institutes of Health to the extent that those Institutes and agencies have responsibilities that are related to pediatric cancer.

NATIONAL CANCER RESEARCH AND DEMONSTRATION CENTERS.

SEC. 414.[285a–3] (a)(1) The Director of the Institute may enter into cooperative agreements with and make grants to public or private nonprofit entities to pay all or part of the cost of planning, establishing, or strengthening, and providing basic operating support for centers for basic and clinical research into, training in, and demonstration of advanced diagnostic, prevention, control, and treatment methods for cancer.

(2) A cooperative agreement or grant under paragraph (1) shall be entered into in accordance with policies established by the Director of NIH and after consultation with the Institute's advisory council.

(b) Federal payments made under a cooperative agreement or grant under subsection (a) may be used for—

(1) construction (notwithstanding any limitation under section 496);

(2) staffing and other basic operating costs, including such patient care costs as are required for research;

(3) clinical training, including training for allied health professionals, continuing education for health professionals and allied health professions personnel, and information programs for the public respecting cancer; and

(4) demonstration purposes.

As used in this paragraph, the term "construction" does not include the acquisition of land, and the term "training" does not include research training for which National Research Service Awards [16] may be provided under section 487.

(c) Support of a center under subsection (a) may be for a period of not to exceed five years. Such period may be extended by the Director for additional periods of not more than five years each if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

(d) Research centers under this section may not be considered centers of excellence for purposes of section 402(b)(10).

[16] Now Ruth L. Kirschstein National Research Service Awards. See section 487.

PRESIDENT'S CANCER PANEL.

SEC. 415.[285a–4] (a)(1) The President's Cancer Panel (hereafter in this section referred to as the "Panel") shall be composed of three persons appointed by the President who by virtue of their training, experience, and background are exceptionally qualified to appraise the National Cancer Program. At least two members of the Panel shall be distinguished scientists or physicians.

(2)(A) Members of the Panel shall be appointed for three-year terms, except that (i) any member appointed to fill a vacancy occurring prior to the expiration of the term for which the member's predecessor was appointed shall be appointed only for the remainder of such term, and (ii) a member may serve until the member's successor has taken office. If a vacancy occurs in the Panel, the President shall make an appointment to fill the vacancy not later than 90 days after the date the vacancy occurred.

(B) The President shall designate one of the members to serve as the chairman of the Panel for a term of one year.

(C) Members of the Panel shall each be entitled to receive the daily equivalent of the annual rate of basic pay in effect for grade GS–18 of the General Schedule for each day (including traveltime) during which they are engaged in the actual performance of duties as members of the Panel and shall be paid or reimbursed, in accordance with title 5, United States Code, for their travel to and from their place of service and for other expenses associated with their assignment.

(3) The Panel shall meet at the call of the chairman, but not less often than four times a year. A transcript shall be kept of the proceedings of each meeting of the Panel, and the chairman shall make such transcript available to the public.

(b) The Panel shall monitor the development and execution of the activities of the National Cancer Program, and shall report directly to the President. Any delays or blockages in rapid execution of the Program shall immediately be brought to the attention of the President. The Panel shall submit to the President periodic progress reports on the National Cancer Program and shall submit to the President, the Secretary, and the Congress an annual evaluation of the efficacy of the Program and suggestions for improvements, and shall submit such other reports as the President shall direct.

ASSOCIATE DIRECTOR FOR PREVENTION.

SEC. 416.[285a–5] (a) There shall be in the Institute an Associate Director for Prevention to coordinate and promote the programs in the Institute concerning the prevention of cancer. The Associate Director shall be appointed by the Director of the Institute from individuals who because of their professional training or experience are experts in public health or preventive medicine.

(b) The Associate Director for Prevention shall prepare for inclusion in the biennial report made under section 407 a description of the prevention activities of the Institute, including a description of the staff and resources allocated to those activities.

BREAST AND GYNECOLOGICAL CANCERS.

SEC. 417.[285a–6] (a) EXPANSION AND COORDINATION OF ACTIVITIES.—The Director of the Institute, in consultation with the National Cancer Advisory Board, shall expand, intensify, and coordinate the activities of the Institute with respect to research on breast cancer, ovarian cancer, and other cancers of the reproductive system of women.

(b) COORDINATION WITH OTHER INSTITUTES.—The Director of the Institute shall coordinate the activities of the Director under subsection (a) with similar activities conducted by other national research institutes and agencies of the National Institutes of Health to the extent that such Institutes and agencies have responsibilities that are related to breast cancer and other cancers of the reproductive system of women.

(c) PROGRAMS FOR BREAST CANCER.—

(1) IN GENERAL.—In carrying out subsection (a), the Director of the Institute shall conduct or support research to expand the understanding of the cause of, and to find a cure for, breast cancer. Activities under such subsection shall provide for an expansion and intensification of the conduct and support of—

(A) basic research concerning the etiology and causes of breast cancer;

(B) clinical research and related activities concerning the causes, prevention, detection and treatment of breast cancer;

(C) control programs with respect to breast cancer in accordance with section 412, including community-based programs designed to assist women who are members of medically underserved populations, low-income populations, or minority groups;

(D) information and education programs with respect to breast cancer in accordance with section 413; and

(E) research and demonstration centers with respect to breast cancer in accordance with section 414, including the development and operation of centers for breast cancer research to bring together basic and clinical, biomedical and behavioral scientists to conduct basic, clinical, epidemiological, psychosocial, prevention and treatment research and related activities on breast cancer.

Not less than six centers shall be operated under subparagraph (E). Activities of such centers should include supporting new and innovative research and training programs for new researchers. Such centers shall give priority to expediting the transfer of research advances to clinical applications.

(2) IMPLEMENTATION OF PLAN FOR PROGRAMS.—

(A) The Director of the Institute shall ensure that the research programs described in paragraph (1) are implemented in accordance with a plan for the programs. Such plan shall include comments and recommendations that the Director of the Institute considers appropriate, with due consideration provided to the professional judgment needs of the Institute as expressed in the annual budget

estimate prepared in accordance with section 413(9)[17]. The Director of the Institute, in consultation with the National Cancer Advisory Board, shall periodically review and revise such plan.

(B) Not later than October 1, 1993, the Director of the Institute shall submit a copy of the plan to the President's Cancer Panel, the Secretary and the Director of NIH.

(C) The Director of the Institute shall submit any revisions of the plan to the President's Cancer Panel, the Secretary, and the Director of NIH.

(D) The Secretary shall provide a copy of the plan submitted under subparagraph (A), and any revisions submitted under subparagraph (C), to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate.

(d) OTHER CANCERS.—In carrying out subsection (a), the Director of the Institute shall conduct or support research on ovarian cancer and other cancers of the reproductive system of women. Activities under such subsection shall provide for the conduct and support of—

(1) basic research concerning the etiology and causes of ovarian cancer and other cancers of the reproductive system of women;

(2) clinical research and related activities into the causes, prevention, detection and treatment of ovarian cancer and other cancers of the reproductive system of women;

(3) control programs with respect to ovarian cancer and other cancers of the reproductive system of women in accordance with section 412;

(4) information and education programs with respect to ovarian cancer and other cancers of the reproductive system of women in accordance with section 413; and

(5) research and demonstration centers with respect to ovarian cancer and cancers of the reproductive system in accordance with section 414.

(e) REPORT.—The Director of the Institute shall prepare, for inclusion in the biennial report submitted under section 407, a report that describes the activities of the National Cancer Institute under the research programs referred to in subsection (a), that shall include—

(1) a description of the research plan with respect to breast cancer prepared under subsection (c);

(2) an assessment of the development, revision, and implementation of such plan;

(3) a description and evaluation of the progress made, during the period for which such report is prepared, in the research programs on breast cancer and cancers of the reproductive system of women;

(4) a summary and analysis of expenditures made, during the period for which such report is made, for activities with re-

[17] So in law. See section 401 of Public Law 103–43 (107 Stat. 153). Probably should be section "413(b)(9)".

spect to breast cancer and cancers of the reproductive system of women conducted and supported by the National Institutes of Health; and

(5) such comments and recommendations as the Director considers appropriate.

PROSTATE CANCER.

SEC. 417A.[285a–7] (a) EXPANSION AND COORDINATION OF ACTIVITIES.—The Director of the Institute, in consultation with the National Cancer Advisory Board, shall expand, intensify, and coordinate the activities of the Institute with respect to research on prostate cancer.

(b) COORDINATION WITH OTHER INSTITUTES.—The Director of the Institute shall coordinate the activities of the Director under subsection (a) with similar activities conducted by other national research institutes and agencies of the National Institutes of Health to the extent that such Institutes and agencies have responsibilities that are related to prostate cancer.

(c) PROGRAMS.—

(1) IN GENERAL.—In carrying out subsection (a), the Director of the Institute shall conduct or support research to expand the understanding of the cause of, and to find a cure for, prostate cancer. Activities under such subsection shall provide for an expansion and intensification of the conduct and support of—

(A) basic research concerning the etiology and causes of prostate cancer;

(B) clinical research and related activities concerning the causes, prevention, detection and treatment of prostate cancer;

(C) prevention and control and early detection programs with respect to prostate cancer in accordance with section 412, particularly as it relates to intensifying research on the role of prostate specific antigen for the screening and early detection of prostate cancer;

(D) an Inter-Institute Task Force, under the direction of the Director of the Institute, to provide coordination between relevant National Institutes of Health components of research efforts on prostate cancer;

(E) control programs with respect to prostate cancer in accordance with section 412;

(F) information and education programs with respect to prostate cancer in accordance with section 413; and

(G) research and demonstration centers with respect to prostate cancer in accordance with section 414, including the development and operation of centers for prostate cancer research to bring together basic and clinical, biomedical and behavioral scientists to conduct basic, clinical, epidemiological, psychosocial, prevention and control, treatment, research, and related activities on prostate cancer.

Not less than six centers shall be operated under subparagraph (G). Activities of such centers should include supporting

new and innovative research and training programs for new researchers. Such centers shall give priority to expediting the transfer of research advances to clinical applications.

(2) IMPLEMENTATION OF PLAN FOR PROGRAMS.—

(A) The Director of the Institute shall ensure that the research programs described in paragraph (1) are implemented in accordance with a plan for the programs. Such plan shall include comments and recommendations that the Director of the Institute considers appropriate, with due consideration provided to the professional judgment needs of the Institute as expressed in the annual budget estimate prepared in accordance with section 413(9)[18]. The Director of the Institute, in consultation with the National Cancer Advisory Board, shall periodically review and revise such plan.

(B) Not later than October 1, 1993, the Director of the Institute shall submit a copy of the plan to the President's Cancer Panel, the Secretary, and the Director of NIH.

(C) The Director of the Institute shall submit any revisions of the plan to the President's Cancer Panel, the Secretary, and the Director of NIH.

(D) The Secretary shall provide a copy of the plan submitted under subparagraph (A), and any revisions submitted under subparagraph (C), to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate.[19]

SEC. 417C.[285a–9] GRANTS FOR EDUCATION, PREVENTION, AND EARLY DETECTION OF RADIOGENIC CANCERS AND DISEASES.

(a) DEFINITION.—In this section the term "entity" means any—

(1) National Cancer Institute-designated cancer center;

(2) Department of Veterans Affairs hospital or medical center;

(3) Federally Qualified Health Center, community health center, or hospital;

(4) agency of any State or local government, including any State department of health; or

(5) nonprofit organization.

(b) IN GENERAL.—The Secretary, acting through the Administrator of the Health Resources and Services Administration in consultation with the Director of the National Institutes of Health and the Director of the Indian Health Service, may make competitive grants to any entity for the purpose of carrying out programs to—

(1) screen individuals described under section 4(a)(1)(A)(i) or 5(a)(1)(A) of the Radiation Exposure Compensation Act (42 U.S.C. 2210 note) for cancer as a preventative health measure;

(2) provide appropriate referrals for medical treatment of individuals screened under paragraph (1) and to ensure, to the extent practicable, the provision of appropriate follow-up services;

[18] So in law. See section 402 of Public Law 103–43 (107 Stat. 155). Probably should be "section 413(b)(9)".

[19] Section 417B was repealed by section 103(b)(15) of Public Law 109–482 (120 Stat. 3687).

(3) develop and disseminate public information and education programs for the detection, prevention, and treatment of radiogenic cancers and diseases; and

(4) facilitate putative applicants in the documentation of claims as described in section 5(a) of the Radiation Exposure Compensation Act (42 U.S.C. 2210 note).

(c) INDIAN HEALTH SERVICE.—The programs under subsection (a) shall include programs provided through the Indian Health Service or through tribal contracts, compacts, grants, or cooperative agreements with the Indian Health Service and which are determined appropriate to raising the health status of Indians.

(d) GRANT AND CONTRACT AUTHORITY.—Entities receiving a grant under subsection (b) may expend the grant to carry out the purpose described in such subsection.

(e) HEALTH COVERAGE UNAFFECTED.—Nothing in this section shall be construed to affect any coverage obligation of a governmental or private health plan or program relating to an individual referred to under subsection (b)(1).

SEC. 417D.[285a–10] RESEARCH, INFORMATION, AND EDUCATION WITH RESPECT TO BLOOD CANCER.[20].

(a) JOE MOAKLEY RESEARCH EXCELLENCE PROGRAM.—

(1) IN GENERAL.—The Director of NIH shall expand, intensify, and coordinate programs for the conduct and support of research with respect to blood cancer, and particularly with respect to leukemia, lymphoma, and multiple myeloma.

(2) ADMINISTRATION.—The Director of NIH shall carry out this subsection through the Director of the National Cancer Institute and in collaboration with any other agencies that the Director determines to be appropriate.

(b) GERALDINE FERRARO CANCER EDUCATION PROGRAM.—

(1) IN GENERAL.—The Secretary shall direct the appropriate agency within the Department of Health and Human Services, in collaboration with the Director of NIH, to establish and carry out a program to provide information and education for patients and the general public with respect to blood cancer, and particularly with respect to the treatment of leukemia, lymphoma, and multiple myeloma.

(2) ADMINISTRATION.—The Agency determined by the Secretary under paragraph (1) shall carry out this subsection in collaboration with private health organizations that have national education and patient assistance programs on blood-related cancers.

SEC. 417E.[285a–11] PEDIATRIC CANCER RESEARCH AND AWARENESS.

(a) PEDIATRIC CANCER RESEARCH.—

(1) PROGRAMS OF RESEARCH EXCELLENCE IN PEDIATRIC CANCER.—The Secretary, in collaboration with the Director of NIH

[20] Section 417D (as amended by Public Law 109–482) is shown after section 417C for the convenience of the reader. Section 3 of Public Law 107–172 (116 Stat. 541) attempts to amend this part by inserting a new section 417D "after section 419C". The amendment cannot be executed, as this part does not contain a section 419C.

and other Federal agencies with interest in prevention and treatment of pediatric cancer, shall continue to enhance, expand, and intensify pediatric cancer research and other activities related to pediatric cancer, including therapeutically applicable research to generate effective treatments, pediatric preclinical testing, and pediatric clinical trials through National Cancer Institute-supported pediatric cancer clinical trial groups and their member institutions. In enhancing, expanding, and intensifying such research and other activities, the Secretary is encouraged to take into consideration the application of such research and other activities for minority, health disparity, and medically underserved communities. For purposes of this section, the term "pediatric cancer research" means research on the causes, prevention, diagnosis, recognition, treatment, and long-term effects of pediatric cancer.

(2) PEER REVIEW REQUIREMENTS.—All grants awarded under this subsection shall be awarded in accordance with section 492.

(b) PUBLIC AWARENESS OF PEDIATRIC CANCERS AND AVAILABLE TREATMENTS AND RESEARCH.—

(1) IN GENERAL.—The Secretary may award grants to childhood cancer professional and direct service organizations for the expansion and widespread implementation of—

(A) activities that provide available information on treatment protocols to ensure early access to the best available therapies and clinical trials for pediatric cancers;

(B) activities that provide available information on the late effects of pediatric cancer treatment to ensure access to necessary long-term medical and psychological care; and

(C) direct resource services such as educational outreach for parents, peer-to-peer and parent-to-parent support networks, information on school re-entry and postsecondary education, and resource directories or referral services for financial assistance, psychological counseling, and other support services.

In awarding grants under this paragraph, the Secretary is encouraged to take into consideration the extent to which an entity would use such grant for purposes of making activities and services described in this paragraph available to minority, health disparity, and medically underserved communities.

(2) PERFORMANCE MEASUREMENT, TRANSPARENCY, AND ACCOUNTABILITY.—For each grant awarded under this subsection, the Secretary shall develop and implement metrics-based performance measures to assess the effectiveness of activities funded under such grant.

(3) INFORMATIONAL REQUIREMENTS.—Any information made available pursuant to a grant awarded under paragraph (1) shall be—

(A) culturally and linguistically appropriate as needed by patients and families affected by childhood cancer; and

(B) approved by the Secretary.

(c) RULE OF CONSTRUCTION.—Nothing in this section shall be construed as being inconsistent with the goals and purposes of the

Minority Health and Health Disparities Research and Education Act of 2000 (42 U.S.C. 202 note)[21].

(d) AUTHORIZATION OF APPROPRIATIONS.—For purposes of carrying out this section and section 399E–1, there are authorized to be appropriated $30,000,000 for each of fiscal years 2009 through 2013. Such authorization of appropriations is in addition to the authorization of appropriations established in section 402A with respect to such purpose. Funds appropriated under this subsection shall remain available until expended.

SEC. 417F.[42 U.S.C. 285a–12] INTERAGENCY BREAST CANCER AND ENVIRONMENTAL RESEARCH COORDINATING COMMITTEE.

(a) INTERAGENCY BREAST CANCER AND ENVIRONMENTAL RESEARCH COORDINATING COMMITTEE.—

(1) ESTABLISHMENT.—Not later than 6 months after the date of the enactment of this section, the Secretary shall establish a committee, to be known as the Interagency Breast Cancer and Environmental Research Coordinating Committee (in this section referred to as the "Committee").

(2) DUTIES.—The Committee shall—

(A) share and coordinate information on existing research activities, and make recommendations to the National Institutes of Health and other Federal agencies regarding how to improve existing research programs, that are related to breast cancer research;

(B) develop a comprehensive strategy and advise the National Institutes of Health and other Federal agencies in the solicitation of proposals for collaborative, multidisciplinary research, including proposals to evaluate environmental and genomic factors that may be related to the etiology of breast cancer that would—

(i) result in innovative approaches to study emerging scientific opportunities or eliminate knowledge gaps in research to improve the research portfolio;

(ii) outline key research questions, methodologies, and knowledge gaps;

(iii) expand the number of research proposals that involve collaboration between 2 or more national research institutes or national centers, including proposals for Common Fund research described in section 402(b)(7) to improve the research portfolio; and

(iv) expand the number of collaborative, multidisciplinary, and multi-institutional research grants;

(C) develop a summary of advances in breast cancer research supported or conducted by Federal agencies relevant to the diagnosis, prevention, and treatment of cancer and other diseases and disorders; and

(D) not later than 2 years after the date of the establishment of the Committee, make recommendations to the Secretary—

(i) regarding any appropriate changes to research activities, including recommendations to improve the

[21] The patenthetical reference to 42 U.S.C. 202 note in subsection (c) probably should be stricken or revised to refer to 42 U.S.C. 201 note.

research portfolio of the National Institutes of Health to ensure that scientifically-based strategic planning is implemented in support of research priorities that impact breast cancer research activities;

(ii) to ensure that the activities of the National Institutes of Health and other Federal agencies, including the Department of Defense, are free of unnecessary duplication of effort;

(iii) regarding public participation in decisions relating to breast cancer research to increase the involvement of patient advocacy and community organizations representing a broad geographical area;

(iv) on how best to disseminate information on breast cancer research progress; and

(v) on how to expand partnerships between public entities, including Federal agencies, and private entities to expand collaborative, cross-cutting research.

(3) RULE OF CONSTRUCTION.—For the purposes of the Committee, when focusing on research to evaluate environmental and genomic factors that may be related to the etiology of breast cancer, nothing in this section shall be construed to restrict the Secretary from including other forms of cancer, as appropriate, when doing so may advance research in breast cancer or advance research in other forms of cancer.

(4) MEMBERSHIP.—

(A) IN GENERAL.—The Committee shall be composed of the following voting members:

(i) Not more than 7 voting Federal representatives as follows:

(I) The Director of the Centers for Disease Control and Prevention.

(II) The Director of the National Institutes of Health and the directors of such national research institutes and national centers (which may include the National Institute of Environmental Health Sciences) as the Secretary determines appropriate.

(III) One representative from the National Cancer Institute Board of Scientific Advisors, appointed by the Director of the National Cancer Institute.

(IV) The heads of such other agencies of the Department of Health and Human Services as the Secretary determines appropriate.

(V) Representatives of other Federal agencies that conduct or support cancer research, including the Department of Defense.

(ii) 12 additional voting members appointed under subparagraph (B).

(B) ADDITIONAL MEMBERS.—The Committee shall include additional voting members appointed by the Secretary as follows:

(i) 6 members shall be appointed from among scientists, physicians, and other health professionals, who—

(I) are not officers or employees of the United States;

(II) represent multiple disciplines, including clinical, basic, and public health sciences;

(III) represent different geographical regions of the United States;

(IV) are from practice settings, academia, or other research settings; and

(V) are experienced in scientific peer review process.

(ii) 6 members shall be appointed from members of the general public, who represent individuals with breast cancer.

(C) NONVOTING MEMBERS.—The Committee shall include such nonvoting members as the Secretary determines to be appropriate.

(5) CHAIRPERSON.—The voting members of the Committee shall select a chairperson from among such members. The selection of a chairperson shall be subject to the approval of the Director of NIH.

(6) MEETINGS.—The Committee shall meet at the call of the chairperson of the Committee or upon the request of the Director of NIH, but in no case less often than once each year.

(b) REVIEW.—The Secretary shall review the necessity of the Committee in calendar year 2011 and, thereafter, at least once every 2 years.

SEC. 417G.[42 U.S.C. 285a–13] SCIENTIFIC FRAMEWORK FOR RECALCITRANT CANCERS.

(a) DEVELOPMENT OF SCIENTIFIC FRAMEWORK.—

(1) IN GENERAL.—For each recalcitrant cancer identified under subsection (b), the Director of the Institute shall develop (in accordance with subsection (c)) a scientific framework for the conduct or support of research on such cancer.

(2) CONTENTS.—The scientific framework with respect to a recalcitrant cancer shall include the following:

(A) CURRENT STATUS.—

(i) REVIEW OF LITERATURE.—A summary of findings from the current literature in the areas of—

(I) the prevention, diagnosis, and treatment of such cancer;

(II) the fundamental biologic processes that regulate such cancer (including similarities and differences of such processes from the biological processes that regulate other cancers); and

(III) the epidemiology of such cancer.

(ii) SCIENTIFIC ADVANCES.—The identification of relevant emerging scientific areas and promising scientific advances in basic, translational, and clinical science relating to the areas described in subclauses (I) and (II) of clause (i).

(iii) RESEARCHERS.—A description of the availability of qualified individuals to conduct scientific research in the areas described in clause (i).

(iv) COORDINATED RESEARCH INITIATIVES.—The identification of the types of initiatives and partnerships for the coordination of intramural and extramural research of the Institute in the areas described in clause (i) with research of the relevant national research institutes, Federal agencies, and non-Federal public and private entities in such areas.

(v) RESEARCH RESOURCES.—The identification of public and private resources, such as patient registries and tissue banks, that are available to facilitate research relating to each of the areas described in clause (i).

(B) IDENTIFICATION OF RESEARCH QUESTIONS.—The identification of research questions relating to basic, translational, and clinical science in the areas described in subclauses (I) and (II) of subparagraph (A)(i) that have not been adequately addressed with respect to such recalcitrant cancer.

(C) RECOMMENDATIONS.—Recommendations for appropriate actions that should be taken to advance research in the areas described in subparagraph (A)(i) and to address the research questions identified in subparagraph (B), as well as for appropriate benchmarks to measure progress on achieving such actions, including the following:

(i) RESEARCHERS.—Ensuring adequate availability of qualified individuals described in subparagraph (A)(iii).

(ii) COORDINATED RESEARCH INITIATIVES.—Promoting and developing initiatives and partnerships described in subparagraph (A)(iv).

(iii) RESEARCH RESOURCES.—Developing additional public and private resources described in subparagraph (A)(v) and strengthening existing resources.

(3) TIMING.—

(A) INITIAL DEVELOPMENT AND SUBSEQUENT UPDATE.—For each recalcitrant cancer identified under subsection (b)(1), the Director of the Institute shall—

(i) develop a scientific framework under this subsection not later than 18 months after the date of the enactment of this section; and

(ii) review and update the scientific framework not later than 5 years after its initial development.

(B) OTHER UPDATES.—The Director of the Institute may review and update each scientific framework developed under this subsection as necessary.

(4) PUBLIC NOTICE.—With respect to each scientific framework developed under subsection (a), not later than 30 days after the date of completion of the framework, the Director of the Institute shall—

(A) submit such framework to the Committee on Energy and Commerce and Committee on Appropriations of

the House of Representatives, and the Committee on Health, Education, Labor, and Pensions and Committee on Appropriations of the Senate; and

(B) make such framework publically available on the Internet website of the Department of Health and Human Services.

(b) IDENTIFICATION OF RECALCITRANT CANCER.—

(1) IN GENERAL.—Not later than 6 months after the date of the enactment of this section, the Director of the Institute shall identify two or more recalcitrant cancers that each—

(A) have a 5-year relative survival rate of less than 20 percent; and

(B) are estimated to cause the death of at least 30,000 individuals in the United States per year.

(2) ADDITIONAL CANCERS.—The Director of the Institute may, at any time, identify other recalcitrant cancers for purposes of this section. In identifying a recalcitrant cancer pursuant to the previous sentence, the Director may consider additional metrics of progress (such as incidence and mortality rates) against such type of cancer.

(c) WORKING GROUPS.—For each recalcitrant cancer identified under subsection (b), the Director of the Institute shall convene a working group comprised of representatives of appropriate Federal agencies and other non-Federal entities to provide expertise on, and assist in developing, a scientific framework under subsection (a). The Director of the Institute (or the Director's designee) shall participate in the meetings of each such working group.

(d) REPORTING.—

(1) BIENNIAL REPORTS.—The Director of NIH shall ensure that each biennial report under section 403 includes information on actions undertaken to carry out each scientific framework developed under subsection (a) with respect to a recalcitrant cancer, including the following:

(A) Information on research grants awarded by the National Institutes of Health for research relating to such cancer.

(B) An assessment of the progress made in improving outcomes (including relative survival rates) for individuals diagnosed with such cancer.

(C) An update on activities pertaining to such cancer under the authority of section 413(b)(7).

(2) ADDITIONAL ONE-TIME REPORT FOR CERTAIN FRAMEWORKS.—For each recalcitrant cancer identified under subsection (b)(1), the Director of the Institute shall, not later than 6 years after the initial development of a scientific framework under subsection (a), submit a report to the Congress on the effectiveness of the framework (including the update required by subsection (a)(3)(A)(ii)) in improving the prevention, detection, diagnosis, and treatment of such cancer.

(e) RECOMMENDATIONS FOR EXCEPTION FUNDING.—The Director of the Institute shall consider each relevant scientific framework developed under subsection (a) when making recommendations for exception funding for grant applications.

(f) DEFINITION.—In this section, the term "recalcitrant cancer" means a cancer for which the five-year relative survival rate is below 50 percent.

Subpart 2—National Heart, Lung, and Blood Institute

PURPOSE OF THE INSTITUTE.

SEC. 418.[285b] The general purpose of the National Heart, Lung, and Blood Institute (hereafter in this subpart referred to as the "Institute") is the conduct and support of research, training, health information dissemination, and other programs with respect to heart, blood vessel, lung, and blood diseases and with respect to the use of blood and blood products and the management of blood resources.

HEART, BLOOD VESSEL, LUNG, AND BLOOD DISEASE PREVENTION AND CONTROL PROGRAMS.

SEC. 419.[285b–1] (a) The Director of the Institute shall conduct and support programs for the prevention and control of heart, blood vessel, lung, and blood diseases. Such programs shall include community-based and population-based programs carried out in cooperation with other Federal agencies, with public health agencies of State or local governments, with nonprofit private entities that are community-based health agencies, or with other appropriate public or nonprofit private entities.

(b) In carrying out programs under subsection (a), the Director of the Institute shall give special consideration to the prevention and control of heart, blood vessel, lung, and blood diseases in children, and in populations that are at increased risk with respect to such diseases.

INFORMATION AND EDUCATION.

SEC. 420.[285b–2] The Director of the Institute shall collect, identify, analyze, and disseminate on a timely basis, through publications and other appropriate means, to patients, families of patients, physicians and other health professionals, and the general public, information on research, prevention, diagnosis, and treatment of heart, blood vessel, lung, and blood diseases, the maintenance of health to reduce the incidence of such diseases, and on the use of blood and blood products and the management of blood resources. In carrying out this section, the Director of the Institute shall place special emphasis upon the utilization of collaborative efforts with both the public and private sectors to—

(1) increase the awareness and knowledge of health care professionals and the public regarding the prevention of heart and blood vessel, lung, and blood diseases and the utilization of blood resources; and

(2) develop and disseminate to health professionals, patients and patient families, and the public information designed to encourage adults and children to adopt healthful practices concerning the prevention of such diseases.

NATIONAL HEART, BLOOD VESSEL, LUNG, AND BLOOD DISEASES AND BLOOD RESOURCES PROGRAM.

SEC. 421.[285b–3] (a)(1) The National Heart, Blood Vessel, Lung, and Blood Diseases and Blood Resources Program (hereafter in this subpart referred to as the "Program" may provide for—

(A) investigation into the epidemiology, etiology, and prevention of all forms and aspects of heart, blood vessel, lung, and blood diseases, including investigations into the social, environmental, behavioral, nutritional, biological, and genetic determinants and influences involved in the epidemiology, etiology, and prevention of such diseases;

(B) studies and research into the basic biological processes and mechanisms involved in the underlying normal and abnormal heart, blood vessel, lung, and blood phenomena;

(C) research into the development, trial, and evaluation of techniques, drugs, and devices (including computers) used in, and approaches to, the diagnosis, treatment (including the provision of emergency medical services), and prevention of heart, blood vessel, lung, and blood diseases and the rehabilitation of patients suffering from such diseases;

(D) establishment of programs that will focus and apply scientific and technological efforts involving the biological, physical, and engineering sciences to all facets of heart, blood vessel, lung, and blood diseases with emphasis on the refinement, development, and evaluation of technological devices that will assist, replace, or monitor vital organs and improve instrumentation for detection, diagnosis, and treatment of and rehabilitation from such diseases;

(E) establishment of programs for the conduct and direction of field studies, large-scale testing and evaluation, and demonstration of preventive, diagnostic, therapeutic, and rehabilitative approaches to, and emergency medical services for, such diseases;

(F) studies and research into blood diseases and blood, and into the use of blood for clinical purposes and all aspects of the management of blood resources in the United States, including the collection, preservation, fractionation, and distribution of blood and blood products;

(G) the education (including continuing education) and training of scientists, clinical investigators, and educators, in fields and specialties (including computer sciences) requisite to the conduct of clinical programs respecting heart, blood vessel, lung, and blood diseases and blood resources;

(H) public and professional education relating to all aspects of such diseases, including the prevention of such diseases, and the use of blood and blood products and the management of blood resources;

(I) establishment of programs for study and research into heart, blood vessel, lung, and blood diseases of children (including cystic fibrosis, hyaline membrane, hemolytic diseases such as sickle cell anemia and Cooley's anemia, and hemophilic diseases) and for the development and demonstration of diag-

nostic, treatment, and preventive approaches to such diseases; and

(J) establishment of programs for study, research, development, demonstrations and evaluation of emergency medical services for people who become critically ill in connection with heart, blood vessel, lung, or blood diseases.

(2) The Program shall be coordinated with other national research institutes to the extent that they have responsibilities respecting such diseases and shall give special emphasis to the continued development in the Institute of programs related to the causes of stroke and to effective coordination of such programs with related stroke programs in the National Institute of Neurological and Communicative Disorders and Stroke. The Director of the Institute, with the advice of the advisory council for the Institute, shall revise annually the plan for the Program and shall carry out the Program in accordance with such plan.

(b) In carrying out the Program, the Director of the Institute, under policies established by the Director of NIH—

(1) may, after consultation with the advisory council for the Institute, obtain (in accordance with section 3109 of title 5, United States Code, but without regard to the limitation in such section on the period of such service) the services of not more than one hundred experts or consultants who have scientific or professional qualifications;

(2)(A) may, in consultation with the advisory council for the Institute, acquire and construct, improve, repair, operate, alter, renovate, and maintain, heart, blood vessel, lung, and blood disease and blood resource laboratories, research, training, and other facilities, equipment, and such other real or personal property as the Director determines necessary;

(B) may, in consultation with the advisory council for the Institute, make grants for construction or renovation of facilities; and

(C) may, in consultation with the advisory council for the Institute, acquire, without regard to the Act of March 3, 1877 (40 U.S.C. 34), by lease or otherwise, through the Administrator of General Services, buildings or parts of buildings in the District of Columbia or communities located adjacent to the District of Columbia for the use of the Institute for a period not to exceed ten years;

(3) subject to section 405(b)(2) and without regard to section 3324 of title 31, United States Code, and section 3709 of the Revised Statutes (41 U.S.C. 5), may enter into such contracts, leases, cooperative agreements, or other transactions, as may be necessary in the conduct of the Director's functions, with any public agency, or with any person, firm, association, corporation, or educational institutions;

(4) may make grants to public and nonprofit private entities to assist in meeting the cost of the care of patients in hospitals, clinics, and related facilities who are participating in research projects; and

(5) shall, in consultation with the advisory council for the Institute, conduct appropriate intramural training and edu-

cation programs, including continuing education and laboratory and clinical research training programs.

Except as otherwise provided, experts and consultants whose services are obtained under paragraph (1) shall be paid or reimbursed, in accordance with title 5, United States Code, for their travel to and from their place of service and for other expenses associated with their assignment. Such expenses shall not be allowed in connection with the assignment of an expert or consultant whose services are obtained under paragraph (1) unless the expert or consultant has agreed in writing to complete the entire period of the assignment or one year of the assignment, whichever is shorter, unless separated or reassigned for reasons which are beyond the control of the expert or consultant and which are acceptable to the Director of the Institute. If the expert or consultant violates the agreement, the money spent by the United States for such expenses is recoverable from the expert or consultant as a debt due the United States. The Secretary may waive in whole or in part a right of recovery under the preceding sentence.

NATIONAL RESEARCH AND DEMONSTRATION CENTERS FOR HEART, BLOOD VESSEL, LUNG, AND BLOOD DISEASES, SICKLE CELL ANEMIA, AND BLOOD RESOURCES.

SEC. 422.[285b–4] (a)(1) The Director of the Institute may provide, in accordance with subsection (c), for the development of—

(A) ten centers for basic and clinical research into, training in, and demonstration of, advanced diagnostic, prevention, and treatment and rehabilitation methods (including methods of providing emergency medical services) for heart and blood vessel diseases;

(B) ten centers for basic and clinical research into, training in, and demonstration of, advanced diagnostic, prevention, and treatment and rehabilitation methods (including methods of providing emergency medical services) for lung diseases (including bronchitis, emphysema, asthma, cystic fibrosis, and other lung diseases of children);

(C) ten centers for basic and clinical research into, training in, and demonstration of, advanced diagnostic, prevention, and treatment methods (including methods of providing emergency medical services) for blood diseases and research into blood, in the use of blood products and in the management of blood resources; and

(D) three centers for basic and clinical research into, training in, and demonstration of, advanced diagnostic, prevention, and treatment (including genetic studies, intrauterine environment studies, postnatal studies, heart arrhythmias, and acquired heart disease and preventive cardiology) for cardiovascular diseases in children.

(2) The centers developed under paragraph (1) shall, in addition to being utilized for research, training, and demonstrations, be utilized for the following prevention programs for cardiovascular, pulmonary, and blood diseases:

(A) Programs to develop improved methods of detecting individuals with a high risk of developing cardiovascular, pulmonary, and blood diseases.

(B) Programs to develop improved methods of intervention against those factors which cause individuals to have a high risk of developing such diseases.

(C) Programs to develop health professions and allied health professions personnel highly skilled in the prevention of such diseases.

(D) Programs to develop improved methods of providing emergency medical services for persons with such diseases.

(E) Programs of continuing education for health and allied health professionals in the diagnosis, prevention, and treatment of such diseases and the maintenance of health to reduce the incidence of such diseases and information programs for the public respecting the prevention and early diagnosis and treatment of such diseases and the maintenance of health.

(3) The research, training, and demonstration activities carried out through any such center may relate to any one or more of the diseases referred to in paragraph (1) of this subsection.

(b) The Director of the Institute shall provide, in accordance with subsection (c), for the development of ten centers for basic and clinical research into the diagnosis, treatment, and control of sickle cell anemia.

(c)(1) The Director of the Institute may enter into cooperative agreements with and make grants to public or private nonprofit entities to pay all or part of the cost of planning, establishing, or strengthening, and providing basic operating support for centers for basic and clinical research into, training in, and demonstration of the management of blood resources and advanced diagnostic, prevention, and treatment methods for heart, blood vessel, lung, or blood diseases.

(2) A cooperative agreement or grant under paragraph (1) shall be entered into in accordance with policies established by the Director of NIH and after consultation with the Institute's advisory council.

(3) Federal payments made under a cooperative agreement or grant under paragraph (1) may be used for—

(A) construction (notwithstanding any limitation under section 496);

(B) staffing and other basic operating costs, including such patient care costs as are required for research;

(C) training, including training for allied health professionals; and

(D) demonstration purposes.

As used in this subsection, the term "construction" does not include the acquisition of land, and the term "training" does not include research training for which National Research Service Awards [22] may be provided under section 487.

(4) Support of a center under paragraph (1) may be for a period of not to exceed five years. Such period may be extended by the Director for additional periods of not more than five years each if the

[22] Now Ruth L. Kirschstein National Research Service Awards. See section 487.

operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

ASSOCIATE DIRECTOR FOR PREVENTION.

SEC. 423.[285b–6] (a) There shall be in the Institute an Associate Director for Prevention to coordinate and promote the programs in the Institute concerning the prevention of heart, blood vessel, lung, and blood diseases. The Associate Director shall be appointed by the Director of the Institute from individuals who because of their professional training or experience are experts in public health or preventive medicine.

(b) The Associate Director for Prevention shall prepare for inclusion in the biennial report made under section 407 a description of the prevention activities of the Institute, including a description of the staff and resources allocated to those activities.

NATIONAL CENTER ON SLEEP DISORDERS RESEARCH.

SEC. 424.[285b–7] (a) Not later than 1 year after the date of the enactment of the National Institutes of Health Revitalization Act of 1993, the Director of the Institute shall establish the National Center on Sleep Disorders Research (in this section referred to as the "Center"). The Center shall be headed by a director, who shall be appointed by the Director of the Institute.

(b) The general purpose of the Center is—

(1) the conduct and support of research, training, health information dissemination, and other activities with respect to sleep disorders, including biological and circadian rhythm research, basic understanding of sleep, chronobiological and other sleep related research; and

(2) to coordinate the activities of the Center with similar activities of other Federal agencies, including the other agencies of the National Institutes of Health, and similar activities of other public entities and nonprofit entities.

(c)(1) The Director of the National Institutes of Health shall establish a board to be known as the Sleep Disorders Research Advisory Board (in this section referred to as the "Advisory Board").

(2) The Advisory Board shall advise, assist, consult with, and make recommendations to the Director of the National Institutes of Health, through the Director of the Institute, and the Director of the Center concerning matters relating to the scientific activities carried out by and through the Center and the policies respecting such activities, including recommendations with respect to the plan required in subsection (c)[23].

(3)(A) The Director of the National Institutes of Health shall appoint to the Advisory Board 12 appropriately qualified representatives of the public who are not officers or employees of the Federal Government. Of such members, eight shall be representatives of health and scientific disciplines with respect to sleep disorders and

[23] So in law. See section 503 of Public Law 103–43 (107 Stat. 159). Probably should be "subsection (d)".

four shall be individuals representing the interests of individuals with or undergoing treatment for sleep disorders.

(B) The following officials shall serve as ex officio members of the Advisory Board:

(i) The Director of the National Institutes of Health.

(ii) The Director of the Center.

(iii) The Director of the National Heart, Lung and Blood Institute.

(iv) The Director of the National Institute of Mental Health.

(v) The Director of the National Institute on Aging.

(vi) The Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development.

(vii) The Director of the National Institute of Neurological Disorders and Stroke.

(viii) The Assistant Secretary for Health.

(ix) The Assistant Secretary of Defense (Health Affairs).

(x) The Chief Medical Director of the Veterans' Administration.

(4) The members of the Advisory Board shall, from among the members of the Advisory Board, designate an individual to serve as the chair of the Advisory Board.

(5) Except as inconsistent with, or inapplicable to, this section, the provisions of section 406 shall apply to the advisory board[24] established under this section in the same manner as such provisions apply to any advisory council established under such section.

(d)(1) After consultation with the Director of the Center and the advisory board established under subsection (c), the Director of the National Institutes of Health shall develop a comprehensive plan for the conduct and support of sleep disorders research.

(2) The plan developed under paragraph (1) shall identify priorities with respect to such research and shall provide for the coordination of such research conducted or supported by the agencies of the National Institutes of Health.

(3) The Director of the National Institutes of Health (after consultation with the Director of the Center and the advisory board established under subsection (c)) shall revise the plan developed under paragraph (1) as appropriate.

(e) The Director of the Center, in cooperation with the Centers for Disease Control and Prevention, is authorized to coordinate activities with the Department of Transportation, the Department of Defense, the Department of Education, the Department of Labor, and the Department of Commerce to collect data, conduct studies, and disseminate public information concerning the impact of sleep disorders and sleep deprivation.

HEART ATTACK, STROKE, AND OTHER CARDIOVASCULAR DISEASES IN WOMEN.

SEC. 424A.[285b–7a] (a) IN GENERAL.—The Director of the Institute shall expand, intensify, and coordinate research and related

[24] So in law. See section 503 of Public Law 103–43 (107 Stat. 159). Probably should be capitalized.

activities of the Institute with respect to heart attack, stroke, and other cardiovascular diseases in women.

(b) COORDINATION WITH OTHER INSTITUTES.—The Director of the Institute shall coordinate activities under subsection (a) with similar activities conducted by the other national research institutes and agencies of the National Institutes of Health to the extent that such Institutes and agencies have responsibilities that are related to heart attack, stroke, and other cardiovascular diseases in women.

(c) CERTAIN PROGRAMS.—In carrying out subsection (a), the Director of the Institute shall conduct or support research to expand the understanding of the causes of, and to develop methods for preventing, cardiovascular diseases in women. Activities under such subsection shall include conducting and supporting the following:

(1) Research to determine the reasons underlying the prevalence of heart attack, stroke, and other cardiovascular diseases in women, including African-American women and other women who are members of racial or ethnic minority groups.

(2) Basic research concerning the etiology and causes of cardiovascular diseases in women.

(3) Epidemiological studies to address the frequency and natural history of such diseases and the differences among men and women, and among racial and ethnic groups, with respect to such diseases.

(4) The development of safe, efficient, and cost-effective diagnostic approaches to evaluating women with suspected ischemic heart disease.

(5) Clinical research for the development and evaluation of new treatments for women, including rehabilitation.

(6) Studies to gain a better understanding of methods of preventing cardiovascular diseases in women, including applications of effective methods for the control of blood pressure, lipids, and obesity.

(7) Information and education programs for patients and health care providers on risk factors associated with heart attack, stroke, and other cardiovascular diseases in women, and on the importance of the prevention or control of such risk factors and timely referral with appropriate diagnosis and treatment. Such programs shall include information and education on health-related behaviors that can improve such important risk factors as smoking, obesity, high blood cholesterol, and lack of exercise.

COORDINATION OF FEDERAL ASTHMA ACTIVITIES.

SEC. 424B[25] [285b–7b] (a) IN GENERAL.—The Director of Institute shall, through the National Asthma Education Prevention Program Coordinating Committee—

(1) identify all Federal programs that carry out asthma-related activities; and

[25] So in law. The section designation lacks a period. See section 521 of Public Law 106–310 (114 Stat. 1116).

(2) develop, in consultation with appropriate Federal agencies and professional and voluntary health organizations, a Federal plan for responding to asthma.

(b) REPRESENTATION OF THE DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT.—A representative of the Department of Housing and Urban Development shall be included on the National Asthma Education Prevention Program Coordinating Committee for the purpose of performing the tasks described in subsection (a).[26]

SEC. 424C.[285b–7c] TUBERCULOSIS.

(a) IN GENERAL.—The Director of the National Institutes of Health may expand, intensify, and coordinate research and development and related activities of the Institutes with respect to tuberculosis including activities toward the goal of eliminating such disease.

(b) CERTAIN ACTIVITIES.—Activities under subsection (a) may include—

(1) enhancing basic and clinical research on tuberculosis, including drug resistant tuberculosis;

(2) expanding research on the relationship between such disease and the human immunodeficiency virus; and

(3) developing new tools for the elimination of tuberculosis, including public health interventions and methods to enhance detection and response to outbreaks of tuberculosis, including multidrug resistant tuberculosis.

SEC. 425.[285b–8] CONGENITAL HEART DISEASE.

(a) IN GENERAL.—The Director of the Institute may expand, intensify, and coordinate research and related activities of the Institute with respect to congenital heart disease, which may include congenital heart disease research with respect to—

(1) causation of congenital heart disease, including genetic causes;

(2) long-term outcomes in individuals with congenital heart disease, including infants, children, teenagers, adults, and elderly individuals;

(3) diagnosis, treatment, and prevention;

(4) studies using longitudinal data and retrospective analysis to identify effective treatments and outcomes for individuals with congenital heart disease; and

(5) identifying barriers to life-long care for individuals with congenital heart disease.

(b) COORDINATION OF RESEARCH ACTIVITIES.—The Director of the Institute may coordinate research efforts related to congenital heart disease among multiple research institutions and may develop research networks.

(c) MINORITY AND MEDICALLY UNDERSERVED COMMUNITIES.—In carrying out the activities described in this section, the Director of the Institute shall consider the application of such research and other activities to minority and medically underserved communities.

[26] Section 425 was repealed by section 103(b)(20) of Public Law 109–482 (120 Stat. 3688).

Subpart 3—National Institute of Diabetes and Digestive and Kidney Diseases

PURPOSE OF THE INSTITUTE.

SEC. 426.[285c] The general purpose of the National Institute of Diabetes and Digestive and Kidney Diseases (hereafter in this subpart referred to as the "Institute") is the conduct and support of research, training, health information dissemination, and other programs with respect to diabetes mellitus and endocrine and metabolic diseases, digestive diseases and nutritional disorders, and kidney, urologic, and hematologic diseases.

DATA SYSTEMS AND INFORMATION CLEARINGHOUSES.

SEC. 427.[285c–1] (a) The Director of the Institute shall (1) establish the National Diabetes Data System for the collection, storage, analysis, retrieval, and dissemination of data derived from patient populations with diabetes, including, where possible, data involving general populations for the purpose of detection of individuals with a risk of developing diabetes, and (2) establish the National Diabetes Information Clearinghouse to facilitate and enhance knowledge and understanding of diabetes on the part of health professionals, patients, and the public through the effective dissemination of information.

(b) The Director of the Institute shall (1) establish the National Digestive Diseases Data System for the collection, storage, analysis, retrieval, and dissemination of data derived from patient populations with digestive diseases, including, where possible, data involving general populations for the purpose of detection of individuals with a risk of developing digestive diseases, and (2) establish the National Digestive Diseases Information Clearinghouse to facilitate and enhance knowledge and understanding of digestive diseases on the part of health professionals, patients, and the public through the effective dissemination of information.

(c) The Director of the Institute shall (1) establish the National Kidney and Urologic Diseases Data System for the collection, storage, analysis, retrieval, and dissemination of data derived from patient populations with kidney and urologic diseases, including, where possible, data involving general populations for the purpose of detection of individuals with a risk of developing kidney and urologic diseases, and (2) establish the National Kidney and Urologic Diseases Information Clearinghouse to facilitate and enhance knowledge and understanding of kidney and urologic diseases on the part of health professionals, patients, and the public through the effective dissemination of information.

DIVISION DIRECTORS FOR DIABETES, ENDOCRINOLOGY, AND METABOLIC DISEASES, DIGESTIVE DISEASES AND NUTRITION, AND KIDNEY, UROLOGIC, AND HEMATOLOGIC DISEASES.

SEC. 428.[285c–2] (a)(1) In the Institute there shall be a Division Director for Diabetes, Endocrinology, and Metabolic Diseases, a Division Director for Digestive Diseases and Nutrition, and a Division Director for Kidney, Urologic, and Hematologic Diseases.

Such Division Directors, under the supervision of the Director of the Institute, shall be responsible for—

(A) developing a coordinated plan (including recommendations for expenditures) for each of the national research institutes within the National Institutes of Health with respect to research and training concerning diabetes, endocrine and metabolic diseases, digestive diseases and nutrition, and kidney, urologic, and hematologic diseases;

(B) assessing the adequacy of management approaches for the activities within such institutes concerning such diseases and nutrition and developing improved approaches if needed;

(C) monitoring and reviewing expenditures by such institutes concerning such diseases and nutrition; and

(D) identifying research opportunities concerning such diseases and nutrition and recommending ways to utilize such opportunities.

(2) The Director of the Institute shall transmit to the Director of NIH the plans, recommendations, and reviews of the Division Directors under subparagraphs (A) through (D) of paragraph (1) together with such comments and recommendations as the Director of the Institute determines appropriate.

(b) The Director of the Institute, acting through the Division Director for Diabetes, Endocrinology, and Metabolic Diseases, the Division Director for Digestive Diseases and Nutrition, and the Division Director for Kidney, Urologic, and Hematologic Diseases, shall—

(1) carry out programs of support for research and training (other than training for which National Research Service Awards[27] may be made under section 487) in the diagnosis, prevention, and treatment of diabetes mellitus and endocrine and metabolic diseases, digestive diseases and nutritional disorders, and kidney, urologic, and hematologic diseases, including support for training in medical schools, graduate clinical training, graduate training in epidemiology, epidemiology studies, clinical trials, and interdisciplinary research programs; and

(2) establish programs of evaluation, planning, and dissemination of knowledge related to such research and training.

INTERAGENCY COORDINATING COMMITTEES.

SEC. 429.[285c–3] (a) For the purpose of—

(1) better coordination of the research activities of all the national research institutes relating to diabetes mellitus, digestive diseases, and kidney, urologic, and hematologic diseases; and

(2) coordinating those aspects of all Federal health programs and activities relating to such diseases to assure the adequacy and technical soundness of such programs and activities and to provide for the full communication and exchange of information necessary to maintain adequate coordination of such programs and activities;

the Secretary shall establish a Diabetes Mellitus Interagency Coordinating Committee, a Digestive Diseases Interagency Coordi-

[27] Now Ruth L. Kirschstein National Research Service Awards. See section 487.

nating Committee, and a Kidney, Urologic, and Hematologic Diseases Coordinating Committee (hereafter in this section individually referred to as a "Committee").

(b) Each Committee shall be composed of the Directors of each of the national research institutes and divisions involved in research with respect to the diseases for which the Committee is established, the Division Director of the Institute for the diseases for which the Committee is established, the Chief Medical Director of the Veterans' Administration, and the Assistant Secretary of Defense for Health Affairs (or the designees of such officers) and shall include representation from all other Federal departments and agencies whose programs involve health functions or responsibilities relevant to such diseases, as determined by the Secretary. Each Committee shall be chaired by the Director of NIH (or the designee of the Director). Each Committee shall meet at the call of the chairman, but not less often than four times a year.

ADVISORY BOARDS.

SEC. 430.[285c–4] (a) The Secretary shall establish in the Institute the National Diabetes Advisory Board, the National Digestive Diseases Advisory Board, and the National Kidney and Urologic Diseases Advisory Board (hereafter in this section individually referred to as an "Advisory Board").

(b) Each Advisory Board shall be composed of eighteen appointed members and nonvoting ex officio members as follows:

(1) The Secretary shall appoint—

(A) twelve members from individuals who are scientists, physicians, and other health professionals, who are not officers or employees of the United States, and who represent the specialties and disciplines relevant to the diseases with respect to which the Advisory Board is established; and

(B) six members from the general public who are knowledgeable with respect to such diseases, including at least one member who is a person who has such a disease and one member who is a parent of a person who has such a disease.

Of the appointed members at least five shall by virtue of training or experience be knowledgeable in the fields of health education, nursing, data systems, public information, and community program development.

(2)(A) The following shall be ex officio members of each Advisory Board:

(i) The Assistant Secretary for Health, the Director of NIH, the Director of the National Institute of Diabetes and Digestive and Kidney Diseases, the Director of the Centers for Disease Control and Prevention, the Chief Medical Director of the Department of Veterans Affairs, the Assistant Secretary of Defense for Health Affairs, and the Division Director of the National Institute of Diabetes and Digestive and Kidney Diseases for the diseases for which the Board is established (or the designees of such officers).

(ii) Such other officers and employees of the United States as the Secretary determines necessary for the Advisory Board to carry out its functions.

(B) In the case of the National Diabetes Advisory Board, the following shall also be ex officio members: The Director of the National Heart, Lung, and Blood Institute, the Director of the National Eye Institute, the Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development, and the Administrator of the Health Resources and Services Administration (or the designees of such officers).

(c) Members of an Advisory Board who are officers or employees of the Federal Government shall serve as members of the Advisory Board without compensation in addition to that received in their regular public employment. Other members of the Board shall receive compensation at rates not to exceed the daily equivalent of the annual rate in effect for grade GS–18 of the General Schedule for each day (including traveltime) they are engaged in the performance of their duties as members of the Board.

(d) The term of office of an appointed member of an Advisory Board is four years, except that no term of office may extend beyond the expiration of the Advisory Board. Any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term. A member may serve after the expiration of the member's term until a successor has taken office. If a vacancy occurs in an Advisory Board, the Secretary shall make an appointment to fill the vacancy not later than 90 days from the date the vacancy occurred.

(e) The members of each Advisory Board shall select a chairman from among the appointed members.

(f) The Secretary shall, after consultation with and consideration of the recommendations of an Advisory Board, provide the Advisory Board with an executive director and one other professional staff member. In addition, the Secretary shall, after consultation with and consideration of the recommendations of the Advisory Board, provide the Advisory Board with such additional professional staff members, such clerical staff members, such services of consultants, such information, and (through contracts or other arrangements) such administrative support services and facilities, as the Secretary determines are necessary for the Advisory Board to carry out its functions.

(g) Each Advisory Board shall meet at the call of the chairman or upon request of the Director of the Institute, but not less often than four times a year.

(h) The National Diabetes Advisory Board and the National Digestive Diseases Advisory Board shall—

(1) review and evaluate the implementation of the plan (referred to in section 433) respecting the diseases with respect to which the Advisory Board was established and periodically update the plan to ensure its continuing relevance;

(2) for the purpose of assuring the most effective use and organization of resources respecting such diseases, advise and make recommendations to the Congress, the Secretary, the Director of NIH, the Director of the Institute, and the heads of

other appropriate Federal agencies for the implementation and revision of such plan; and

(3) maintain liaison with other advisory bodies related to Federal agencies involved in the implementation of such plan, the coordinating committee for such diseases, and with key non-Federal entities involved in activities affecting the control of such diseases.

(i) In carrying out its functions, each Advisory Board may establish subcommittees, convene workshops and conferences, and collect data. Such subcommittees may be composed of Advisory Board members and nonmember consultants with expertise in the particular area addressed by such subcommittees. The subcommittees may hold such meetings as are necessary to enable them to carry out their activities.

(j) The National Diabetes Advisory Board and the National Digestive Diseases Advisory Board in existence on the date of enactment of the Health Research Extension Act of 1985 shall terminate upon the appointment of a successor Board under subsection (a). The Secretary shall make appointments to the Advisory Boards established under subsection (a) before the expiration of 90 days after such date. The members of the Boards in existence on such date may be appointed, in accordance with subsections (b) and (d), to the Boards established under subsection (a) for diabetes and digestive diseases, except that at least one-half of the members of the National Diabetes Advisory Board in existence on the date of enactment of the Health Research Extension Act of 1985 shall be appointed to the National Diabetes Advisory Board first established under subsection (a).

RESEARCH AND TRAINING CENTERS.

SEC. 431.[285c–5] (a)(1) Consistent with applicable recommendations of the National Commission on Diabetes, the Director of the Institute shall provide for the development or substantial expansion of centers for research and training in diabetes mellitus and related endocrine and metabolic diseases. Each center developed or expanded under this subsection shall—

(A) utilize the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such research and training qualifications as may be prescribed by the Secretary; and

(B) conduct—

(i) research in the diagnosis and treatment of diabetes mellitus and related endocrine and metabolic diseases and the complications resulting from such diseases;

(ii) training programs for physicians and allied health personnel in current methods of diagnosis and treatment of such diseases and complications, and in research in diabetes; and

(iii) information programs for physicians and allied health personnel who provide primary care for patients with such diseases or complications.

(2) A center may use funds provided under paragraph (1) to provide stipends for nurses and allied health professionals enrolled in research training programs described in paragraph (1)(B)(ii).

(b) Consistent with applicable recommendations of the National Digestive Diseases Advisory Board, the Director shall provide for the development or substantial expansion of centers for research in digestive diseases and related functional, congenital, metabolic disorders, and normal development of the digestive tract. Each center developed or expanded under this subsection—

(1) shall utilize the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such research qualifications as may be prescribed by the Secretary;

(2) shall develop and conduct basic and clinical research into the cause, diagnosis, early detection, prevention, control, and treatment of digestive diseases and nutritional disorders and related functional, congenital, or metabolic complications resulting from such diseases or disorders;

(3) shall encourage research into and programs for—

(A) providing information for patients with such diseases and the families of such patients, physicians and others who care for such patients, and the general public;

(B) model programs for cost effective and preventive patient care; and

(C) training physicians and scientists in research on such diseases, disorders, and complications; and

(4) may perform research and participate in epidemiological studies and data collection relevant to digestive diseases and disorders and disseminate such research, studies, and data to the health care profession and to the public.

(c) The Director shall provide for the development or substantial expansion of centers for research in kidney and urologic diseases. Each center developed or expanded under this subsection—

(1) shall utilize the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such research qualifications as may be prescribed by the Secretary;

(2) shall develop and conduct basic and clinical research into the cause, diagnosis, early detection, prevention, control, and treatment of kidney and urologic diseases;

(3) shall encourage research into and programs for—

(A) providing information for patients with such diseases, disorders, and complications and the families of such patients, physicians and others who care for such patients, and the general public;

(B) model programs for cost effective and preventive patient care; and

(C) training physicians and scientists in research on such diseases; and

(4) may perform research and participate in epidemiological studies and data collection relevant to kidney and urologic diseases in order to disseminate such research, studies, and data to the health care profession and to the public.

(d)(1) The Director of the Institute shall, subject to the extent of amounts made available in appropriations Acts, provide for the development or substantial expansion of centers for research and training regarding nutritional disorders, including obesity.

(2) The Director of the Institute shall carry out paragraph (1) in collaboration with the Director of the National Cancer Institute and with the Directors of such other agencies of the National Institutes of Health as the Director of NIH determines to be appropriate.

(3) Each center developed or expanded under paragraph (1) shall—

(A) utilize the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such research and training qualifications as may be prescribed by the Director;

(B) conduct basic and clinical research into the cause, diagnosis, early detection, prevention, control and treatment of nutritional disorders, including obesity and the impact of nutrition and diet on child development;

(C) conduct training programs for physicians and allied health professionals in current methods of diagnosis and treatment of such diseases and complications, and in research in such disorders; and

(D) conduct information programs for physicians and allied health professionals who provide primary care for patients with such disorders or complications.

(e) Insofar as practicable, centers developed or expanded under this section should be geographically dispersed throughout the United States and in environments with proven research capabilities. Support of a center under this section may be for a period of not to exceed five years and such period may be extended by the Director of the Institute for additional periods of not more than five years each if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

ADVISORY COUNCIL SUBCOMMITTEES.

SEC. 432.[285c–6] There are established within the advisory council for the Institute appointed under section 406 a subcommittee on diabetes and endocrine and metabolic diseases, a subcommittee on digestive diseases and nutrition, and a subcommittee on kidney, urologic, and hematologic diseases. The subcommittees shall be composed of members of the advisory council who are outstanding in the diagnosis, prevention, and treatment of the diseases for which the subcommittees are established and members of the advisory council who are leaders in the fields of education and public affairs. The subcommittees are authorized to review applications made to the Director of the Institute for grants for research and training projects relating to the diagnosis, prevention, and treatment of the diseases for which the subcommittees are established and shall recommend to the advisory council those applications and contracts that the subcommittees determine will

best carry out the purposes of the Institute. The subcommittees shall also review and evaluate the diabetes and endocrine and metabolic diseases, digestive diseases and nutrition, and kidney, urologic, and hematologic diseases programs of the Institute and recommend to the advisory council such changes in the administration of such programs as the subcommittees determine are necessary.

BIENNIAL REPORT.

SEC. 433.[285c–7] The Director of the Institute shall prepare for inclusion in the biennial report made under section 407 a description of the Institute's activities—

(1) under the current diabetes plan under the National Diabetes Mellitus Research and Education Act; and

(2) under the current digestive diseases plan formulated under the Arthritis, Diabetes, and Digestive Diseases Amendments of 1976.

The description submitted by the Director shall include an evaluation of the activities of the centers supported under section 431.

NUTRITIONAL DISORDERS PROGRAM.

SEC. 434.[285c–8] (a) The Director of the Institute, in consultation with the Director of NIH, shall establish a program of conducting and supporting research, training, health information dissemination, and other activities with respect to nutritional disorders, including obesity.

(b) In carrying out the program established under subsection (a), the Director of the Institute shall conduct and support each of the activities described in such subsection.

(c) In carrying out the program established under subsection (a), the Director of the Institute shall carry out activities to facilitate and enhance knowledge and understanding of nutritional disorders, including obesity, on the part of health professionals, patients, and the public through the effective dissemination of information.

JUVENILE DIABETES.

SEC. 434A.[285c–9] (a) LONG-TERM EPIDEMIOLOGY STUDIES.—The Director of the Institute shall conduct or support long-term epidemiology studies in which individuals with or at risk for type 1, or juvenile, diabetes are followed for 10 years or more. Such studies shall investigate the causes and characteristics of the disease and its complications.

(b) CLINICAL TRIAL INFRASTRUCTURE/INNOVATIVE TREATMENTS FOR JUVENILE DIABETES.—The Secretary, acting through the Director of the National Institutes of Health, shall support regional clinical research centers for the prevention, detection, treatment, and cure of juvenile diabetes.

(c) PREVENTION OF TYPE 1 DIABETES.—The Secretary, acting through the appropriate agencies, shall provide for a national effort to prevent type 1 diabetes. Such effort shall provide for a combination of increased efforts in research and development of prevention strategies, including consideration of vaccine development, coupled

with appropriate ability to test the effectiveness of such strategies in large clinical trials of children and young adults.

Subpart 4—National Institute of Arthritis and Musculoskeletal and Skin Diseases

PURPOSE OF THE INSTITUTE.

SEC. 435.[285d] The general purpose of the National Institute of Arthritis and Musculoskeletal and Skin Diseases (hereafter in this subpart referred to as the "Institute") is the conduct and support of research and training, the dissemination of health information, and other programs with respect to arthritis and musculoskeletal and skin diseases (including sports-related disorders), with particular attention to the effect of these diseases on children.

NATIONAL ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES PROGRAM.

SEC. 436.[285d–1] (a) The Director of the Institute, with the advice of the Institute's advisory council, shall prepare and transmit to the Director of NIH a plan for a national arthritis and musculoskeletal and skin diseases program to expand, intensify, and coordinate the activities of the Institute respecting arthritis and musculoskeletal and skin diseases. The plan shall include such comments and recommendations as the Director of the Institute determines appropriate. The plan shall place particular emphasis upon expanding research into better understanding the causes and the development of effective treatments for arthritis affecting children. The Director of the Institute shall periodically review and revise such plan and shall transmit any revisions of such plan to the Director of NIH.

(b) Activities under the national arthritis and musculoskeletal and skin diseases program shall be coordinated with the other national research institutes to the extent that such institutes have responsibilities respecting arthritis and musculoskeletal and skin diseases, and shall, at least, provide for—

(1) investigation into the epidemiology, etiology, and prevention of all forms of arthritis and musculoskeletal and skin diseases, including sports-related disorders, primarily through the support of basic research in such areas as immunology, genetics, biochemistry, microbiology, physiology, bioengineering, and any other scientific discipline which can contribute important knowledge to the treatment and understanding of arthritis and musculoskeletal and skin diseases;

(2) research into the development, trial, and evaluation of techniques, drugs, and devices used in the diagnosis, treatment, including medical rehabilitation, and prevention of arthritis and musculoskeletal and skin diseases;

(3) research on the refinement, development, and evaluation of technological devices that will replace or be a substitute for damaged bone, muscle, and joints and other supporting structures;

(4) the establishment of mechanisms to monitor the causes of athletic injuries and identify ways of preventing such injuries on scholastic athletic fields; and

(5) research into the causes of arthritis affecting children and the development, trial, and evaluation of techniques, drugs and devices used in the diagnosis, treatment (including medical rehabilitation), and prevention of arthritis in children.

(c) The Director of the Institute shall carry out the national arthritis and musculoskeletal and skin diseases program in accordance with the plan prepared under subsection (a) and any revisions of such plan made under such subsection.

RESEARCH AND TRAINING.

SEC. 437.[285d–2] The Director of the Institute shall—

(1) carry out programs of support for research and training (other than training for which National Research Service Awards[28] may be made under section 487) in the diagnosis, prevention, and treatment of arthritis and musculoskeletal and skin diseases, including support for training in medical schools, graduate clinical training, graduate training in epidemiology, epidemiology studies, clinical trials, and interdisciplinary research programs; and

(2) establish programs of evaluation, planning, and dissemination of knowledge related to such research and training.

DATA SYSTEM AND INFORMATION CLEARINGHOUSE.

SEC. 438.[285d–3] (a) The Director of the Institute shall establish the National Arthritis and Musculoskeletal and Skin Diseases Data System for the collection, storage, analysis, retrieval, and dissemination of data derived from patient populations with arthritis and musculoskeletal and skin diseases, including where possible, data involving general populations for the purpose of detection of individuals with a risk of developing arthritis and musculoskeletal and skin diseases.

(b) The Director of the Institute shall establish the National Arthritis and Musculoskeletal and Skin Diseases Information Clearinghouse to facilitate and enhance, through the effective dissemination of information, knowledge and understanding of arthritis and musculoskeletal and skin diseases, including juvenile arthritis and related conditions, by health professionals, patients, and the public.

INTERAGENCY COORDINATING COMMITTEES.

SEC. 439.[285d–4] (a) For the purpose of—

(1) better coordination of the research activities of all the national research institutes relating to arthritis, musculoskeletal diseases, and skin diseases, including sports-related disorders; and

(2) coordinating the aspects of all Federal health programs and activities relating to arthritis, musculoskeletal diseases, and skin diseases in order to assure the adequacy and tech-

[28] Now Ruth L. Kirschstein National Research Service Awards. See section 487.

nical soundness of such programs and activities and in order to provide for the full communication and exchange of information necessary to maintain adequate coordination of such programs and activities,

the Secretary shall establish an Arthritis and Musculoskeletal Diseases Interagency Coordinating Committee and a Skin Diseases Interagency Coordinating Committee (hereafter in this section individually referred to as a "Committee").

(b) Each Committee shall be composed of the Directors of each of the national research institutes and divisions involved in research regarding the diseases with respect to which the Committee is established, the Chief Medical Director of the Department of Veterans Affairs, and the Assistant Secretary of Defense for Health Affairs (or the designees of such officers), and representatives of all other Federal departments and agencies (as determined by the Secretary) whose programs involve health functions or responsibilities relevant to arthritis and musculoskeletal diseases or skin diseases, as the case may be. Each Committee shall be chaired by the Director of NIH (or the designee of the Director). Each Committee shall meet at the call of the chairman, but not less often than four times a year.

ARTHRITIS AND MUSCULOSKELETAL DISEASES DEMONSTRATION PROJECTS.

SEC. 440.[285d–5] (a) The Director of the Institute may make grants to public and private nonprofit entities to establish and support projects for the development and demonstration of methods for screening, detection, and referral for treatment of arthritis and musculoskeletal diseases and for the dissemination of information on such methods to the health and allied health professions. Activities under such projects shall be coordinated with Federal, State, local, and regional health agencies, centers assisted under section 441, and the data system established under subsection (c).

(b) Projects supported under this section shall include—

(1) programs which emphasize the development and demonstration of new and improved methods of screening and early detection, referral for treatment, and diagnosis of individuals with a risk of developing arthritis and musculoskeletal diseases;

(2) programs which emphasize the development and demonstration of new and improved methods for patient referral from local hospitals and physicians to appropriate centers for early diagnosis and treatment;

(3) programs which emphasize the development and demonstration of new and improved means of standardizing patient data and recordkeeping;

(4) programs which emphasize the development and demonstration of new and improved methods of dissemination of knowledge about the programs, methods, and means referred to in paragraphs (1), (2), and (3) of this subsection to health and allied health professionals;

(5) programs which emphasize the development and demonstration of new and improved methods for the dissemination to the general public of information—

(A) on the importance of early detection of arthritis and musculoskeletal diseases, of seeking prompt treatment, and of following an appropriate regimen; and

(B) to discourage the promotion and use of unapproved and ineffective diagnostic, preventive treatment, and control methods for arthritis and unapproved and ineffective drugs and devices for arthritis and musculoskeletal diseases; and

(6) projects for investigation into the epidemiology of all forms and aspects of arthritis and musculoskeletal diseases, including investigations into the social, environmental, behavioral, nutritional, and genetic determinants and influences involved in the epidemiology of arthritis and musculoskeletal diseases.

(c) The Director shall provide for the standardization of patient data and recordkeeping for the collection, storage, analysis, retrieval, and dissemination of such data in cooperation with projects assisted under this section, centers assisted under section 441, and other persons engaged in arthritis and musculoskeletal disease programs.

MULTIPURPOSE ARTHRITIS AND MUSCULOSKELETAL DISEASES CENTERS.

SEC. 441.[285d–6] (a) The Director of the Institute shall, after consultation with the advisory council for the Institute, provide for the development, modernization, and operation (including staffing and other operating costs such as the costs of patient care required for research) of new and existing centers for arthritis and musculoskeletal diseases. For purposes of this section, the term "modernization" means the alteration, remodeling, improvement, expansion, and repair of existing buildings and the provision of equipment for such buildings to the extent necessary to make them suitable for use as centers described in the preceding sentence.

(b) Each center assisted under this section shall—

(1)(A) use the facilities of a single institution or a consortium of cooperating institutions, and (B) meet such qualifications as may be prescribed by the Secretary; and

(2) conduct—

(A) basic and clinical research into the cause, diagnosis, early detection, prevention, control, and treatment of and rehabilitation from arthritis and musculoskeletal diseases and complications resulting from arthritis and musculoskeletal diseases, including research into implantable biomaterials and biomechanical and other orthopedic procedures;

(B) training programs for physicians, scientists, and other health and allied health professionals;

(C) information and continuing education programs for physicians and other health and allied health professionals

who provide care for patients with arthritis and musculoskeletal diseases; and

(D) programs for the dissemination to the general public of information—

(i) on the importance of early detection of arthritis and musculoskeletal diseases, of seeking prompt treatment, and of following an appropriate regimen; and

(ii) to discourage the promotion and use of unapproved and ineffective diagnostic, preventive, treatment, and control methods and unapproved and ineffective drugs and devices.

A center may use funds provided under subsection (a) to provide stipends for health professionals enrolled in training programs described in paragraph (2)(B).

(c) Each center assisted under this section may conduct programs to—

(1) establish the effectiveness of new and improved methods of detection, referral, and diagnosis of individuals with a risk of developing arthritis and musculoskeletal diseases;

(2) disseminate the results of research, screening, and other activities, and develop means of standardizing patient data and recordkeeping; and

(3) develop community consultative services to facilitate the referral of patients to centers for treatment.

(d) The Director of the Institute shall, insofar as practicable, provide for an equitable geographical distribution of centers assisted under this section. The Director shall give appropriate consideration to the need for centers especially suited to meeting the needs of children affected by arthritis and musculoskeletal diseases.

(e) Support of a center under this section may be for a period of not to exceed five years. Such period may be extended by the Director of the Institute for one or more additional periods of not more than five years if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

(f) Not later than October 1, 1993, the Director shall establish a multipurpose arthritis and musculoskeletal disease center for the purpose of expanding the level of research into the cause, diagnosis, early detection, prevention, control, and treatment of, and rehabilitation of children with arthritis and musculoskeletal diseases.

LUPUS.

SEC. 441A.[285d–6a] (a) IN GENERAL.—The Director of the Institute shall expand and intensify research and related activities of the Institute with respect to lupus.

(b) COORDINATION WITH OTHER INSTITUTES.—The Director of the Institute shall coordinate the activities of the Director under subsection (a) with similar activities conducted by the other national research institutes and agencies of the National Institutes of Health to the extent that such Institutes and agencies have responsibilities that are related to lupus.

(c) PROGRAMS FOR LUPUS.—In carrying out subsection (a), the Director of the Institute shall conduct or support research to expand the understanding of the causes of, and to find a cure for, lupus. Activities under such subsection shall include conducting and supporting the following:

(1) Research to determine the reasons underlying the elevated prevalence of lupus in women, including African-American women.

(2) Basic research concerning the etiology and causes of the disease.

(3) Epidemiological studies to address the frequency and natural history of the disease and the differences among the sexes and among racial and ethnic groups with respect to the disease.

(4) The development of improved diagnostic techniques.

(5) Clinical research for the development and evaluation of new treatments, including new biological agents.

(6) Information and education programs for health care professionals and the public.

ADVISORY BOARD.

SEC. 442.[285d–7] (a) The Secretary shall establish in the Institute the National Arthritis and Musculoskeletal and Skin Diseases Advisory Board (hereafter in this section referred to as the "Advisory Board").

(b) The Advisory Board shall be composed of twenty appointed members and nonvoting, ex officio members, as follows:

(1) The Secretary shall appoint—

(A) twelve members from individuals who are scientists, physicians, and other health professionals, who are not officers or employees of the United States, and who represent the specialties and disciplines relevant to arthritis, musculoskeletal diseases, and skin diseases; and

(B) eight members from the general public who are knowledgeable with respect to such diseases, including one member who is a person who has such a disease, one person who is the parent of an adult with such a disease, and two members who are parents of children with arthritis.

Of the appointed members at least five shall by virtue of training or experience be knowledgeable in health education, nursing, data systems, public information, or community program development.

(2) The following shall be ex officio members of the Advisory Board:

(A) the Assistant Secretary for Health, the Director of NIH, the Director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the Director of the Centers for Disease Control and Prevention, the Chief Medical Director of the Department of Veterans Affairs, and the Assistant Secretary of Defense for Health Affairs (or the designees of such officers), and

(B) such other officers and employees of the United States as the Secretary determines necessary for the Advisory Board to carry out its functions.

(c) Members of the Advisory Board who are officers or employees of the Federal Government shall serve as members of the Advisory Board without compensation in addition to that received in their regular public employment. Other members of the Advisory Board shall receive compensation at rates not to exceed the daily equivalent of the annual rate in effect for grade GS–18 of the General Schedule for each day (including traveltime) they are engaged in the performance of their duties as members of the Advisory Board.

(d) The term of office of an appointed member of the Advisory Board is four years. Any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term. A member may serve after the expiration of the member's term until a successor has taken office. If a vacancy occurs in the Advisory Board, the Secretary shall make an appointment to fill the vacancy not later than 90 days after the date the vacancy occurred.

(e) The members of the Advisory Board shall select a chairman from among the appointed members.

(f) The Secretary shall, after consultation with and consideration of the recommendations of the Advisory Board, provide the Advisory Board with an executive director and one other professional staff member. In addition, the Secretary shall, after consultation with and consideration of the recommendations of the Advisory Board, provide the Advisory Board with such additional professional staff members, such clerical staff members, and (through contracts or other arrangements) with such administrative support services and facilities, such information, and such services of consultants, as the Secretary determines are necessary for the Advisory Board to carry out its functions.

(g) The Advisory Board shall meet at the call of the chairman or upon request of the Director of the Institute, but not less often than four times a year.

(h) The Advisory Board shall—

(1) review and evaluate the implementation of the plan prepared under section 436(a) and periodically update the plan to ensure its continuing relevance;

(2) for the purpose of assuring the most effective use and organization of resources respecting arthritis, musculoskeletal diseases and skin diseases, advise and make recommendations to the Congress, the Secretary, the Director of NIH, the Director of the Institute, and the heads of other appropriate Federal agencies for the implementation and revision of such plan; and

(3) maintain liaison with other advisory bodies for Federal agencies involved in the implementation of such plan, the interagency coordinating committees for such diseases established under section 439, and with key non-Federal entities involved in activities affecting the control of such diseases.

(i) In carrying out its functions, the Advisory Board may establish subcommittees, convene workshops and conferences, and collect data. Such subcommittees may be composed of Advisory Board members and nonmember consultants with expertise in the par-

ticular area addressed by such subcommittees. The subcommittees may hold such meetings as are necessary to enable them to carry out their activities.

(j) The National Arthritis Advisory Board in existence on the date of enactment of the Health Research Extension Act of 1985 shall terminate upon the appointment of a successor Board under subsection (a). The Secretary shall make appointments to the Advisory Board established under subsection (a) before the expiration of 90 days after such date. The members of the Board in existence on such date may be appointed, in accordance with subsections (b) and (d), to the Advisory Board established under subsection (a).

JUVENILE ARTHRITIS AND RELATED CONDITIONS.

SEC. 442A.[285d–8] (a) EXPANSION AND COORDINATION OF ACTIVITIES.—The Director of the Institute, in coordination with the Director of the National Institute of Allergy and Infectious Diseases, shall expand and intensify the programs of such Institutes with respect to research and related activities concerning juvenile arthritis and related conditions.

(b) COORDINATION.—The Directors referred to in subsection (a) shall jointly coordinate the programs referred to in such subsection and consult with the Arthritis and Musculoskeletal Diseases Interagency Coordinating Committee.

Subpart 5—National Institute on Aging

PURPOSE OF THE INSTITUTE.

SEC. 443.[285e] The general purpose of the National Institute on Aging (hereafter in this subpart referred to as the "Institute") is the conduct and support of biomedical, social, and behavioral research, training, health information dissemination, and other programs with respect to the aging process and the diseases and other special problems and needs of the aged.

SPECIAL FUNCTIONS.

SEC. 444.[285e–1] (a) In carrying out the training responsibilities under this Act or any other Act for health and allied health professions personnel, the Secretary shall take appropriate steps to insure the education and training of adequate numbers of allied health, nursing, and paramedical personnel in the field of health care for the aged.

(b) The Director of the Institute shall conduct scientific studies to measure the impact on the biological, medical, social, and psychological aspects of aging of programs and activities assisted or conducted by the Department of Health and Human Services.

(c) The Director of the Institute shall carry out public information and education programs designed to disseminate as widely as possible the findings of research sponsored by the Institute, other relevant aging research and studies, and other information about the process of aging which may assist elderly and near-elderly persons in dealing with, and all Americans in understanding, the problems and processes associated with growing older.

(d) The Director of the Institute shall make grants to public and private nonprofit institutions to conduct research relating to Alzheimer's Disease.

ALZHEIMER'S DISEASE CENTERS.

SEC. 445.[285e–2] (a)(1) The Director of the Institute may enter into cooperative agreements with and make grants to public or private nonprofit entities (including university medical centers) to pay all or part of the cost of planning, establishing, or strengthening, and providing basic operating support (including staffing) for centers for basic and clinical research (including multidisciplinary research) into, training in, and demonstration of advanced diagnostic, prevention, and treatment methods for Alzheimer's disease.

(2) A cooperative agreement or grant under paragraph (1) shall be entered into in accordance with policies established by the Director of NIH and after consultation with the Institute's advisory council.

(b)(1) Federal payments made under a cooperative agreement or grant under subsection (a) may, with respect to Alzheimer's disease, be used for—

(A) diagnostic examinations, patient assessments, patient care costs, and other costs necessary for conducting research;

(B) training, including training for allied health professionals;

(C) diagnostic and treatment clinics designed to meet the special needs of minority and rural populations and other underserved populations;

(D) activities to educate the public; and

(E) the dissemination of information.

(2) For purposes of paragraph (1), the term "training" does not include research training for which National Research Service Awards[29] may be provided under section 487.

(c) Support of a center under subsection (a) may be for a period of not to exceed five years. Such period may be extended by the Director for additional periods of not more than five years each if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

CLAUDE D. PEPPER OLDER AMERICANS INDEPENDENCE CENTERS.

SEC. 445A.[285e–3] (a) The Director of the Institute shall enter into cooperative agreements with, and make grants to, public and private nonprofit entities for the development or expansion of not less than 10 centers of excellence in geriatric research and training of researchers. Each such center shall be known as a Claude D. Pepper Older Americans Independence Center.

(b) Each center developed or expanded under this section shall—

(1) utilize the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such re-

[29] Now Ruth L. Kirschstein National Research Service Awards. See section 487.

search and training qualifications as may be prescribed by the Director; and

(2) conduct—

(A) research into the aging processes and into the diagnosis and treatment of diseases, disorders, and complications related to aging, including menopause, which research includes research on such treatments, and on medical devices and other medical interventions regarding such diseases, disorders, and complications, that can assist individuals in avoiding institutionalization and prolonged hospitalization and in otherwise increasing the independence of the individuals; and

(B) programs to develop individuals capable of conducting research described in subparagraph (A).

(c) In making cooperative agreements and grants under this section for the development or expansion of centers, the Director of the Institute shall ensure that, to the extent practicable, any such centers are distributed equitably among the principal geographic regions of the United States.

(d) For purposes of this section, the term "independence", with respect to diseases, disorders, and complications of aging, means the functional ability of individuals to perform activities of daily living or instrumental activities of daily living without assistance or supervision.

AWARDS AUTHORIZED.

SEC. 445B.[30] [285e–4] (a) The Director of the Institute shall make awards to senior researchers who have made distinguished achievements in biomedical research in areas relating to Alzheimer's disease and related dementias. Awards under this section shall be used by the recipients to support research in areas relating to such disease and dementias, and may be used by the recipients to train junior researchers who demonstrate exceptional promise to conduct research in such areas.

(b) The Director of the Institute may make awards under this section to researchers at centers supported under section 445 and to researchers at other public and nonprofit private entities.

(c) The Director of the Institute shall make awards under this section only to researchers who have been recommended for such awards by the National Advisory Council on Aging.

(d) The Director of the Institute shall establish procedures for the selection of the recipients of awards under this section.

(e) Awards under this section shall be made for a one-year period, and may be renewed for not more than six additional consecutive one-year periods.

RESEARCH PROGRAM AND PLAN.

SEC. 445C. [285e–5] (a) The Director of the Institute shall conduct, or make grants for the conduct of, research relevant to appro-

[30] Sections 445B through 445F were originally enacted as provisions of title IX of Public Law 99–660, and were transferred to the Public Health Service Act by section 142 of Public Law 100–607. (Various provisions relating to Alzheimer's disease remain in such title IX, which is included in this compilation.)

priate services for individuals with Alzheimer's disease and related dementias and their families.

(b)(1) Within 6 months after the date of enactment of the Alzheimer's Disease and Related Dementias Services Research Act of 1986, the Director of the Institute shall prepare and transmit to the Chairman of the Council on Alzheimer's Disease (in this section referred to as the "Council") a plan for the research to be conducted under subsection (a). The plan shall—

(A) provide for research concerning—

(i) the epidemiology of, and the identification of risk factors for, Alzheimer's disease and related dementias; and

(ii) the development and evaluation of reliable and valid multidimensional diagnostic and assessment procedures and instruments; and

(B) ensure that research carried out under the plan is coordinated with, and uses, to the maximum extent feasible, resources of, other Federal programs relating to Alzheimer's disease and related dementias, including centers supported under section 445, centers supported by the National Institute of Mental Health on the psychopathology of the elderly, relevant activities of the Administration on Aging, other programs and centers involved in research on Alzheimer's disease and related dementias supported by the Department, and other programs relating to Alzheimer's disease and related dementias which are planned or conducted by Federal agencies other than the Department, State or local agencies, community organizations, or private foundations.

(2) Within one year after transmitting the plan required under paragraph (1), and annually thereafter, the Director of the Institute shall prepare and transmit to the Chairman of the Council such revisions of such plan as the Director considers appropriate.

(c) In preparing and revising the plan required by subsection (b), the Director of the Institute shall consult with the Chairman of the Council and the heads of agencies within the Department.

(d) the[31] Director of the Institute may develop, or make grants to develop—

(1) model techniques to—

(A) promote greater independence, including enhanced independence in performing activities of daily living and instrumental activities of daily living, for persons with Alzheimer's disease and related disorders; and

(B) prevent or reduce the severity of secondary disabilities, including confusional episodes, falls, bladder and bowel incontinence, and adverse effects of prescription and over-the-counter medications, in such persons; and

(2) model curricula for health care professionals, health care paraprofessionals, and family caregivers, for training and application in the use of such techniques.

[31] So in law. See section 9 of Public Law 102–507 (106 Stat. 3287). Probably should be "The".

(e) For purposes of this section, the term "Council on Alzheimer's Disease" means the council established in section 911(a)[32] of Public Law 99–660.

DISSEMINATION.

SEC. 445D.[285e–6] The Director of the Institute shall disseminate the results of research conducted under section 445C and this section to appropriate professional entities and to the public.

CLEARINGHOUSE ON ALZHEIMER'S DISEASE.

SEC. 445E.[285e–7] (a) The Director of the Institute shall establish the Clearinghouse on Alzheimer's Disease (hereinafter referred to as the "Clearinghouse"). The purpose of the Clearinghouse is the dissemination of information concerning services available for individuals with Alzheimer's disease and related dementias and their families. The Clearinghouse shall—

(1) compile, archive, and disseminate information concerning research, demonstration, evaluation, and training programs and projects concerning Alzheimer's disease and related dementias; and

(2) annually publish a summary of the information compiled under paragraph (1) during the preceding 12-month period, and make such information available upon request to appropriate individuals and entities, including educational institutions, research entities, and Federal and public agencies.

(b) The Clearinghouse may charge an appropriate fee for information provided through the toll-free telephone line established under subsection (a)(3).[33]

(c) The Director of the Institute, the Director of the National Institute of Mental Health, and the Director of the National Center for Health Services Research and Health Care Technology Assessment shall provide to the Clearinghouse summaries of the findings of research conducted under part D.

DISSEMINATION PROJECT.

SEC. 445F.[285e–8] (a) The Director of the Institute shall make a grant to, or enter into a contract with, a national organization representing individuals with Alzheimer's disease and related dementias for the conduct of the activities described in subsection (b).

(b) The organization receiving a grant or contract under this section shall—

(1) establish a central computerized information system to—

(A) compile and disseminate information concerning initiatives by State and local governments and private entities to provide programs and services for individuals with Alzheimer's disease and related dementias; and

(B) translate scientific and technical information concerning such initiatives into information readily under-

[32] Section 911 was repealed by section 601(a)(2)(E) of Public Law 105–362 (112 Stat. 3286).
[33] So in law. Section 445E does not contain a subsection (a)(3). Section 445F(b)(2) provides for a toll-free telephone line.

standable by the general public, and make such information available upon request; and

(2) establish a national toll-free telephone line to make available the information described in paragraph (1), and information concerning Federal programs, services and benefits for individuals with Alzheimer's disease and related dementias and their families.

(c) The organization receiving a grant or contract under this section may charge appropriate fees for information provided through the toll-free telephone line established under subsection (b)(2), and may make exceptions to such fees for individuals and organizations who are not financially able to pay such fees.

(d) In order to receive a grant or contract under this section, an organization shall submit an application to the Director of the Institute. Such application shall contain—

(1) information demonstrating that such organization has a network of contacts which will enable such organization to receive information necessary to the operation of the central computerized information system described in subsection (b)(1);

(2) information demonstrating that, by the end of fiscal year 1991, such organization will be financially able to, and will, carry out the activities described in subsection (b) without a grant or contract from the Federal Government; and

(3) such other information as the Director may prescribe.

ALZHEIMER'S DISEASE REGISTRY.

SEC. 445G.[285e–9] (a) IN GENERAL.—The Director of the Institute may make a grant to develop a registry for the collection of epidemiological data about Alzheimer's disease and its incidence in the United States, to train personnel in the collection of such data, and for other matters respecting such disease.

(b) QUALIFICATIONS.—To qualify for a grant under subsection (a) an applicant shall—

(1) be an accredited school of medicine or public health which has expertise in the collection of epidemiological data about individuals with Alzheimer's disease and in the development of disease registries, and

(2) have access to a large patient population, including a patient population representative of diverse ethnic backgrounds.

AGING PROCESSES REGARDING WOMEN.

SEC. 445H.[285e–10] The Director of the Institute, in addition to other special functions specified in section 444 and in cooperation with the Directors of the other national research institutes and agencies of the National Institutes of Health, shall conduct research into the aging processes of women, with particular emphasis given to the effects of menopause and the physiological and behavioral changes occurring during the transition from pre- to postmenopause, and into the diagnosis, disorders, and complications related to aging and loss of ovarian hormones in women.

SEC. 445I.[285e–10a] ALZHEIMER'S CLINICAL RESEARCH AND TRAINING AWARDS.

(a) IN GENERAL.—The Director of the Institute is authorized to establish and maintain a program to enhance and promote the translation of new scientific knowledge into clinical practice related to the diagnosis, care and treatment of individuals with Alzheimer's disease.

(b) SUPPORT OF PROMISING CLINICIANS.—In order to foster the application of the most current developments in the etiology, pathogenesis, diagnosis, prevention and treatment of Alzheimer's disease, amounts made available under this section shall be directed to the support of promising clinicians through awards for research, study, and practice at centers of excellence in Alzheimer's disease research and treatment.

(c) EXCELLENCE IN CERTAIN FIELDS.—Research shall be carried out under awards made under subsection (b) in environments of demonstrated excellence in neuroscience, neurobiology, geriatric medicine, and psychiatry and shall foster innovation and integration of such disciplines or other environments determined suitable by the Director of the Institute.

Subpart 6—National Institute of Allergy and Infectious Diseases

PURPOSE OF THE INSTITUTE.

SEC. 446.[285f] The general purpose of the National Institute of Allergy and Infectious Diseases is the conduct and support of research, training, health information dissemination, and other programs with respect to allergic and immunologic diseases and disorders and infectious diseases, including tropical diseases.

RESEARCH CENTERS REGARDING CHRONIC FATIGUE SYNDROME.

SEC. 447.[285f–1] (a) The Director of the Institute, after consultation with the advisory council for the Institute, may make grants to, or enter into contracts with, public or nonprofit private entities for the development and operation of centers to conduct basic and clinical research on chronic fatigue syndrome.

(b) Each center assisted under this section shall use the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such requirements as may be prescribed by the Director of the Institute.

RESEARCH AND RESEARCH TRAINING REGARDING TUBERCULOSIS.

SEC. 447A.[285f–2] In carrying out section 446, the Director of the Institute shall conduct or support research and research training regarding the cause, diagnosis, early detection, prevention and treatment of tuberculosis.

SEC. 447B.[285f–3] SEXUALLY TRANSMITTED DISEASE CLINICAL RESEARCH AND TRAINING AWARDS.

(a) IN GENERAL.—The Director of the Institute is authorized to establish and maintain a program to enhance and promote the translation of new scientific knowledge into clinical practice related to the diagnosis, care and treatment of individuals with sexually transmitted diseases.

(b) SUPPORT OF PROMISING CLINICIANS.—In order to foster the application of the most current developments in the etiology, pathogenesis, diagnosis, prevention and treatment of sexually transmitted diseases, amounts made available under this section shall be directed to the support of promising clinicians through awards for research, study, and practice at centers of excellence in sexually transmitted disease research and treatment.

(c) EXCELLENCE IN CERTAIN FIELDS.—Research shall be carried out under awards made under subsection (b) in environments of demonstrated excellence in the etiology and pathogenesis of sexually transmitted diseases and shall foster innovation and integration of such disciplines or other environments determined suitable by the Director of the Institute.

SEC. 447C.[285f–4] MICROBICIDE RESEARCH AND DEVELOPMENT.

The Director of the Institute, acting through the head of the Division of AIDS, shall, consistent with the peer-review process of the National Institutes of Health, carry out research on, and development of, safe and effective methods for use by women to prevent the transmission of the human immunodeficiency virus, which may include microbicides.

Subpart 7—Eunice Kennedy Shriver National Institute of Child Health and Human Development [34]

PURPOSE OF THE INSTITUTE.

SEC. 448.[285g] The general purpose of the National Institute of Child Health and Human Development [35] (hereafter in this subpart referred to as the "Institute") is the conduct and support of research, training, health information dissemination, and other programs with respect to gynecologic health, maternal health, child health, intellectual disabilities, human growth and development, including prenatal development, population research, and special health problems and requirements of mothers and children.

SUDDEN INFANT DEATH SYNDROME.

SEC. 449.[285g–1] The Director of the Institute shall conduct and support research which specifically relates to sudden infant death syndrome.

SEC. 450.[285g–2] RESEARCH ON INTELLECTUAL DISABILITIES.

The Director of the Institute shall conduct and support research and related activities into the causes, prevention, and treatment of intellectual disabilities.

[34] Section 1004 of Public Law 106–310 (114 Stat. 1130) authorizes the Director of the Institute to conduct a national longitudinal study of environmental influences (including physical, chemical, biological, and psychosocial) on children's health and development. Subsection (d) of such section requires periodic reports to the Congress regarding the study. The first report is required to be submitted not later than three years after the date of the enactment of the Public Law, which was enacted October 17, 2000.

[35] The probable intent of the Congress is to refer to the "Eunice Kennedy Shriver National Institute of Child Health and Human Development". Section 1(b)(7) of Public Law 110–154 (121 Stat 1827) struck the term "National Institute of Child Health and Human Development" and inserted "Eunice Kennedy Shriver National Institute of Child Health and Human Development" each place such term appeared in the heading of subpart 7 of part C of title IV, but not in the text of section 448.

ASSOCIATE DIRECTOR FOR PREVENTION.

SEC. 451.[285g–3] There shall be in the Institute an Associate Director for Prevention to coordinate and promote the programs in the Institute concerning the prevention of health problems of mothers and children. The Associate Director shall be appointed by the Director of the Institute from individuals who because of their professional training or experience are experts in public health or preventive medicine.

NATIONAL CENTER FOR MEDICAL REHABILITATION RESEARCH.

SEC. 452.[285g–4] (a) There shall be in the Institute an agency to be known as the National Center for Medical Rehabilitation Research (hereafter in this section referred to as the "Center")[36]. The Director of the Institute shall appoint a qualified individual to serve as Director of the Center. The Director of the Center shall report directly to the Director of the Institute.

(b) The general purpose of the Center is the conduct and support of research and research training (including research on the development of orthotic and prosthetic devices), the dissemination of health information, and other programs with respect to the rehabilitation of individuals with physical disabilities resulting from diseases or disorders of the neurological, musculoskeletal, cardiovascular, pulmonary, or any other physiological system (hereafter in this section referred to as "medical rehabilitation").

(c)(1) In carrying out the purpose described in subsection (b), the Director of the Center may—

(A) provide for clinical trials regarding medical rehabilitation;

(B) provide for research regarding model systems of medical rehabilitation;

(C) coordinate the activities of the Center with similar activities of other agencies of the Federal Government, including the other agencies of the National Institutes of Health, and with similar activities of other public entities and of private entities;

(D) support multidisciplinary medical rehabilitation research conducted or supported by more than one such agency;

(E) in consultation with the advisory council for the Institute and with the approval of the Director of NIH—

(i) establish technical and scientific peer review groups in addition to those appointed under section 402(b)(16); and

(ii) appoint the members of peer review groups established under subparagraph (A); and

(F) support medical rehabilitation research and training centers.

The Federal Advisory Committee Act shall not apply to the duration of a peer review group appointed under subparagraph (E).

[36] Section 3(b) of Public Law 101–613 requires that Federal agencies, as appropriate, enter into agreements for preventing duplication among Federal programs regarding medical rehabilitation. Such section requires that the agreements be made not later than one year after the date of the enactment of the Public Law, which was enacted November 16, 1990.

(2) In carrying out this section, the Director of the Center may make grants and enter into cooperative agreements and contracts.

(d)(1) In consultation with the Director of the Center, the coordinating committee established under subsection (e), and the advisory board established under subsection (f), the Director of the Institute shall develop a comprehensive plan for the conduct and support of medical rehabilitation research (hereafter in this section referred to as the "Research Plan").

(2) The Research Plan shall—

(A) identify current medical rehabilitation research activities conducted or supported by the Federal Government, opportunities and needs for additional research, and priorities for such research; and

(B) make recommendations for the coordination of such research conducted or supported by the National Institutes of Health and other agencies of the Federal Government.

(3)(A) Not later than 18 months after the date of the enactment of the National Institutes of Health Revitalization Amendments of 1990,[37] the Director of the Institute shall transmit the Research Plan to the Director of NIH, who shall submit the Plan to the President and the Congress.

(B) Subparagraph (A) shall be carried out independently of the process of reporting that is required in sections 403 and 407.

(4) The Director of the Institute shall periodically revise and update the Research Plan as appropriate, after consultation with the Director of the Center, the coordinating committee established under subsection (e), and the advisory board established under subsection (f). A description of any revisions in the Research Plan shall be contained in each report prepared under section 407 by the Director of the Institute.

(e)(1) The Director of NIH shall establish a committee to be known as the Medical Rehabilitation Coordinating Committee (hereafter in this section referred to as the "Coordinating Committee").

(2) The Coordinating Committee shall make recommendations to the Director of the Institute and the Director of the Center with respect to the content of the Research Plan and with respect to the activities of the Center that are carried out in conjunction with other agencies of the National Institutes of Health and with other agencies of the Federal Government.

(3) The Coordinating Committee shall be composed of the Director of the Center, the Director of the Institute, and the Directors of the National Institute on Aging, the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the National Heart, Lung, and Blood Institute, the National Institute of Neurological Disorders and Stroke, and such other national research institutes and such representatives of other agencies of the Federal Government as the Director of NIH determines to be appropriate.

(4) The Coordinating Committee shall be chaired by the Director of the Center.

[37] So in law. No Act with such a short title was enacted during 1990. The probable intent of the Congress was to make a reference to Public Law 101–613, the National Institutes of Health Amendments of 1990, which added section 452 and which was enacted November 16, 1990.

(f)(1) Not later than 90 days after the date of the enactment of the National Institutes of Health Revitalization Amendments of 1990,[38] the Director of NIH shall establish a National Advisory Board on Medical Rehabilitation Research (hereafter in this section referred to as the "Advisory Board").

(2) The Advisory Board shall review and assess Federal research priorities, activities, and findings regarding medical rehabilitation research, and shall advise the Director of the Center and the Director of the Institute on the provisions of the Research Plan.

(3)(A) The Director of NIH shall appoint to the Advisory Board 18 qualified representatives of the public who are not officers or employees of the Federal Government. Of such members, 12 shall be representatives of health and scientific disciplines with respect to medical rehabilitation and 6 shall be individuals representing the interests of individuals undergoing, or in need of, medical rehabilitation.

(B) The following officials shall serve as ex officio members of the Advisory Board:

(i) The Director of the Center.

(ii) The Director of the Institute.

(iii) The Director of the National Institute on Aging.

(iv) The Director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases.

(v) The Director of the National Institute on Deafness and Other Communication Disorders.

(vi) The Director of the National Heart, Lung, and Blood Institute.

(vii) The Director of the National Institute of Neurological Disorders and Stroke.

(viii) The Director of the National Institute on Disability and Rehabilitation Research.

(ix) The Commissioner for Rehabilitation Services Administration.

(x) The Assistant Secretary of Defense (Health Affairs).

(xi) The Chief Medical Director of the Department of Veterans Affairs.

(4) The members of the Advisory Board shall, from among the members appointed under paragraph (3)(A), designate an individual to serve as the chair of the Advisory Board.

RESEARCH CENTERS WITH RESPECT TO CONTRACEPTION AND INFERTILITY.

SEC. 452A.[285g–5] (a) The Director of the Institute, after consultation with the advisory council for the Institute, shall make grants to, or enter into contracts with, public or nonprofit private entities for the development and operation of centers to conduct activities for the purpose of improving methods of contraception and centers to conduct activities for the purpose of improving methods of diagnosis and treatment of infertility.

(b) In carrying out subsection (a), the Director of the Institute shall, subject to the extent of amounts made available in appropriations Acts, provide for the establishment of three centers with re-

[38] See footnote for subsection (d)(3)(A).

spect to contraception and for two centers with respect to infertility.

(c)(1) Each center assisted under this section shall, in carrying out the purpose of the center involved—

(A) conduct clinical and other applied research, including—

(i) for centers with respect to contraception, clinical trials of new or improved drugs and devices for use by males and females (including barrier methods); and

(ii) for centers with respect to infertility, clinical trials of new or improved drugs and devices for the diagnosis and treatment of infertility in males and females;

(B) develop protocols for training physicians, scientists, nurses, and other health and allied health professionals;

(C) conduct training programs for such individuals;

(D) develop model continuing education programs for such professionals; and

(E) disseminate information to such professionals and the public.

(2) A center may use funds provided under subsection (a) to provide stipends for health and allied health professionals enrolled in programs described in subparagraph (C) of paragraph (1), and to provide fees to individuals serving as subjects in clinical trials conducted under such paragraph.

(d) The Director of the Institute shall, as appropriate, provide for the coordination of information among the centers assisted under this section.

(e) Each center assisted under subsection (a) shall use the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such requirements as may be prescribed by the Director of the Institute.

(f) Support of a center under subsection (a) may be for a period not exceeding 5 years. Such period may be extended for one or more additional periods not exceeding 5 years if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

PROGRAM REGARDING OBSTETRICS AND GYNECOLOGY.

SEC. 452B.[285g–6] The Director of the Institute shall establish and maintain within the Institute an intramural laboratory and clinical research program in obstetrics and gynecology.

CHILD HEALTH RESEARCH CENTERS.

SEC. 452C.[285g–7] The Director of the Institute shall develop and support centers for conducting research with respect to child health. Such centers shall give priority to the expeditious transfer of advances from basic science to clinical applications and improving the care of infants and children.

PROSPECTIVE LONGITUDINAL STUDY ON ADOLESCENT HEALTH.

SEC. 452D.[285g–8] (a) IN GENERAL.—Not later than October 1, 1993, the Director of the Institute shall commence a study for

the purpose of providing information on the general health and well-being of adolescents in the United States, including, with respect to such adolescents, information on—

(1) the behaviors that promote health and the behaviors that are detrimental to health; and

(2) the influence on health of factors particular to the communities in which the adolescents reside.

(b) DESIGN OF STUDY.—

(1) IN GENERAL.—The study required in subsection (a) shall be a longitudinal study in which a substantial number of adolescents participate as subjects. With respect to the purpose described in such subsection, the study shall monitor the subjects throughout the period of the study to determine the health status of the subjects and any change in such status over time.

(2) POPULATION-SPECIFIC ANALYSES.—The study required in subsection (a) shall be conducted with respect to the population of adolescents who are female, the population of adolescents who are male, various socioeconomic populations of adolescents, and various racial and ethnic populations of adolescents. The study shall be designed and conducted in a manner sufficient to provide for a valid analysis of whether there are significant differences among such populations in health status and whether and to what extent any such differences are due to factors particular to the populations involved.

(c) COORDINATION WITH WOMEN'S HEALTH INITIATIVE.—With respect to the national study of women being conducted by the Secretary and known as the Women's Health Initiative, the Secretary shall ensure that such study is coordinated with the component of the study required in subsection (a) that concerns adolescent females, including coordination in the design of the 2 studies.

FRAGILE X.

SEC. 452E.[285g–9] (a) EXPANSION AND COORDINATION OF RESEARCH ACTIVITIES.—The Director of the Institute, after consultation with the advisory council for the Institute, shall expand, intensify, and coordinate the activities of the Institute with respect to research on the disease known as fragile X.

(b) RESEARCH CENTERS.—

(1) IN GENERAL.—The Director of the Institute shall make grants or enter into contracts for the development and operation of centers to conduct research for the purposes of improving the diagnosis and treatment of, and finding the cure for, fragile X.

(2) NUMBER OF CENTERS.—

(A) IN GENERAL.—In carrying out paragraph (1), the Director of the Institute shall, to the extent that amounts are appropriated, and subject to subparagraph (B), provide for the establishment of at least three fragile X research centers.

(B) PEER REVIEW REQUIREMENT.—The Director of the Institute shall make a grant to, or enter into a contract with, an entity for purposes of establishing a center under

paragraph (1) only if the grant or contract has been recommended after technical and scientific peer review required by regulations under section 492.

(3) ACTIVITIES.—The Director of the Institute, with the assistance of centers established under paragraph (1), shall conduct and support basic and biomedical research into the detection and treatment of fragile X.

(4) COORDINATION AMONG CENTERS.—The Director of the Institute shall, as appropriate, provide for the coordination of the activities of the centers assisted under this section, including providing for the exchange of information among the centers.

(5) CERTAIN ADMINISTRATIVE REQUIREMENTS.—Each center assisted under paragraph (1) shall use the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such requirements as may be prescribed by the Director of the Institute.

(6) DURATION OF SUPPORT.—Support may be provided to a center under paragraph (1) for a period not exceeding 5 years. Such period may be extended for one or more additional periods, each of which may not exceed 5 years, if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period be extended.

INVESTMENT IN TOMORROW'S PEDIATRIC RESEARCHERS.

SEC. 452G.[39] [285g–10] In order to ensure the future supply of researchers dedicated to the care and research needs of children, the Director of the Institute, after consultation with the Administrator of the Health Resources and Services Administration, shall support activities to provide for—

(1) an increase in the number and size of institutional training grants to institutions supporting pediatric training; and

(2) an increase in the number of career development awards for health professionals who intend to build careers in pediatric basic and clinical research, including pediatric pharmacological research.

Subpart 8—National Institute of Dental Research[40]

PURPOSE OF THE INSTITUTE.

SEC. 453. [285h] The general purpose of the National Institute of Dental Research is the conduct and support of research, training, health information dissemination, and other programs with respect to the cause, prevention, and methods of diagnosis and treatment of dental and oral diseases and conditions.

[39] So in law. Probably should be "SEC. 452F.". See amendments made by sections 201 and 1002 of Public Law 106–310 (114 Stat. 1109, 1128). (In amending this subpart to add section 452G above, such section 1002 made a reference to this subpart "as amended by section 921" of Public Law 106–310, but no section 921 appeared in the Public Law.)

[40] See footnote for section 401(b)(1)(H).

Subpart 9—National Eye Institute

PURPOSE OF THE INSTITUTE.

SEC. 455.[285i] The general purpose of the National Eye Institute (hereafter in this subpart referred to as the "Institute") is the conduct and support of research, training, health information dissemination, and other programs with respect to blinding eye diseases, visual disorders, mechanisms of visual function, preservation of sight, and the special health problems and requirements of the blind. Subject to section 456, the Director of the Institute may carry out a program of grants for public and private nonprofit vision research facilities.

CLINICAL RESEARCH ON EYE CARE AND DIABETES.

SEC. 456.[285i–1] (a) PROGRAM OF GRANTS.—The Director of the Institute, in consultation with the advisory council for the Institute, may award research grants to one or more Diabetes Eye Research Institutions for the support of programs in clinical or health services aimed at—

(1) providing comprehensive eye care services for people with diabetes, including a full complement of preventive, diagnostic and treatment procedures;

(2) developing new and improved techniques of patient care through basic and clinical research;

(3) assisting in translation of the latest research advances into clinical practice; and

(4) expanding the knowledge of the eye and diabetes through further research.

(b) USE OF FUNDS.—Amounts received under a grant awarded under this section shall be used for the following:

(1) Establishing the biochemical, cellular, and genetic mechanisms associated with diabetic eye disease and the earlier detection of pending eye abnormalities. The focus of work under this paragraph shall require that ophthalmologists have training in the most up-to-date molecular and cell biological methods.

(2) Establishing new frontiers in technology, such as video-based diagnostic and research resources, to—

(A) provide improved patient care;

(B) provide for the evaluation of retinal physiology and its affect on diabetes; and

(C) provide for the assessment of risks for the development and progression of diabetic eye disease and a more immediate evaluation of various therapies aimed at preventing diabetic eye disease.

Such technologies shall be designed to permit evaluations to be performed both in humans and in animal models.

(3) The translation of the results of vision research into the improved care of patients with diabetic eye disease. Such translation shall require the application of institutional resources that encompass patient care, clinical research and basic laboratory research.

(4) The conduct of research concerning the outcomes of eye care treatments and eye health education programs as they relate to patients with diabetic eye disease, including the evaluation of regional approaches to such research.

(c) AUTHORIZED EXPENDITURES.—The purposes for which a grant under subsection (a) may be expended include equipment for the research described in such subsection.

Subpart 10—National Institute of Neurological Disorders and Stroke

PURPOSE OF THE INSTITUTE.

SEC. 457.[285j] The general purpose of the National Institute of Neurological Disorders and Stroke (hereafter in this subpart referred to as the "Institute") is the conduct and support of research, training, health information dissemination, and other programs with respect to neurological disease and disorder and stroke.

SPINAL CORD REGENERATION RESEARCH.

SEC. 458.[285j–1] The Director of the Institute shall conduct and support research into spinal cord regeneration.

BIOENGINEERING RESEARCH.

SEC. 459.[285j–2] The Director of the Institute shall make grants or enter into contracts for research on the means to overcome paralysis of the extremities through electrical stimulation and the use of computers.

RESEARCH ON MULTIPLE SCLEROSIS.

SEC. 460.[285j–3] The Director of the Institute shall conduct and support research on multiple sclerosis, especially research on effects of genetics and hormonal changes on the progress of the disease.

Subpart 11—National Institute of General Medical Sciences

SEC. 461.[285k] NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES.

(a) GENERAL PURPOSE.—The general purpose of the National Institute of General Medical Sciences is the conduct and support of research, training, and, as appropriate, health information dissemination, and other programs with respect to general or basic medical sciences and related natural or behavioral sciences which have significance for two or more other national research institutes or are outside the general area of responsibility of any other national research institute.

(b) INSTITUTIONAL DEVELOPMENT AWARD PROGRAM.—

(1)(A) In the case of entities described in subparagraph (B), the Director of NIH, acting through the Director of the National Institute of General Medical Sciences, shall establish a program to enhance the competitiveness of such entities in obtaining funds from the national research institutes for conducting biomedical and behavioral research.

(B) The entities referred to in subparagraph (A) are entities that conduct biomedical and behavioral research and are located in a State in which the aggregate success rate for applications to the national research institutes for assistance for such research by the entities in the State has historically constituted a low success rate of obtaining such funds, relative to such aggregate rate for such entities in other States.

(C) With respect to enhancing competitiveness for purposes of subparagraph (A), the Director of NIH, in carrying out the program established under such subparagraph, may—

(i) provide technical assistance to the entities involved, including technical assistance in the preparation of applications for obtaining funds from the national research institutes;

(ii) assist the entities in developing a plan for biomedical or behavioral research proposals; and

(iii) assist the entities in implementing such plan.

(2) The Director of NIH shall establish a program of supporting projects of biomedical or behavioral research whose principal researchers are individuals who have not previously served as the principal researchers of such projects supported by the Director.

Subpart 12—National Institute of Environmental Health Sciences

PURPOSE OF THE INSTITUTE.

SEC. 463.[285l] The general purpose of the National Institute of Environmental Health Sciences (in this subpart referred to as the "Institute") is the conduct and support of research, training, health information dissemination, and other programs with respect to factors in the environment that affect human health, directly or indirectly.

APPLIED TOXICOLOGICAL RESEARCH AND TESTING PROGRAM.

SEC. 463A.[285l–1] (a) There is established within the Institute a program for conducting applied research and testing regarding toxicology, which program shall be known as the Applied Toxicological Research and Testing Program.

(b) In carrying out the program established under subsection (a), the Director of the Institute shall, with respect to toxicology, carry out activities—

(1) to expand knowledge of the health effects of environmental agents;

(2) to broaden the spectrum of toxicology information that is obtained on selected chemicals;

(3) to develop and validate assays and protocols, including alternative methods that can reduce or eliminate the use of animals in acute or chronic safety testing;

(4) to establish criteria for the validation and regulatory acceptance of alternative testing and to recommend a process through which scientifically validated alternative methods can be accepted for regulatory use;

(5) to communicate the results of research to government agencies, to medical, scientific, and regulatory communities, and to the public; and

(6) to integrate related activities of the Department of Health and Human Services.

METHODS OF CONTROLLING CERTAIN INSECT AND VERMIN POPULATIONS.

SEC. 463B.[285l–6] The Director of the Institute shall conduct or support research to identify or develop methods of controlling insect and vermin populations that transmit to humans diseases that have significant adverse health consequences.

Subpart 13—National Institute on Deafness and Other Communication Disorders

PURPOSE OF THE INSTITUTE.

SEC. 464.[285m] The general purpose of the National Institute on Deafness and Other Communication Disorders (hereafter referred to in this subpart as the "Institute") is the conduct and support of research and training, the dissemination of health information, and other programs with respect to disorders of hearing and other communication processes, including diseases affecting hearing, balance, voice, speech, language, taste, and smell.

NATIONAL DEAFNESS AND OTHER COMMUNICATION DISORDERS PROGRAM.

SEC. 464A.[285m–1] (a) The Director of the Institute, with the advice of the Institute's advisory council, shall establish a National Deafness and Other Communication Disorders Program (hereafter in this section referred to as the "Program"). The Director or[41] the Institute shall, with respect to the Program, prepare and transmit to the Director of NIH a plan to initiate, expand, intensify and coordinate activities of the Institute respecting disorders of hearing (including tinnitus) and other communication processes, including diseases affecting hearing, balance, voice, speech, language, taste, and smell. The plan shall include such comments and recommendations as the Director of the Institute determines appropriate. The Director of the Institute shall periodically review and revise the plan and shall transmit any revisions of the plan to the Director of NIH.

(b) Activities under the Program shall include—

(1) investigation into the etiology, pathology, detection, treatment, and prevention of all forms of disorders of hearing and other communication processes, primarily through the support of basic research in such areas as anatomy, audiology, biochemistry, bioengineering, epidemiology, genetics, immunology, microbiology, molecular biology, the neurosciences, otolaryngology, psychology, pharmacology, physiology, speech and language pathology, and any other scientific disciplines that can

[41] So in law. See section 2(4) of Public Law 100–553 (102 Stat. 2769). Probably should be "Director of".

contribute important knowledge to the understanding and elimination of disorders of hearing and other communication processes;

(2) research into the evaluation of techniques (including surgical, medical, and behavioral approaches) and devices (including hearing aids, implanted auditory and nonauditory prosthetic devices and other communication aids) used in diagnosis, treatment, rehabilitation, and prevention of disorders of hearing and other communication processes;

(3) research into prevention, and early detection and diagnosis, of hearing loss and speech and language disturbances (including stuttering) and research into preventing the effects of such disorders on learning and learning disabilities with extension of programs for appropriate referral and rehabilitation;

(4) research into the detection, treatment, and prevention of disorders of hearing and other communication processes in the growing elderly population with extension of rehabilitative programs to ensure continued effective communication skills in such population;

(5) research to expand knowledge of the effects of environmental agents that influence hearing or other communication processes; and

(6) developing and facilitating intramural programs on clinical and fundamental aspects of disorders of hearing and all other communication processes.

DATA SYSTEM AND INFORMATION CLEARINGHOUSE.

SEC. 464B.[285m–2] (a) The Director of the Institute shall establish a National Deafness and Other Communication Disorders Data System for the collection, storage, analysis, retrieval, and dissemination of data derived from patient populations with disorders of hearing or other communication processes, including where possible, data involving general populations for the purpose of identifying individuals at risk of developing such disorders.

(b) The Director of the Institute shall establish a National Deafness and Other Communication Disorders Information Clearinghouse to facilitate and enhance, through the effective dissemination of information, knowledge and understanding of disorders of hearing and other communication processes by health professionals, patients, industry, and the public.

MULTIPURPOSE DEAFNESS AND OTHER COMMUNICATION DISORDERS CENTER.

SEC. 464C.[285m–3] (a) The Director of the Institute shall, after consultation with the advisory council for the Institute, provide for the development, modernization, and operation (including care required for research) of new and existing centers for studies of disorders of hearing and other communication processes. For purposes of this section, the term "modernization" means the alteration, remodeling, improvement, expansion, and repair of existing buildings and the provision of equipment for such buildings to the extent necessary to make them suitable for use as centers described in the preceding sentence.

(b) Each center assisted under this section shall—

(1) use the facilities of a single institution or a consortium of cooperating institutions; and

(2) meet such qualifications as may be prescribed by the Secretary.

(c) Each center assisted under this section shall, at least, conduct—

(1) basic and clinical research into the cause diagnosis, early detection, prevention, control and treatment of disorders of hearing and other communication processes and complications resulting from such disorders, including research into rehabilitative aids, implantable biomaterials, auditory speech processors, speech production devices, and other otolaryngologic procedures;

(2) training programs for physicians, scientists, and other health and allied health professionals;

(3) information and continuing education programs for physicians and other health and allied health professionals who will provide care for patients with disorders of hearing or other communication processes; and

(4) programs for the dissemination to the general public of information—

(A) on the importance of early detection of disorders of hearing and other communication processes, of seeking prompt treatment, rehabilitation, and of following an appropriate regimen; and

(B) on the importance of avoiding exposure to noise and other environmental toxic agents that may affect disorders of hearing or other communication processes.

(d) A center may use funds provided under subsection (a) to provide stipends for health professionals enrolled in training programs described in subsection (c)(2).

(e) Each center assisted under this section may conduct programs—

(1) to establish the effectiveness of new and improved methods of detection, referral, and diagnosis of individuals at risk of developing disorders of hearing or other communication processes; and

(2) to disseminate the results of research, screening, and other activities, and develop means of standardizing patient data and recordkeeping.

(f) The Director of the Institute shall, to the extent practicable, provide for an equitable geographical distribution of centers assisted under this section. The Director shall give appropriate consideration to the need for centers especially suited to meeting the needs of the elderly, and of children (particularly with respect to their education and training), affected by disorders of hearing or other communication processes.

(g) Support of a center under this section may be for a period not to exceed seven years. Such period may be extended by the Director of the Institute for one or more additional periods of not more than five years if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director, with the advice of the Institute's advi-

sory council, if such group has recommended to the Director that such period should be extended.

NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION DISORDERS ADVISORY BOARD.

SEC. 464D.[285m–4] (a) The Secretary shall establish in the Institute the National Deafness and Other Communications Disorders Advisory Board (hereafter in this section referred to as the "Advisory Board").

(b) The Advisory Board shall be composed of eighteen appointed members and nonvoting ex officio members as follows:

(1) The Secretary shall appoint—

(A) twelve members from individuals who are scientists, physicians, and other health and rehabilitation professionals, who are not officers or employees of the United States, and who represent the specialties and disciplines relevant to deafness and other communication disorders, including not less than two persons with a communication disorder; and

(B) six members from the general public who are knowledgeable with respect to such disorders, including not less than one person with a communication disorder and not less than one person who is a parent of an individual with such a disorder.

Of the appointed members, not less than five shall by virtue of training or experience be knowledgeable in diagnoses and rehabilitation of communication disorders, education of the hearing, speech, or language impaired, public health, public information, community program development, occupational hazards to communications senses, or the aging process.

(2) The following shall be ex officio members of each Advisory Board:

(A) The Assistant Secretary for Health, the Director of NIH, the Director of the National Institute on Deafness and Other Communication Disorders, the Director of the Centers for Disease Control and Prevention, the Chief Medical Director of the Department of Veterans Affairs, and the Assistant Secretary of Defense for Health Affairs (or the designees of such officers).

(B) Such other officers and employees of the United States as the Secretary determines necessary for the Advisory Board to carry out its functions.

(c) Members of an Advisory Board who are officers or employees of the Federal Government shall serve as members of the Advisory Board without compensation in addition to that received in their regular public employment. Other members of the Board shall receive compensation at rates not to exceed the daily equivalent of the annual rate in effect for grade GS–18 of the General Schedule for each day (including traveltime) they are engaged in the performance of their duties as members of the Board.

(d) The term of office of an appointed member of the Advisory Board is four years, except that no term of office may extend beyond the expiration of the Advisory Board. Any member appointed

to fill a vacancy for an unexpired term shall be appointed for the remainder of such term. A member may serve after the expiration of the member's term until a successor has taken office. If a vacancy occurs in the Advisory Board, the Secretary shall make an appointment to fill the vacancy not later than 90 days from the date the vacancy occurred.

(e) The members of the Advisory Board shall select a chairman from among the appointed members.

(f) The Secretary shall, after consultation with and consideration of the recommendations of the Advisory Board, provide the Advisory Board with an executive director and one other professional staff member. In addition, the Secretary shall, after consultation with and consideration of the recommendations of the Advisory Board, provide the Advisory Board with such additional professional staff members, such clerical staff members, such services of consultants, such information, and (through contracts or other arrangements) such administrative support services and facilities, as the Secretary determines are necessary for the Advisory Board to carry out its functions.

(g) The Advisory Board shall meet at the call of the chairman or upon request of the Director of the Institute, but not less often than four times a year.

(h) The Advisory Board shall—

(1) review and evaluate the implementation of the plan prepared under section 464A(a) and periodically update the plan to ensure its continuing relevance;

(2) for the purpose of assuring the most effective use and organization of resources respecting deafness and other communication disorders, advise and make recommendations to the Congress, the Secretary, the Director of NIH, the Director of the Institute, and the heads of other appropriate Federal agencies for the implementation and revision of such plan; and

(3) maintain liaison with other advisory bodies related to Federal agencies involved in the implementation of such plan and with key non-Federal entities involved in activities affecting the control of such disorders.

(i) In carrying out its functions, the Advisory Board may establish subcommittees, convene workshops and conferences, and collect data. Such subcommittees may be composed of Advisory Board members and nonmember consultants with expertise in the particular area addressed by such subcommittees. The subcommittees may hold such meetings as are necessary to enable them to carry out their activities.

(k)[42] The National Deafness and Other Communication Disorders Advisory Board shall be established not later than April 1, 1989.

INTERAGENCY COORDINATING COMMITTEE.

SEC. 464E.[285m–5] (a) The Secretary may establish a committee to be known as the Deafness and Other Communication Disorders Interagency Coordinating Committee (hereafter in this section referred to as the "Coordinating Committee").

[42] So in law. There is no subsection (j) in section 464D.

(b) The Coordinating Committee shall, with respect to deafness and other communication disorders—

(1) provide for the coordination of the activities of the national research institutes; and

(2) coordinate the aspects of all Federal health programs and activities relating to deafness and other communication disorders in order to assure the adequacy and technical soundness of such programs and activities and in order to provide for the full communication and exchange of information necessary to maintain adequate coordination of such programs and activities.

(c) The Coordinating Committee shall be composed of the directors of each of the national research institutes and divisions involved in research with respect to deafness and other communication disorders and representatives of all other Federal departments and agencies whose programs involve health functions or responsibilities relevant to deafness and other communication disorders.

(d) The Coordinating Committee shall be chaired by the Director of NIH (or the designee of the Director). The Committee shall meet at the call of the chair, but not less often than four times a year.

LIMITATION ON ADMINISTRATIVE EXPENSES.

SEC. 464F.[285m–6] With respect to amounts appropriated for a fiscal year for the National Institutes of Health, the limitation established in section 408(a)(1) on the expenditure of such amounts for administrative expenses shall apply to administrative expenses of the National Institute on Deafness and Other Communication Disorders.

Subpart 14—National Institute on Alcohol Abuse and Alcoholism

PURPOSE OF INSTITUTE.

SEC. 464H.[285n] (a) IN GENERAL.—The general purpose of the National Institute on Alcohol Abuse and Alcoholism (hereafter in this subpart referred to as the "Institute") is the conduct and support of biomedical and behavioral research, health services research, research training, and health information dissemination with respect to the prevention of alcohol abuse and the treatment of alcoholism.

(b) RESEARCH PROGRAM.—The research program established under this subpart shall encompass the social, behavioral, and biomedical etiology, mental and physical health consequences, and social and economic consequences of alcohol abuse and alcoholism. In carrying out the program, the Director of the Institute is authorized to—

(1) collect and disseminate through publications and other appropriate means (including the development of curriculum materials), information as to, and the practical application of, the research and other activities under the program;

(2) make available research facilities of the Public Health Service to appropriate public authorities, and to health officials and scientists engaged in special study;

(3) make grants to universities, hospitals, laboratories, and other public or nonprofit institutions, and to individuals for such research projects as are recommended by the National Advisory Council on Alcohol Abuse and Alcoholism, giving special consideration to projects relating to—

(A) the relationship between alcohol abuse and domestic violence,

(B) the effects of alcohol use during pregnancy,

(C) the impact of alcoholism and alcohol abuse on the family, the workplace, and systems for the delivery of health services,

(D) the relationship between the abuse of alcohol and other drugs,

(E) the effect on the incidence of alcohol abuse and alcoholism of social pressures, legal requirements respecting the use of alcoholic beverages, the cost of such beverages, and the economic status and education of users of such beverages,

(F) the interrelationship between alcohol use and other health problems,

(G) the comparison of the cost and effectiveness of various treatment methods for alcoholism and alcohol abuse and the effectiveness of prevention and intervention programs for alcoholism and alcohol abuse, and

(H) alcoholism and alcohol abuse among women;

(4) secure from time to time and for such periods as he deems advisable, the assistance and advice of experts, scholars, and consultants from the United States or abroad;

(5) promote the coordination of research programs conducted by the Institute, and similar programs conducted by the National Institute of Drug Abuse and by other departments, agencies, organizations, and individuals, including all National Institutes of Health research activities which are or may be related to the problems of individuals suffering from alcoholism or alcohol abuse or those of their families or the impact of alcohol abuse on other health problems;

(6) conduct an intramural program of biomedical, behavioral, epidemiological, and social research, including research into the most effective means of treatment and service delivery, and including research involving human subjects, which is—

(A) located in an institution capable of providing all necessary medical care for such human subjects, including complete 24-hour medical diagnostic services by or under the supervision of physicians, acute and intensive medical care, including 24-hour emergency care, psychiatric care, and such other care as is determined to be necessary for individuals suffering from alcoholism and alcohol abuse; and

(B) associated with an accredited medical or research training institution;

(7) for purposes of study, admit and treat at institutions, hospitals, and stations of the Public Health Service, persons not otherwise eligible for such treatment;

(8) provide to health officials, scientists, and appropriate public and other nonprofit institutions and organizations, technical advice and assistance on the application of statistical and other scientific research methods to experiments, studies, and surveys in health and medical fields;

(9) enter into contracts under this title without regard to sections 3648 and 3709 of the Revised Statutes (31 U.S.C. 529;[43] 41 U.S.C. 5); and

(10) adopt, upon recommendation of the National Advisory Council on Alcohol Abuse and Alcoholism, such additional means as he deems necessary or appropriate to carry out the purposes of this section.

(c) COLLABORATION.—The Director of the Institute shall collaborate with the Administrator of the Substance Abuse and Mental Health Services Administration in focusing the services research activities of the Institute and in disseminating the results of such research to health professionals and the general public.

ASSOCIATE DIRECTOR FOR PREVENTION.

SEC. 464I.[285n–1] (a) IN GENERAL.—There shall be in the Institute an Associate Director for Prevention who shall be responsible for the full-time coordination and promotion of the programs in the Institute concerning the prevention of alcohol abuse and alcoholism. The Associate Director shall be appointed by the Director of the Institute from individuals who because of their professional training or expertise are experts in alcohol abuse and alcoholism or the prevention of such.

(b) BIENNIAL REPORT.—The Associate Director for Prevention shall prepare for inclusion in the biennial report made under section 407 a description of the prevention activities of the Institute, including a description of the staff and resources allocated to those activities.

NATIONAL ALCOHOL RESEARCH CENTER.

SEC. 464J.[285n–2] (a) The Secretary acting through the Institute may designate National Alcohol Research Centers for the purpose of interdisciplinary research relating to alcoholism and other biomedical, behavioral, and social issues related to alcoholism and alcohol abuse. No entity may be designated as a Center unless an application therefor has been submitted to, and approved by, the Secretary. Such an application shall be submitted in such manner and contain such information as the Secretary may reasonably require. The Secretary may not approve such an application unless—

(1) the application contains or is supported by reasonable assurances that—

(A) the applicant has the experience, or capability, to conduct, through biomedical, behavioral, social, and related disciplines, long-term research on alcoholism and other alcohol problems and to provide coordination of such research among such disciplines;

[43] Now codified to section 3324 of title 31, United States Code.

(B) the applicant has available to it sufficient facilities (including laboratory, reference, and data analysis facilities) to carry out the research plan contained in the application,

(C) the applicant has facilities and personnel to provide training in the prevention and treatment of alcoholism and other alcohol problems;

(D) the applicant has the capacity to train predoctoral and postdoctoral students for careers in research on alcoholism and other alcohol problems;

(E) the applicant has the capacity to conduct courses on alcohol problems and research on alcohol problems for undergraduate and graduate students, and medical and osteopathic, nursing, social work, and other specialized graduate students; and

(F) the applicant has the capacity to conduct programs of continuing education in such medical, legal, and social service fields as the Secretary may require.[44]

(2) the application contains a detailed five-year plan for research relating to alcoholism and other alcohol problems.

(b) The Secretary shall, under such conditions as the Secretary may reasonably require, make annual grants to Centers which have been designated under this section. No funds provided under a grant under this subsection may be used for the purchase of any land or the purchase, construction, preservation, or repair of any building. For the purposes of the preceding sentence, the term "construction" has the meaning given that term by section 701(1).[45] The Secretary shall include in the grants made under this section for fiscal year beginning after September 30, 1981, a grant to a designated Center for research on the effects of alcohol on the elderly.

Subpart 15—National Institute on Drug Abuse

PURPOSE OF INSTITUTE.

SEC. 464L.[285o] (a) IN GENERAL.—The general purpose of the National Institute on Drug Abuse (hereafter in this subpart referred to as the "Institute") is the conduct and support of biomedical and behavioral research, health services research, research training, and health information dissemination with respect to the prevention of drug abuse and the treatment of drug abusers.

(b) RESEARCH PROGRAM.—The research program established under this subpart shall encompass the social, behavioral, and biomedical etiology, mental and physical health consequences, and social and economic consequences of drug abuse. In carrying out the program, the Director of the Institute shall give special consideration to projects relating to drug abuse among women (particularly with respect to pregnant women).

[44] So in law. See section 16(a)(5) of Public Law 96–180 (93 Stat. 1305). The period probably should be "; and". (Section 464J formerly was section 504 of another law. The amendment made by Public Law 96–180 was directed to section 504 of that other law, which was Public Law 91–616.)

[45] So in law. See section 2(a) of Public Law 102–352 (106 Stat. 938). Section 701(1) does not provide a definition for the term "construction", but former section 701(1) did provide such a definition. Public Law 102–408 amended title VII generally; definitions for the title are now provided in section 799, and that section does not define the term "construction".

(c) COLLABORATION.—The Director of the Institute shall collaborate with the Substance Abuse and Mental Health Services Administration in focusing the services research activities of the Institute and in disseminating the results of such research to health professionals and the general public.

ASSOCIATE DIRECTOR FOR PREVENTION.

SEC. 464M.[285o–1] (a) IN GENERAL.—There shall be in the Institute an Associate Director for Prevention who shall be responsible for the full-time coordination and promotion of the programs in the Institute concerning the prevention of drug abuse. The Associate Director shall be appointed by the Director of the Institute from individuals who because of their professional training or expertise are experts in drug abuse and the prevention of such abuse.

(b) REPORT.—The Associate Director for Prevention shall prepare for inclusion in the biennial report made under section 407 a description of the prevention activities of the Institute, including a description of the staff and resources allocated to those activities.

DRUG ABUSE RESEARCH CENTERS.

SEC. 464N.[285o–2] (a) AUTHORITY.—The Director of the Institute may designate National Drug Abuse Research Centers for the purpose of interdisciplinary research relating to drug abuse and other biomedical, behavioral, and social issues related to drug abuse. No entity may be designated as a Center unless an application therefore has been submitted to, and approved by, the Secretary. Such an application shall be submitted in such manner and contain such information as the Secretary may reasonably require. The Secretary may not approve such an application unless—

(1) the application contains or is supported by reasonable assurances that—

(A) the applicant has the experience, or capability, to conduct, through biomedical, behavioral, social, and related disciplines, long-term research on drug abuse and to provide coordination of such research among such disciplines;

(B) the applicant has available to it sufficient facilities (including laboratory, reference, and data analysis facilities) to carry out the research plan contained in the application;

(C) the applicant has facilities and personnel to provide training in the prevention and treatment of drug abuse;

(D) the applicant has the capacity to train predoctoral and postdoctoral students for careers in research on drug abuse;

(E) the applicant has the capacity to conduct courses on drug abuse problems and research on drug abuse for undergraduate and graduate students, and medical and osteopathic, nursing, social work, and other specialized graduate students; and

(F) the applicant has the capacity to conduct programs of continuing education in such medical, legal, and social service fields as the Secretary may require.[46]

(2) the application contains a detailed five-year plan for research relating to drug abuse.

(b) GRANTS.—The Director of the Institute shall, under such conditions as the Secretary may reasonably require, make annual grants to Centers which have been designated under this section. No funds provided under a grant under this subsection may be used for the purchase of any land or the purchase, construction, preservation, or repair of any building. For the purposes of the preceding sentence, the term "construction" has the meaning given that term by section 701(1).[47]

(c) DRUG ABUSE AND ADDITION[48] RESEARCH.—

(1) GRANTS OR COOPERATIVE AGREEMENTS.—The Director of the Institute may make grants or enter into cooperative agreements to expand the current and ongoing interdisciplinary research and clinical trials with treatment centers of the National Drug Abuse Treatment Clinical Trials Network relating to drug abuse and addiction, including related biomedical, behavioral, and social issues.

(2) USE OF FUNDS.—Amounts made available under a grant or cooperative agreement under paragraph (1) for drug abuse and addiction may be used for research and clinical trials relating to—

(A) the effects of drug abuse on the human body, including the brain;

(B) the addictive nature of drugs and how such effects differ with respect to different individuals;

(C) the connection between drug abuse and mental health;

(D) the identification and evaluation of the most effective methods of prevention of drug abuse and addiction;

(E) the identification and development of the most effective methods of treatment of drug addiction, including pharmacological treatments;

(F) risk factors for drug abuse;

(G) effects of drug abuse and addiction on pregnant women and their fetuses; and

(H) cultural, social, behavioral, neurological, and psychological reasons that individuals abuse drugs, or refrain from abusing drugs.

(3) RESEARCH RESULTS.—The Director shall promptly disseminate research results under this subsection to Federal, State, and local entities involved in combating drug abuse and addiction.

[46] So in law. See section 123(b) of Public Law 102–321 (106 Stat. 361). The period probably should be "; and".

[47] See footnote for section 464J(b).

[48] Probably should be "ADDICTION". See section 2203 of Public Law 107–273 (116 Stat. 1794).

OFFICE ON AIDS.

SEC. 464O.[285o–3] The Director of the Institute shall establish within the Institute an Office on AIDS. The Office shall be responsible for the coordination of research and determining the direction of the Institute with respect to AIDS research related to—

(1) primary prevention of the spread of HIV, including transmission via drug abuse;

(2) drug abuse services research; and

(3) other matters determined appropriate by the Director.

MEDICATION DEVELOPMENT PROGRAM.

SEC. 464P.[285o–4] (a) ESTABLISHMENT.—There is established in the Institute a Medication Development Program through which the Director of such Institute shall—

(1) conduct periodic meetings with the Commissioner of Food and Drugs to discuss measures that may facilitate the approval process of drug abuse treatments;

(2) encourage and promote (through grants, contracts, international collaboration, or otherwise) expanded research programs, investigations, experiments, community trials, and studies, into the development and use of medications to treat drug addiction;

(3) establish or provide for the establishment of research facilities;

(4) report on the activities of other relevant agencies relating to the development and use of pharmacotherapeutic treatments for drug addiction;

(5) collect, analyze, and disseminate data useful in the development and use of pharmacotherapeutic treatments for drug addiction and collect, catalog, analyze, and disseminate through international channels, the results of such research;

ctly or through grants, contracts, or cooperative agreements, support training in the fundamental sciences and clinical disciplines related to the pharmacotherapeutic treatment of drug abuse, including the use of training stipends, fellowships, and awards where appropriate; and

(7) coordinate the activities conducted under this section with related activities conducted within the National Institute on Alcohol Abuse and Alcoholism, the National Institute of Mental Health, and other appropriate institutes and shall consult with the Directors of such Institutes.

(b) DUTIES.—In carrying out the activities described in subsection (a), the Director of the Institute—

(1) shall collect and disseminate through publications and other appropriate means, information pertaining to the research and other activities under this section;

(2) shall make grants to or enter into contracts and cooperative agreements with individuals and public and private entities to further the goals of the program;

(3) may, in accordance with section 496, and in consultation with the National Advisory Council on Drug Abuse, acquire, construct, improve, repair, operate, and maintain pharmacotherapeutic research centers, laboratories, and other

necessary facilities and equipment, and such other real or personal property as the Director determines necessary, and may, in consultation with such Advisory Council, make grants for the construction or renovation of facilities to carry out the purposes of this section;

(4) may accept voluntary and uncompensated services;

(5) may accept gifts, or donations of services, money, or property, real, personal, or mixed, tangible or intangible; and

(6) shall take necessary action to ensure that all channels for the dissemination and exchange of scientific knowledge and information are maintained between the Institute and the other scientific, medical, and biomedical disciplines and organizations nationally and internationally.

(c) REPORT.—

(1) IN GENERAL.—Not later than December 31, 1992, and each December 31 thereafter, the Director of the Institute shall submit to the Office of National Drug Control Policy established under section 1002 of the Anti-Drug Abuse Act of 1988 (21 U.S.C. 1501) a report, in accordance with paragraph (3), that describes the objectives and activities of the program assisted under this section.

(2) NATIONAL DRUG CONTROL STRATEGY.—The Director of National Drug Control Policy shall incorporate, by reference or otherwise, each report submitted under this subsection in the National Drug Control Strategy submitted the following February 1 under section 1005 of the Anti-Drug Abuse Act of 1988 (21 U.S.C. 1504).

(d) DEFINITION.—For purposes of this section, the term "pharmacotherapeutics" means medications used to treat the symptoms and disease of drug abuse, including medications to—

(1) block the effects of abused drugs;

(2) reduce the craving for abused drugs;

(3) moderate or eliminate withdrawal symptoms;

(4) block or reverse the toxic effect of abused drugs; or

(5) prevent relapse in persons who have been detoxified from drugs of abuse.

Subpart 16—National Institute of Mental Health

PURPOSE OF INSTITUTE.

SEC. 464R.[285p] (a) IN GENERAL.—The general purpose of the National Institute of Mental Health (hereafter in this subpart referred to as the "Institute") is the conduct and support of biomedical and behavioral research, health services research, research training, and health information dissemination with respect to the cause, diagnosis, treatment, control and prevention of mental illness.

(b) RESEARCH PROGRAM.—The research program established under this subpart shall include support for biomedical and behavioral neuroscience and shall be designed to further the treatment and prevention of mental illness, the promotion of mental health, and the study of the psychological, social and legal factors that influence behavior.

(c) COLLABORATION.—The Director of the Institute shall collaborate with the Administrator of the Substance Abuse and Mental Health Services Administration in focusing the services research activities of the Institute and in disseminating the results of such research to health professionals and the general public.

(d) INFORMATION WITH RESPECT TO SUICIDE.—

(1) IN GENERAL.—The Director of the Institute shall—

(A) develop and publish information with respect to the causes of suicide and the means of preventing suicide; and

(B) make such information generally available to the public and to health professionals.

(2) YOUTH SUICIDE.—Information described in paragraph (1) shall especially relate to suicide among individuals under 24 years of age.

(e) ASSOCIATE DIRECTOR FOR SPECIAL POPULATIONS.—

(1) IN GENERAL.—The Director of the Institute shall designate an Associate Director for Special Populations.

(2) DUTIES.—The Associate Director for Special Populations shall—

(A) develop and coordinate research policies and programs to assure increased emphasis on the mental health needs of women and minority populations;

(B) support programs of basic and applied social and behavioral research on the mental health problems of women and minority populations;

(C) study the effects of discrimination on institutions and individuals, including majority institutions and individuals;

(D) support and develop research designed to eliminate institutional discrimination; and

(E) provide increased emphasis on the concerns of women and minority populations in training programs, service delivery programs, and research endeavors of the Institute.

ASSOCIATE DIRECTOR FOR PREVENTION.

SEC. 464S.[285p–1] (a) IN GENERAL.—There shall be in the Institute an Associate Director for Prevention who shall be responsible for the full-time coordination and promotion of the programs in the Institute concerning the prevention of mental disorder. The Associate Director shall be appointed by the Director of the Institute from individuals who because of their professional training or expertise are experts in mental disorder and the prevention of such.

(b) REPORT.—The Associate Director for Prevention shall prepare for inclusion in the biennial report made under section 407 a description of the prevention activities of the Institute, including a description of the staff and resources allocated to those activities.

OFFICE OF RURAL MENTAL HEALTH RESEARCH.

SEC. 464T.[285p–2] (a) IN GENERAL.—There is established within the Institute an office to be known as the Office of Rural

Mental Health Research (hereafter in this section referred to as the "Office"). The Office shall be headed by a director, who shall be appointed by the Director of such Institute from among individuals experienced or knowledgeable in the provision of mental health services in rural areas. The Secretary shall carry out the authorities established in this section acting through the Director of the Office.

(b) COORDINATION OF ACTIVITIES.—The Director of the Office, in consultation with the Director of the Institute and with the Director of the Office of Rural Health Policy, shall—

(1) coordinate the research activities of the Department of Health and Human Services as such activities relate to the mental health of residents of rural areas; and

(2) coordinate the activities of the Office with similar activities of public and nonprofit private entities.

(c) RESEARCH, DEMONSTRATIONS, EVALUATIONS, AND DISSEMINATION.—The Director of the Office may, with respect to the mental health of adults and children residing in rural areas—

(1) conduct research on conditions that are unique to the residents of rural areas, or more serious or prevalent in such residents;

(2) conduct research on improving the delivery of services in such areas; and

(3) disseminate information to appropriate public and nonprofit private entities.

(d) AUTHORITY REGARDING GRANTS AND CONTRACTS.—The Director of the Office may carry out the authorities established in subsection (c) directly and through grants, cooperative agreements, or contracts with public or nonprofit private entities.

OFFICE ON AIDS.

SEC. 464U.[285p–3] The Director of the Institute shall establish within the Institute an Office on AIDS. The Office shall be responsible for the coordination of research and determining the direction of the Institute with respect to AIDS research related to—

(1) primary prevention of the spread of HIV, including transmission via sexual behavior;

(2) mental health services research; and

(3) other matters determined appropriate by the Director.

Subpart 17—National Institute of Nursing Research

PURPOSE OF THE INSTITUTE.

SEC. 464V.[285q] The general purpose of the National Institute of Nursing Research (in this subpart referred to as the "Institute") is the conduct and support of, and dissemination of information respecting, basic and clinical nursing research, training, and other programs in patient care research.

SPECIFIC AUTHORITIES.

SEC. 464W.[285q–1] To carry out section 464V, the Director of the Institute may provide research training and instruction and establish, in the Institute and other nonprofit institutions, research

traineeships and fellowships in the study and investigation of the prevention of disease, health promotion, and the nursing care of individuals with and the families of individuals with acute and chronic illnesses. The Director of the Institute may provide individuals receiving such training and instruction or such traineeships or fellowships with such stipends and allowances (including amounts for travel and subsistence and dependency allowances) as the Director determines necessary. The Director may make grants to nonprofit institutions to provide such training and instruction and traineeships and fellowships.

ADVISORY COUNCIL.

SEC. 464X.[285q–2] (a)(1) The Secretary shall appoint an advisory council for the Institute which shall advise, assist, consult with, and make recommendations to the Secretary and the Director of the Institute on matters related to the activities carried out by and through the Institute and the policies respecting such activities.

(2) The advisory council for the Institute may recommend to the Secretary acceptance, in accordance with section 2701,[49] of conditional gifts for study, investigations, and research and for the acquisition of grounds or construction, equipping, or maintenance of facilities for the Institute.

(3) The advisory council for the Institute—

(A)(i) may make recommendations to the Director of the Institute respecting research conducted at the Institute,

(ii) may review applications for grants and cooperative agreements for research or training and recommend for approval applications for projects which show promise of making valuable contributions to human knowledge, and

(iii) may review any grant, contract, or cooperative agreement proposed to be made or entered into by the Institute;

(B) may collect, by correspondence or by personal investigation, information as to studies which are being carried on in the United States or any other country as to the diseases, disorders, or other aspects of human health with respect to which the Institute is concerned and with the approval of the Director of the Institute make available such information through appropriate publications for the benefit of public and private health entities and health professions personnel and scientists and for the information of the general public; and

(C) may appoint subcommittees and convene workshops and conferences.

(b)(1) The advisory council shall consist of ex officio members and not more than eighteen members appointed by the Secretary.

(2) The ex officio members of the advisory council shall consist of—

[49] Probably should be section 231. That section formerly was section 2701, and was redesignated by subsection (a)(2) of section 2010 of Public Law 103–43 (107 Stat. 213). Subsection (b)(5) of such section purported to conform the above reference, but the amendment cannot be executed because the amendment applied to the incorrect section. (The conforming amendment applied to section 485. Section 464X formerly was section 485, and was redesignated by section 1511(b)(2)(B) of Public Law 103–43 (107 Stat. 179).)

(A) the Secretary, the Director of NIH, the Director of the Institute, the chief nursing officer of the Department of Veterans Affairs, the Assistant Secretary of Defense for Health Affairs, the Director of the Division of Nursing of the Health Resources and Services Administration (or the designees of such officers), and

(B) such additional officers or employees of the United States as the Secretary determines necessary for the advisory council to effectively carry out its functions.

(3) The members of the advisory council who are not ex officio members shall be appointed as follows:

(A) Two-thirds of the members shall be appointed by the Secretary from among the leading representatives of the health and scientific disciplines (including public health and the behavioral or social sciences) relevant to the activities of the Institute. Of the members appointed pursuant to this subparagraph, at least seven shall be professional nurses who are recognized experts in the area of clinical practice, education, or research.

(B) One-third of the members shall be appointed by the Secretary from the general public and shall include leaders in fields of public policy, law, health policy, economics, and management.

(4) Members of the advisory council who are officers or employees of the United States shall not receive any compensation for service on the advisory council. The other members of the advisory council shall receive, for each day (including traveltime) they are engaged in the performance of the functions of the advisory council, compensation at rates not to exceed the daily equivalent of the annual rate in effect for grade GS–18 of the General Schedule.

(c) The term of office of an appointed member of the advisory council is four years, except that any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term and the Secretary shall make appointments to an advisory council in such a manner as to ensure that the terms of the members do not all expire in the same year. A member may serve after the expiration of the member's term until a successor has taken office. A member who has been appointed for a term of four years may not be reappointed to an advisory council before two years from the date of expiration of such term of office. If a vacancy occurs in the advisory council among the appointed members, the Secretary shall make an appointment to fill the vacancy within 90 days from the date the vacancy occurs.

(d) The chairman of the advisory council shall be selected by the Secretary from among the appointed members, except that the Secretary may select the Director of the Institute to be the chairman of the advisory council. The term of office of the chairman shall be two years.

(e) The advisory council shall meet at the call of the chairman or upon the request of the Director of the Institute, but at least three times each fiscal year. The location of the meetings of the advisory council is subject to the approval of the Director of the Institute.

(f) The Director of the Institute shall designate a member of the staff of the Institute to serve as the executive secretary of the advisory council. The Director of the Institute shall make available to the advisory council such staff, information, and other assistance as it may require to carry out its functions. The Director of the Institute shall provide orientation and training for new members of the advisory council to provide them with such information and training as may be appropriate for their effective participation in the functions of the advisory council.

(g) The advisory council may prepare, for inclusion in the biennial report made under section 464Y, (1) comments respecting the activities of the advisory council in the fiscal years respecting which the report is prepared, (2) comments on the progress of the Institute in meeting its objectives, and (3) recommendations respecting the future directions and program and policy emphasis of the Institute. The advisory council may prepare such additional reports as it may determine appropriate.

BIENNIAL REPORT.

SEC. 464Y.[285q–3] The Director of the Institute after consultation with the advisory council for the Institute, shall prepare for inclusion in the biennial report made under section 403 a biennial report which shall consist of a description of the activities of the Institute and program policies of the Director of the Institute in the fiscal years respecting which the report is prepared. The Director of the Institute may prepare such additional reports as the Director determines appropriate. The Director of the Institute shall provide the advisory council of the Institute an opportunity for the submission of the written comments referred to in section 464X(g).

Subpart 18—National Institute of Biomedical Imaging and Bioengineering

PURPOSE OF THE INSTITUTE.

SEC. 464z.[285r] (a) The general purpose of the National Institute of Biomedical Imaging and Bioengineering (in this section referred to as the "Institute") is the conduct and support of research, training, the dissemination of health information, and other programs with respect to biomedical imaging, biomedical engineering, and associated technologies and modalities with biomedical applications (in this section referred to as "biomedical imaging and bioengineering").

(b)(1) The Director of the Institute, with the advice of the Institute's advisory council, shall establish a National Biomedical Imaging and Bioengineering Program (in this section referred to as the "Program").

(2) Activities under the Program shall include the following with respect to biomedical imaging and bioengineering:

(A) Research into the development of new techniques and devices.

(B) Related research in physics, engineering, mathematics, computer science, and other disciplines.

(C) Technology assessments and outcomes studies to evaluate the effectiveness of biologics, materials, processes, devices, procedures, and informatics.

(D) Research in screening for diseases and disorders.

(E) The advancement of existing imaging and bioengineering modalities, including imaging, biomaterials, and informatics.

(F) The development of target-specific agents to enhance images and to identify and delineate disease.

(G) The development of advanced engineering and imaging technologies and techniques for research from the molecular and genetic to the whole organ and body levels.

(H) The development of new techniques and devices for more effective interventional procedures (such as image-guided interventions).

(3)(A) With respect to the Program, the Director of the Institute shall prepare and transmit to the Secretary and the Director of NIH a plan to initiate, expand, intensify, and coordinate activities of the Institute with respect to biomedical imaging and bioengineering. The plan shall include such comments and recommendations as the Director of the Institute determines appropriate. The Director of the Institute shall periodically review and revise the plan and shall transmit any revisions of the plan to the Secretary and the Director of NIH.

(B) The plan under subparagraph (A) shall include the recommendations of the Director of the Institute with respect to the following:

(i) Where appropriate, the consolidation of programs of the National Institutes of Health for the express purpose of enhancing support of activities regarding basic biomedical imaging and bioengineering research.

(ii) The coordination of the activities of the Institute with related activities of the other agencies of the National Institutes of Health and with related activities of other Federal agencies.

(c) The establishment under section 406 of an advisory council for the Institute is subject to the following:

(1) The number of members appointed by the Secretary shall be 12.

(2) Of such members—

(A) six members shall be scientists, engineers, physicians, and other health professionals who represent disciplines in biomedical imaging and bioengineering and who are not officers or employees of the United States; and

(B) six members shall be scientists, engineers, physicians, and other health professionals who represent other disciplines and are knowledgeable about the applications of biomedical imaging and bioengineering in medicine, and who are not officers or employees of the United States.

(3) In addition to the ex officio members specified in section 406(b)(2), the ex officio members of the advisory council shall include the Director of the Centers for Disease Control and Prevention, the Director of the National Science Founda-

tion, and the Director of the National Institute of Standards and Technology (or the designees of such officers).

Subpart 19—National Human Genome Research Institute

PURPOSE OF THE CENTER [50].

SEC. 464z–1.[285s] (a) The general purpose of the National Human Genome Research Institute (in this subpart referred to as the "Institute") is to characterize the structure and function of the human genome, including the mapping and sequencing of individual genes. Such purpose includes—

(1) planning and coordinating the research goal of the genome project;

(2) reviewing and funding research proposals;

(3) developing training programs;

(4) coordinating international genome research;

(5) communicating advances in genome science to the public; and

(6) reviewing and funding proposals to address the ethical and legal issues associated with the genome project (including legal issues regarding patents).

(b) The Director of the Institute may conduct and support research training—

(1) for which fellowship support is not provided under section 487; and

(2) that is not residency training of physicians or other health professionals.

(c)(1) Except as provided in paragraph (2), of the amounts appropriated to carry out subsection (a) for a fiscal year, the Director of the Institute shall make available not less than 5 percent for carrying out paragraph (6) of such subsection.

(2) With respect to providing funds under subsection (a)(6) for proposals to address the ethical issues associated with the genome project, paragraph (1) shall not apply for a fiscal year if the Director of the Institute certifies to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, that the Director has determined that an insufficient number of such proposals meet the applicable requirements of sections 491 and 492.

Subpart 20—National Institute on Minority Health and Health Disparities

SEC. 464z–3.[285t] PURPOSE OF CENTER [51].

(a) IN GENERAL.—The general purpose of the National Institute on Minority Health and Health Disparities (in this subpart referred to as the "Institute") is the conduct and support of research, training, dissemination of information, and other programs with re-

[50] The word "CENTER" in the section heading probably should read "INSTITUTE". Section 101(c)(4)(C) of Public Law 109–482 (120 Stat. 3675) struck "center" each place such term appeared in this subpart and inserted "institute". However, this amendment was not effective with respect to the section heading because the word "CENTER" appears in small caps.

[51] The word "CENTER" in the section heading for section 464z–3 probably should read "INSTITUTE". See amendment made by section 10334(c)(1)(D)(iii) of Public Law 111–148.

spect to minority health conditions and other populations with health disparities.

(b) PRIORITIES.—The Director of the Institute shall in expending amounts appropriated under this subpart give priority to conducting and supporting minority health disparities research.

(c) MINORITY HEALTH DISPARITIES RESEARCH.—For purposes of this subpart:

(1) The term "minority health disparities research" means basic, clinical, and behavioral research on minority health conditions (as defined in paragraph (2)), including research to prevent, diagnose, and treat such conditions.

(2) The term "minority health conditions", with respect to individuals who are members of minority groups, means all diseases, disorders, and conditions (including with respect to mental health and substance abuse)—

(A) unique to, more serious, or more prevalent in such individuals;

(B) for which the factors of medical risk or types of medical intervention may be different for such individuals, or for which it is unknown whether such factors or types are different for such individuals; or

(C) with respect to which there has been insufficient research involving such individuals as subjects or insufficient data on such individuals.

(3) The term "minority group" has the meaning given the term "racial and ethnic minority group" in section 1707.

(4) The terms "minority" and "minorities" refer to individuals from a minority group.

(d) HEALTH DISPARITY POPULATIONS.—For purposes of this subpart:

(1) A population is a health disparity population if, as determined by the Director of the Institute after consultation with the Director of the Agency for Healthcare Research and Quality, there is a significant disparity in the overall rate of disease incidence, prevalence, morbidity, mortality, or survival rates in the population as compared to the health status of the general population.

(2) The Director shall give priority consideration to determining whether minority groups qualify as health disparity populations under paragraph (1).

(3) The term "health disparities research" means basic, clinical, and behavioral research on health disparity populations (including individual members and communities of such populations) that relates to health disparities as defined under paragraph (1), including the causes of such disparities and methods to prevent, diagnose, and treat such disparities.

(e) COORDINATION OF ACTIVITIES.—The Director of the Institute shall act as the primary Federal official with responsibility for coordinating all minority health disparities research and other health disparities research conducted or supported by the National Institutes of Health, and—

(1) shall represent the health disparities research program of the National Institutes of Health, including the minority

health disparities research program, at all relevant Executive branch task forces, committees and planning activities; and

(2) shall maintain communications with all relevant Public Health Service agencies, including the Indian Health Service, and various other departments of the Federal Government to ensure the timely transmission of information concerning advances in minority health disparities research and other health disparities research between these various agencies for dissemination to affected communities and health care providers.

(f) COLLABORATIVE COMPREHENSIVE PLAN AND BUDGET.—

(1) IN GENERAL.—Subject to the provisions of this section and other applicable law, the Director of NIH, the Director of the Institute, and the directors of the other agencies of the National Institutes of Health in collaboration (and in consultation with the advisory council for the Institute) shall—

(A) establish a comprehensive plan and budget for the conduct and support of all minority health disparities research and other health disparities research activities of the agencies of the National Institutes of Health (which plan and budget shall be first established under this subsection not later than 12 months after the date of the enactment of this subpart);

(B) ensure that the plan and budget establish priorities among the health disparities research activities that such agencies are authorized to carry out;

(C) ensure that the plan and budget establish objectives regarding such activities, describes the means for achieving the objectives, and designates the date by which the objectives are expected to be achieved;

(D) ensure that, with respect to amounts appropriated for activities of the Institute, the plan and budget give priority in the expenditure of funds to conducting and supporting minority health disparities research;

(E) ensure that all amounts appropriated for such activities are expended in accordance with the plan and budget;

(F) review the plan and budget not less than annually, and revise the plan and budget as appropriate;

(G) ensure that the plan and budget serve as a broad, binding statement of policies regarding minority health disparities research and other health disparities research activities of the agencies, but do not remove the responsibility of the heads of the agencies for the approval of specific programs or projects, or for other details of the daily administration of such activities, in accordance with the plan and budget; and

(H) promote coordination and collaboration among the agencies conducting or supporting minority health or other health disparities research.

(2) CERTAIN COMPONENTS OF PLAN AND BUDGET.—With respect to health disparities research activities of the agencies of the National Institutes of Health, the Director of the Institute shall ensure that the plan and budget under paragraph (1) provide for—

(A) basic research and applied research, including research and development with respect to products;

(B) research that is conducted by the agencies;

(C) research that is supported by the agencies;

(D) proposals developed pursuant to solicitations by the agencies and for proposals developed independently of such solicitations; and

(E) behavioral research and social sciences research, which may include cultural and linguistic research in each of the agencies.

(3) MINORITY HEALTH DISPARITIES RESEARCH.—The plan and budget under paragraph (1) shall include a separate statement of the plan and budget for minority health disparities research.

(g) PARTICIPATION IN CLINICAL RESEARCH.—The Director of the Institute shall work with the Director of NIH and the directors of the agencies of the National Institutes of Health to carry out the provisions of section 492B that relate to minority groups.

(h) RESEARCH ENDOWMENTS.—

(1) IN GENERAL.—The Director of the Institute may carry out a program to facilitate minority health disparities research and other health disparities research by providing for research endowments—

(1) at centers of excellence under section 736; and

(2) at centers of excellence under section 464z–4.[52]

(2) ELIGIBILITY.—The Director of the Institute may provide for a research endowment under paragraph (1) only if the institution involved meets the following conditions:

(A) The institution does not have an endowment that is worth in excess of an amount equal to 50 percent of the national median of endowment funds at institutions that conduct similar biomedical research or training of health professionals.

(B) The application of the institution under paragraph (1) regarding a research endowment has been recommended pursuant to technical and scientific peer review and has been approved by the advisory council under subsection (j).

(i) CERTAIN ACTIVITIES.—In carrying out subsection (a), the Director of the Institute—

(1) shall assist the Director of NIH[53] in carrying out section 404I(c)(2) and in committing resources for construction at Institutions of Emerging Excellence under such section;

(2) shall establish projects to promote cooperation among Federal agencies, State, local, tribal, and regional public health

[52] So in law. Section 10334(c)(2)(A) of Public Law 111–148 amends (h)(1) by striking and inserting text that results in two paragraphs (1) and (2). The second paragraph (1) and the first paragraph (2) proabbly should be redesignated as subparagraphs (A) and (B), respectively (and moving margins to the right so that they align with subparagraphs cpmtaomed in paragraph (2)).

[53] Section 221(d)(3)(A) of division F of Public Law 112–74 provided for an amendment to strike "Director of National Institute for Research Resources" and inserting "Director of NIH". The amendment probably should have been to strike "Director of National Institute for Research Resources", but was carried out to reflect the probable intent of Congress.

agencies, and private entities in health disparities research; and

(3) may utilize information from previous health initiatives concerning minorities and other health disparity populations.

(j) ADVISORY COUNCIL.—

(1) IN GENERAL.—The Secretary shall, in accordance with section 406, establish an advisory council to advise, assist, consult with, and make recommendations to the Director of the Institute on matters relating to the activities described in subsection (a), and with respect to such activities to carry out any other functions described in section 406 for advisory councils under such section. Functions under the preceding sentence shall include making recommendations on budgetary allocations made in the plan under subsection (f), and shall include reviewing reports under subsection (k) before the reports are submitted under such subsection.

(2) MEMBERSHIP.—With respect to the membership of the advisory council under paragraph (1), a majority of the members shall be individuals with demonstrated expertise regarding minority health disparity and other health disparity issues; representatives of communities impacted by minority and other health disparities shall be included; and a diversity of health professionals shall be represented. The membership shall in addition include a representative of the Office of Behavioral and Social Sciences Research under section 404A.

(h)[54] INTERAGENCY COORDINATION.—The Director of the Institute, as the primary Federal officials with responsibility for coordinating all research and activities conducted or supported by the National Institutes of Health on minority health and health disparities, shall plan, coordinate, review and evaluate research and other activities conducted or supported by the Institutes and Centers of the National Institutes of Health.

SEC. 464z–4.[285t–1] CENTERS OF EXCELLENCE FOR RESEARCH EDUCATION AND TRAINING.

(a) IN GENERAL.—The Director of the Institute shall make awards of grants or contracts to designated biomedical and behavioral research institutions under paragraph (1) of subsection (c), or to consortia under paragraph (2) of such subsection, for the purpose of assisting the institutions in supporting programs of excellence in biomedical and behavioral research training for individuals who are members of minority health disparity populations or other health disparity populations.

(b) REQUIRED USE OF FUNDS.—An award may be made under subsection (a) only if the applicant involved agrees that the grant will be expended—

(1) to train members of minority health disparity populations or other health disparity populations as professionals in the area of biomedical or behavioral research or both; or

(2) to expand, remodel, renovate, or alter existing research facilities or construct new research facilities for the purpose of

[54] So in law. Section 10334(c)(2)(C) of Public Law 111–148 amends section 464z–3 (as redesignated) by adding a subsection (h) at the end. Probably should be a subsection (k).

conducting minority health disparities research and other health disparities research.

(c) CENTERS OF EXCELLENCE.—

(1) IN GENERAL.—For purposes of this section, a designated biomedical and behavioral research institution is a biomedical and behavioral research institution that—

(A) has a significant number of members of minority health disparity populations or other health disparity populations enrolled as students in the institution (including individuals accepted for enrollment in the institution);

(B) has been effective in assisting such students of the institution to complete the program of education or training and receive the degree involved;

(C) has made significant efforts to recruit minority students to enroll in and graduate from the institution, which may include providing means-tested scholarships and other financial assistance as appropriate; and

(D) has made significant recruitment efforts to increase the number of minority or other members of health disparity populations serving in faculty or administrative positions at the institution.

(2) CONSORTIUM.—Any designated biomedical and behavioral research institution involved may, with other biomedical and behavioral institutions (designated or otherwise), including tribal health programs, form a consortium to receive an award under subsection (a).

(3) APPLICATION OF CRITERIA TO OTHER PROGRAMS.—In the case of any criteria established by the Director of the Institute for purposes of determining whether institutions meet the conditions described in paragraph (1), this section may not, with respect to minority health disparity populations or other health disparity populations, be construed to authorize, require, or prohibit the use of such criteria in any program other than the program established in this section.

(d) DURATION OF GRANT.—The period during which payments are made under a grant under subsection (a) may not exceed 5 years. Such payments shall be subject to annual approval by the Director of the Institute and to the availability of appropriations for the fiscal year involved to make the payments.

(e) MAINTENANCE OF EFFORT.—

(1) IN GENERAL.—With respect to activities for which an award under subsection (a) is authorized to be expended, the Director of the Institute may not make such an award to a designated research institution or consortium for any fiscal year unless the institution, or institutions in the consortium, as the case may be, agree to maintain expenditures of non-Federal amounts for such activities at a level that is not less than the level of such expenditures maintained by the institutions involved for the fiscal year preceding the fiscal year for which such institutions receive such an award.

(2) USE OF FEDERAL FUNDS.—With respect to any Federal amounts received by a designated research institution or consortium and available for carrying out activities for which an award under subsection (a) is authorized to be expended, the

Director of the Institute may make such an award only if the institutions involved agree that the institutions will, before expending the award, expend the Federal amounts obtained from sources other than the award.

(f) CERTAIN EXPENDITURES.—The Director of the Institute may authorize a designated biomedical and behavioral research institution to expend a portion of an award under subsection (a) for research endowments.

(g) DEFINITIONS.—For purposes of this section:

(1) The term "designated biomedical and behavioral research institution" has the meaning indicated for such term in subsection (c)(1). Such term includes any health professions school receiving an award of a grant or contract under section 736.

(2) The term "program of excellence" means any program carried out by a designated biomedical and behavioral research institution with an award under subsection (a), if the program is for purposes for which the institution involved is authorized in subsection (b) to expend the grant.

SEC. 464z–5.[285t–2] LOAN REPAYMENT PROGRAM FOR MINORITY HEALTH DISPARITIES RESEARCH.

(a) IN GENERAL.—The Director of the Institute shall establish a program of entering into contracts with qualified health professionals under which such health professionals agree to engage in minority health disparities research or other health disparities research in consideration of the Federal Government agreeing to repay, for each year of engaging in such research, not more than $35,000 of the principal and interest of the educational loans of such health professionals.

(b) SERVICE PROVISIONS.—The provisions of sections 338B, 338C, and 338E shall, except as inconsistent with subsection (a), apply to the program established in such subsection to the same extent and in the same manner as such provisions apply to the National Health Service Corps Loan Repayment Program established in subpart III of part D of title III.

(c) REQUIREMENT REGARDING HEALTH DISPARITY POPULATIONS.—The Director of the Institute shall ensure that not fewer than 50 percent of the contracts entered into under subsection (a) are for appropriately qualified health professionals who are members of a health disparity population.

(d) PRIORITY.—With respect to minority health disparities research and other health disparities research under subsection (a), the Secretary shall ensure that priority is given to conducting projects of biomedical research.

SEC. 464z–6.[285t–3] GENERAL PROVISIONS REGARDING THE CENTER.

The Secretary, acting through the Director of the National Institutes of Health, shall provide administrative support and support services to the Director of the Institute and shall ensure that such support takes maximum advantage of existing administrative structures at the agencies of the National Institutes of Health.

PART D—NATIONAL LIBRARY OF MEDICINE

Subpart 1—General Provisions

PURPOSE, ESTABLISHMENT, AND FUNCTIONS OF THE NATIONAL LIBRARY OF MEDICINE.

SEC. 465.[286] (a) In order to assist the advancement of medical and related sciences and to aid the dissemination and exchange of scientific and other information important to the progress of medicine and to the public health, there is established the National Library of Medicine (hereafter in this part referred to as the "Library").

(b) The Secretary, through the Library and subject to subsection (d), shall—

(1) acquire and preserve books, periodicals, prints, films, recordings, and other library materials pertinent to medicine;

(2) organize the materials specified in paragraph (1) by appropriate cataloging, indexing, and bibliographical listings;

(3) publish and disseminate the catalogs, indexes, and bibliographies referred to in paragraph (2);

(4) make available, through loans, photographic or other copying procedures, or otherwise, such materials in the Library as the Secretary determines appropriate;

(5) provide reference and research assistance;

(6) publicize the availability from the Library of the products and services described in any of paragraphs (1) through (5);

(7) promote the use of computers and telecommunications by health professionals (including health professionals in rural areas) for the purpose of improving access to biomedical information for health care delivery and medical research; and

(8) engage in such other activities as the Secretary determines appropriate and as the Library's resources permit.

(c) The Secretary may exchange, destroy, or otherwise dispose of any books, periodicals, films, and other library materials not needed for the permanent use of the Library.

(d)(1) The Secretary may, after obtaining the advice and recommendations of the Board of Regents, prescribe rules under which the Library will—

(A) provide copies of its publications or materials,

(B) will make available its facilities for research, or

(C) will make available its bibliographic, reference, or other services,

to public and private entities and individuals.

(2) Rules prescribed under paragraph (1) may provide for making available such publications, materials, facilities, or services—

(A) without charge as a public service,

(B) upon a loan, exchange, or charge basis, or

(C) in appropriate circumstances, under contract arrangements made with a public or other nonprofit entity.

(e) Whenever the Secretary, with the advice of the Board of Regents, determines that—

(1) in any geographic area of the United States there is no regional medical library adequate to serve such area;

(2) under criteria prescribed for the administration of section 475, there is a need for a regional medical library to serve such area; and

(3) because there is no medical library located in such area which, with financial assistance under section 475, can feasibly be developed into a regional medical library adequate to serve such area,

the Secretary may establish, as a branch of the Library, a regional medical library to serve the needs of such area.

(f) Section 231 shall be applicable to the acceptance and administration of gifts made for the benefit of the Library or for carrying out any of its functions, and the Board of Regents shall make recommendations to the Secretary relating to establishment within the Library of suitable memorials to the donors.

(g) For purposes of this part, the terms "medicine" and "medical", except when used in section 466, include preventive and therapeutic medicine, dentistry, pharmacy, hospitalization, nursing, public health, and the fundamental sciences related thereto, and other related fields of study, research, or activity.

BOARD OF REGENTS.

SEC. 466.[286a] (a)(1)(A) The Board of Regents of the National Library of Medicine consists of ex officio members and ten members appointed by the Secretary.

(B) The ex officio members are the Surgeons General of the Public Health Service, the Army, the Navy, and the Air Force, the Chief Medical Director of the Department of Veterans Affairs, the Dean of the Uniformed Services University of the Health Sciences, the Assistant Director for Biological, Behavioral, and Social Sciences of the National Science Foundation, the Director of the National Agricultural Library, and the Librarian of Congress (or their designees).

(C) The appointed members shall be selected from among leaders in the various fields of the fundamental sciences, medicine, dentistry, public health, hospital administration, pharmacology, health communications technology, or scientific or medical library work, or in public affairs. At least six of the appointed members shall be selected from among leaders in the fields of medical, dental, or public health research or education.

(2) The Board shall annually elect one of the appointed members to serve as chairman until the next election. The Secretary shall designate a member of the Library staff to act as executive secretary of the Board.

(b) The Board shall advise, consult with, and make recommendations to the Secretary on matters of policy in regard to the Library, including such matters as the acquisition of materials for the Library, the scope, content, and organization of the Library's services, and the rules under which its materials, publications, facilities, and services shall be made available to various kinds of users. The Secretary shall include in the annual report of the Secretary to the Congress a statement covering the recommendations made by the Board and the disposition thereof. The Secretary may use the services of any member of the Board in con-

nection with matters related to the work of the Library, for such periods, in addition to conference periods, as the Secretary may determine.

(c) Each appointed member of the Board shall hold office for a term of four years, except that any member appointed to fill a vacancy occurring prior to the expiration of the term for which the predecessor of such member was appointed shall be appointed for the remainder of such term. None of the appointed members shall be eligible for reappointment within one year after the end of the preceding term of such member.

LIBRARY FACILITIES.

SEC. 467.[286a–1] The Administrator of General Services may acquire, by purchase, condemnation, donation, or otherwise, a suitable site or sites, selected by the Secretary in accordance with the direction of the Board, for suitable and adequate buildings and facilities for use of the Library and to erect thereon, furnish, and equip such buildings and facilities. Amounts appropriated to carry out this section may be used for the cost of preparation of drawings and specifications, supervision of construction, and other administrative expenses incident to the work. The Administrator of General Services shall prepare the plans and specifications, make all necessary contracts, and supervise construction.

Subpart 2—Financial Assistance

DEFINITIONS.

SEC. 470.[286b–1] As used in this subpart—

(1) the term "medical library" means a library related to the sciences related to health; and

(2) the term "sciences related to health" includes medicine, osteopathy, dentistry, and public health, and fundamental and applied sciences when related thereto.

NATIONAL MEDICAL LIBRARIES ASSISTANCE ADVISORY BOARD.

SEC. 471.[286b–2] (a) The Board of Regents of the National Library of Medicine shall also serve as the National Medical Libraries Assistance Advisory Board (hereafter in this subpart referred to as the "Board").

(b) The Board shall advise and assist the Secretary in the preparation of general regulations and with respect to policy matters arising in the administration of this subpart.

(c) The Secretary may use the services of any member of the Board, in connection with matters related to the administration of this part for such periods, in addition to conference periods, as the Secretary may determine.

(d) Appointed members of the Board who are not otherwise in the employ of the United States, while attending conferences of the Board or otherwise serving at the request of the Secretary in connection with the administration of this subpart, shall be entitled to receive compensation, per diem in lieu of subsistence, and travel expenses in the same manner and under the same conditions as that prescribed under section 208(c) when attending conferences,

traveling, or serving at the request of the Secretary in connection with the Board's function under this section.

GRANTS FOR TRAINING IN MEDICAL LIBRARY SCIENCES.

SEC. 472.[286b–3] The Secretary shall make grants—

(1) to individuals to enable them to accept traineeships and fellowships leading to postbaccalaureate academic degrees in the field of medical library science, in related fields pertaining to sciences related to health, or in the field of the communication of information;

(2) to individuals who are librarians or specialists in information on sciences relating to health, to enable them to undergo intensive training or retraining so as to attain greater competence in their occupations (including competence in the fields of automatic data processing and retrieval);

(3) to assist appropriate public and private nonprofit institutions in developing, expanding, and improving training programs in library science and the field of communications of information pertaining to sciences relating to health; and

(4) to assist in the establishment of internship programs in established medical libraries meeting standards which the Secretary shall prescribe.

ASSISTANCE FOR SPECIAL SCIENTIFIC PROJECTS, AND FOR RESEARCH AND DEVELOPMENT IN MEDICAL LIBRARY SCIENCE AND RELATED FIELDS.

SEC. 473.[286b–4] (a) The Secretary shall make grants to physicians and other practitioners in the sciences related to health, to scientists, and to public or nonprofit private institutions on behalf of such physicians, other practitioners, and scientists for the compilation of existing, or the writing of original, contributions relating to scientific, social, or cultural advancements in sciences related to health. In making such grants, the Secretary shall make appropriate arrangements under which the facilities of the Library and the facilities of libraries of public and private nonprofit institutions of higher learning may be made available in connection with the projects for which such grants are made.

(b) The Secretary shall make grants to appropriate public or private nonprofit institutions and enter into contracts with appropriate persons, for purposes of carrying out projects of research, investigations, and demonstrations in the field of medical library science and related activities and for the development of new techniques, systems, and equipment, for processing, storing, retrieving, and distributing information pertaining to sciences related to health.

(c)(1) The Secretary shall make grants to public or nonprofit private institutions for the purpose of carrying out projects of research on, and development and demonstration of, new education technologies.

(2) The purposes for which a grant under paragraph (1) may be made include projects concerning—

(A) computer-assisted teaching and testing of clinical competence at health professions and research institutions;

(B) the effective transfer of new information from research laboratories to appropriate clinical applications;

(C) the expansion of the laboratory and clinical uses of computer-stored research databases; and

(D) the testing of new technologies for training health care professionals.

(3) The Secretary may not make a grant under paragraph (1) unless the applicant for the grant agrees to make the projects available with respect to—

(A) assisting in the training of health professions students; and

(B) enhancing and improving the capabilities of health professionals regarding research and teaching.

GRANTS FOR ESTABLISHING, EXPANDING, AND IMPROVING THE BASIC RESOURCES OF MEDICAL LIBRARIES AND RELATED INSTRUMENTALITIES.

SEC. 474.[286b–5] (a) The Secretary shall make grants of money, materials, or both, to public or private nonprofit medical libraries and related scientific communication instrumentalities for the purpose of establishing, expanding, and improving their basic medical library or related resources. A grant under this subsection may be used for—

(1) the acquisition of books, journals, photographs, motion picture and other films, and other similar materials;

(2) cataloging, binding, and other services and procedures for processing library resource materials for use by those who are served by the library or related instrumentality;

(3) the acquisition of duplication devices, facsimile equipment, film projectors, recording equipment, and other equipment to facilitate the use of the resources of the library or related instrumentality by those who are served by it; and

(4) the introduction of new technologies in medical librarianship.

(b)(1) The amount of any grant under this section to any medical library or related instrumentality shall be determined by the Secretary on the basis of the scope of library or related services provided by such library or instrumentality in relation to the population and purposes served by it. In making a determination of the scope of services served by any medical library or related instrumentality, the Secretary shall take into account—

(A) the number of graduate and undergraduate students making use of the resources of such library or instrumentality;

(B) the number of physicians and other practitioners in the sciences related to health utilizing the resources of such library or instrumentality;

(C) the type of supportive staffs, if any, available to such library or instrumentality;

(D) the type, size, and qualifications of the faculty of any school with which such library or instrumentality is affiliated;

(E) the staff of any hospital or hospitals or of any clinic or clinics with which such library or instrumentality is affiliated; and

(F) the geographic area served by such library or instrumentality and the availability within such area of medical library or related services provided by other libraries or related instrumentalities.

(2) Grants to such medical libraries or related instrumentalities under this section shall be in such amounts as the Secretary may by regulation prescribe with a view to assuring adequate continuing financial support for such libraries or instrumentalities from other sources during and after the period for which grants are provided, except that in no case shall any grant under this section to a medical library or related instrumentality for any fiscal year exceed $1,000,000.

GRANTS AND CONTRACTS FOR ESTABLISHMENT OF REGIONAL MEDICAL LIBRARIES.

SEC. 475.[286b–6] (a) The Secretary, with the advice of the Board, shall make grants to and enter into contracts with existing public or private nonprofit medical libraries so as to enable each of them to serve as the regional medical library for the geographical area in which it is located.

(b) The uses for which grants and contracts under this section may be employed include the—

(1) acquisition of books, journals, and other similar materials;

(2) cataloging, binding, and other procedures for processing library resource materials for use by those who are served by the library;

(3) acquisition of duplicating devices and other equipment to facilitate the use of the resources of the library by those who are served by it;

(4) acquisition of mechanisms and employment of personnel for the speedy transmission of materials from the regional library to local libraries in the geographic area served by the regional library; and

(5) planning for services and activities under this section.

(c)(1) Grants and contracts under this section shall only be made to or entered into with medical libraries which agree—

(A) to modify and increase their library resources, and to supplement the resources of cooperating libraries in the region, so as to be able to provide adequate supportive services to all libraries in the region as well as to individual users of library services; and

(B) to provide free loan services to qualified users and make available photoduplicated or facsimile copies of biomedical materials which qualified requesters may retain.

(2) The Secretary, in awarding grants and contracts under this section, shall give priority to medical libraries having the greatest potential of fulfilling the needs for regional medical libraries. In determining the priority to be assigned to any medical library, the Secretary shall consider—

(A) the adequacy of the library (in terms of collections, personnel, equipment, and other facilities) as a basis for a regional medical library; and

(B) the size and nature of the population to be served in the region in which the library is located.

(d) Grants and contracts under this section for basic resource materials to a library may not exceed—

(1) 50 percent of the library's annual operating expense (exclusive of Federal financial assistance under this part) for the preceding year; or

(2) in case of the first year in which the library receives a grant under this section for basic resource materials, 50 percent of its average annual operating expenses over the past three years (or if it had been in operation for less than three years, its annual operating expenses determined by the Secretary in accordance with regulations).

FINANCIAL SUPPORT OF BIOMEDICAL SCIENTIFIC PUBLICATIONS.

SEC. 476.[286b–7] (a) The Secretary, with the advice of the Board, shall make grants to, and enter into appropriate contracts with, public or private nonprofit institutions of higher education and individual scientists for the purpose of supporting biomedical scientific publications of a nonprofit nature and to procure the compilation, writing, editing, and publication of reviews, abstracts, indices, handbooks, bibliographies, and related matter pertaining to scientific works and scientific developments.

(b) Grants under subsection (a) in support of any single periodical publication may not be made for more than three years, except in those cases in which the Secretary determines that further support is necessary to carry out the purposes of subsection (a).

GRANT PAYMENTS, RECORDS, AND AUDIT.

SEC. 477.[286b–8] (a) Payments under grants made under sections 472, 473, 474, 475, and 476 may be made in advance or by way of reimbursement and in such installments as the Secretary shall prescribe by regulation after consultation with the Board.

(b)(1) Each recipient of a grant under this subpart shall keep such records as the Secretary shall prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of such grant, the total cost of the project or undertaking in connection with which such grant is given or used, and the amount of that portion of the cost of the project or undertaking supplied by other sources, and such other records as will facilitate an effective audit.

(2) The Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of such recipients that are pertinent to any grant received under this subpart.

Subpart 3—National Center for Biotechnology Information

PURPOSE, ESTABLISHMENT, FUNCTIONS, AND FUNDING OF THE NATIONAL CENTER FOR BIOTECHNOLOGY INFORMATION.

SEC. 478.[286c] (a) In order to focus and expand the collection, storage, retrieval, and dissemination of the results of biotechnology

research by information systems, and to support and enhance the development of new information technologies to aid in the understanding of the molecular processes that control health and disease, there is established the National Center for Biotechnology Information (hereinafter in this section referred to as the "Center") in the National Library of Medicine.

(b) The Secretary, through the Center and subject to section 465(d), shall—

(1) design, develop, implement, and manage automated systems for the collection, storage, retrieval, analysis, and dissemination of knowledge concerning human molecular biology, biochemistry, and genetics;

(2) perform research into advanced methods of computer-based information processing capable of representing and analyzing the vast number of biologically important molecules and compounds;

(3) enable persons engaged in biotechnology research and medical care to use systems developed under paragraph (1) and methods described in paragraph (2); and

(4) coordinate, as much as is practicable, efforts to gather biotechnology information on an international basis.

Subpart 4—National Information Center on Health Services Research and Health Care Technology

NATIONAL INFORMATION CENTER.

SEC. 478A.[286d] (a) There is established within the Library an entity to be known as the National Information Center on Health Services Research and Health Care Technology (in this section referred to as the "Center").

(b) The purpose of the Center is the collection, storage, analysis, retrieval, and dissemination of information on health services research, clinical practice guidelines, and on health care technology, including the assessment of such technology. Such purpose includes developing and maintaining data bases and developing and implementing methods of carrying out such purpose.

(c) The Director of the Center shall ensure that information under subsection (b) concerning clinical practice guidelines is collected and maintained electronically and in a convenient format. Such Director shall develop and publish criteria for the inclusion of practice guidelines and technology assessments in the information center database.

(d) The Secretary, acting through the Center, shall coordinate the activities carried out under this section through the Center with related activities of the Administrator for Health Care Policy and Research.

PART E—OTHER AGENCIES OF NIH

Subpart 1—National Center for Advancing Translational Sciences

SEC. 479.[287] NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES.

(a) PURPOSE.—The purpose of the National Center for Advancing Translational Sciences (in this subpart referred to as the "Center") is to advance translational sciences, including by—

(1) coordinating and developing resources that leverage basic research in support of translational science; and

(2) developing partnerships and working cooperatively to foster synergy in ways that do not create duplication, redundancy, and competition with industry activities.

(b) CLINICAL TRIAL ACTIVITIES.—

(1) IN GENERAL.—The Center may develop and provide infrastructure and resources for all phases of clinical trials research. Except as provided in paragraph (2), the Center may support clinical trials only through the end of phase IIA.

(2) EXCEPTION.—The Center may support clinical trial activities through the end of phase IIB for a treatment for a rare disease or condition (as defined in section 526 of the Federal Food, Drug, and Cosmetic Act) so long as—

(A) the Center gives public notice for a period of at least 120 days of the Center's intention to support the clinical trial activities in phase IIB;

(B) no public or private organization provides credible written intent to the Center that the organization has timely plans to further the clinical trial activities or conduct clinical trials of a similar nature beyond phase IIA; and

(C) the Center ensures that support of the clinical trial activities in phase IIB will not increase the Federal Government's liability beyond the award value of the Center's support.

(c) ANNUAL REPORT.—The Center shall publish an annual report that, with respect to all research supported by the Center, includes a complete list of—

(1) the molecules being studied;

(2) clinical trial activities being conducted;

(3) the methods and tools in development;

(4) ongoing partnerships, including—

(A) the rationale for each partnership;

(B) the status of each partnership;

(C) the funding provided by the Center to other entities pursuant to each partnership, and

(D) the activities which have been transferred to industry pursuant to each partnership; and

(5) known research activity of other entities that is or will expand upon research activity of the Center.

SEC. 480.[287a] CURES ACCELERATION NETWORK.

(a) DEFINITIONS.—In this section:

(1) BIOLOGICAL PRODUCT.—The term "biological product" has the meaning given such term in section 351 of the Public Health Service Act.

(2) DRUG; DEVICE.—The terms "drug" and "device" have the meanings given such terms in section 201 of the Federal Food, Drug, and Cosmetic Act.

(3) HIGH NEED CURE.—The term "high need cure" means a drug (as that term is defined by section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act, biological product (as that term is defined by section 262(i)), or device (as that term is defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act) that, in the determination of the Director of the Center—

(A) is a priority to diagnose, mitigate, prevent, or treat harm from any disease or condition; and

(B) for which the incentives of the commercial market are unlikely to result in its adequate or timely development.

(4) MEDICAL PRODUCT.—The term "medical product" means a drug, device, biological product, or product that is a combination of drugs, devices, and biological products.

(b) ESTABLISHMENT OF THE CURES ACCELERATION NETWORK.—Subject to the appropriation of funds as described in subsection (g), there is established within the Center a program to be known as the Cures Acceleration Network (referred to in this section as "CAN"), which shall—

(1) be under the direction of the Director of the Center, taking into account the recommendations of a CAN Review Board (referred to in this section as the "Board"), described in subsection (d); and

(2) award grants and contracts to eligible entities, as described in subsection (e), to accelerate the development of high need cures, including through the development of medical products and behavioral therapies.

(c) FUNCTIONS.—The functions of the CAN are to—

(1) conduct and support revolutionary advances in basic research, translating scientific discoveries from bench to bedside;

(2) award grants and contracts to eligible entities to accelerate the development of high need cures;

(3) provide the resources necessary for government agencies, independent investigators, research organizations, biotechnology companies, academic research institutions, and other entities to develop high need cures;

(4) reduce the barriers between laboratory discoveries and clinical trials for new therapies; and

(5) facilitate review in the Food and Drug Administration for the high need cures funded by the CAN, through activities that may include—

(A) the facilitation of regular and ongoing communication with the Food and Drug Administration regarding the status of activities conducted under this section;

(B) ensuring that such activities are coordinated with the approval requirements of the Food and Drug Adminis-

tration, with the goal of expediting the development and approval of countermeasures and products; and

(C) connecting interested persons with additional technical assistance made available under section 565 of the Federal Food, Drug, and Cosmetic Act.

(d) CAN BOARD.—

(1) ESTABLISHMENT.—There is established a Cures Acceleration Network Review Board (referred to in this section as the "Board"), which shall advise the Director of the Center on the conduct of the activities of the Cures Acceleration Network.

(2) MEMBERSHIP.—

(A) IN GENERAL.—

(i) APPOINTMENT.—The Board shall be comprised of 24 members who are appointed by the Secretary and who serve at the pleasure of the Secretary.

(ii) CHAIRPERSON AND VICE CHAIRPERSON.—The Secretary shall designate, from among the 24 members appointed under clause (i), one Chairperson of the Board (referred to in this section as the "Chairperson") and one Vice Chairperson.

(B) TERMS.—

(i) IN GENERAL.—Each member shall be appointed to serve a 4-year term, except that any member appointed to fill a vacancy occurring prior to the expiration of the term for which the member's predecessor was appointed shall be appointed for the remainder of such term.

(ii) CONSECUTIVE APPOINTMENTS; MAXIMUM TERMS.—A member may be appointed to serve not more than 3 terms on the Board, and may not serve more than 2 such terms consecutively.

(C) QUALIFICATIONS.—

(i) IN GENERAL.—The Secretary shall appoint individuals to the Board based solely upon the individual's established record of distinguished service in one of the areas of expertise described in clause (ii). Each individual appointed to the Board shall be of distinguished achievement and have a broad range of disciplinary interests.

(ii) EXPERTISE.—The Secretary shall select individuals based upon the following requirements:

(I) For each of the fields of—

(aa) basic research;

(bb) medicine;

(cc) biopharmaceuticals;

(dd) discovery and delivery of medical products;

(ee) bioinformatics and gene therapy;

(ff) medical instrumentation; and

(gg) regulatory review and approval of medical products,

the Secretary shall select at least 1 individual who is eminent in such fields.

(II) At least 4 individuals shall be recognized leaders in professional venture capital or private equity organizations and have demonstrated experience in private equity investing.

(III) At least 8 individuals shall represent disease advocacy organizations.

(3) EX-OFFICIO MEMBERS.—

(A) APPOINTMENT.—In addition to the 24 Board members described in paragraph (2), the Secretary shall appoint as ex-officio members of the Board—

(i) a representative of the National Institutes of Health, recommended by the Secretary of the Department of Health and Human Services;

(ii) a representative of the Office of the Assistant Secretary of Defense for Health Affairs, recommended by the Secretary of Defense;

(iii) a representative of the Office of the Under Secretary for Health for the Veterans Health Administration, recommended by the Secretary of Veterans Affairs;

(iv) a representative of the National Science Foundation, recommended by the Chair of the National Science Board; and

(v) a representative of the Food and Drug Administration, recommended by the Commissioner of Food and Drugs.

(B) TERMS.—Each ex-officio member shall serve a 3-year term on the Board, except that the Chairperson may adjust the terms of the initial ex-officio members in order to provide for a staggered term of appointment for all such members.

(4) RESPONSIBILITIES OF THE BOARD AND THE DIRECTOR OF THE CENTER.—

(A) RESPONSIBILITIES OF THE BOARD.—

(i) IN GENERAL.—The Board shall advise, and provide recommendations to, the Director of the Center with respect to—

(I) policies, programs, and procedures for carrying out the duties of the Director of the Center under this section; and

(II) significant barriers to successful translation of basic science into clinical application (including issues under the purview of other agencies and departments).

(ii) REPORT.—In the case that the Board identifies a significant barrier, as described in clause (i)(II), the Board shall submit to the Secretary a report regarding such barrier.

(B) RESPONSIBILITIES OF THE DIRECTOR OF THE CENTER.—With respect to each recommendation provided by the Board under subparagraph (A)(i), the Director of the Center shall respond in writing to the Board, indicating whether such Director will implement such recommendation. In the case that the Director of the Center indicates

a recommendation of the Board will not be implemented, such Director shall provide an explanation of the reasons for not implementing such recommendation.

(5) MEETINGS.—

(A) IN GENERAL.—The Board shall meet 4 times per calendar year, at the call of the Chairperson.

(B) QUORUM; REQUIREMENTS; LIMITATIONS.—

(i) QUORUM.—A quorum shall consist of a total of 13 members of the Board, excluding ex-officio members, with diverse representation as described in clause (iii).

(ii) CHAIRPERSON OR VICE CHAIRPERSON.—Each meeting of the Board shall be attended by either the Chairperson or the Vice Chairperson.

(iii) DIVERSE REPRESENTATION.—At each meeting of the Board, there shall be not less than one scientist, one representative of a disease advocacy organization, and one representative of a professional venture capital or private equity organization.

(6) COMPENSATION AND TRAVEL EXPENSES.—

(A) COMPENSATION.—Members shall receive compensation at a rate to be fixed by the Chairperson but not to exceed a rate equal to the daily equivalent of the annual rate of basic pay prescribed for level IV of the Executive Schedule under section 5315 of title 5, United States Code, for each day (including travel time) during which the member is engaged in the performance of the duties of the Board. All members of the Board who are officers or employees of the United States shall serve without compensation in addition to that received for their services as officers or employees of the United States.

(B) TRAVEL EXPENSES.—Members of the Board shall be allowed travel expenses, including per diem in lieu of subsistence, at rates authorized for persons employed intermittently by the Federal Government under section 5703(b) of title 5, United States Code, while away from their homes or regular places of business in the performance of services for the Board.

(e) GRANT PROGRAM.—

(1) SUPPORTING INNOVATION.—To carry out the purposes described in this section, the Director of the Center shall award contracts, grants, or cooperative agreements to the entities described in paragraph (2), to—

(A) promote innovation in technologies supporting the advanced research and development and production of high need cures, including through the development of medical products and behavioral therapies.

(B) accelerate the development of high need cures, including through the development of medical products, behavioral therapies, and biomarkers that demonstrate the safety or effectiveness of medical products; or

(C) help the award recipient establish protocols that comply with Food and Drug Administration standards and otherwise permit the recipient to meet regulatory require-

ments at all stages of development, manufacturing, review, approval, and safety surveillance of a medical product.

(2) ELIGIBLE ENTITIES.—To receive assistance under paragraph (1), an entity shall—

(A) be a public or private entity, which may include a private or public research institution, an institution of higher education, a medical center, a biotechnology company, a pharmaceutical company, a disease advocacy organization, a patient advocacy organization, or an academic research institution;

(B) submit an application containing—

(i) a detailed description of the project for which the entity seeks such grant or contract;

(ii) a timetable for such project;

(iii) an assurance that the entity will submit—

(I) interim reports describing the entity's—

(aa) progress in carrying out the project; and

(bb) compliance with all provisions of this section and conditions of receipt of such grant or contract; and

(II) a final report at the conclusion of the grant period, describing the outcomes of the project; and

(iv) a description of the protocols the entity will follow to comply with Food and Drug Administration standards and regulatory requirements at all stages of development, manufacturing, review, approval, and safety surveillance of a medical product; and

(C) provide such additional information as the Director of the Center may require.

(3) AWARDS.—

(A) THE CURES ACCELERATION PARTNERSHIP AWARDS.—

(i) INITIAL AWARD AMOUNT.—Each award under this subparagraph shall be not more than $15,000,000 per project for the first fiscal year for which the project is funded, which shall be payable in one payment.

(ii) FUNDING IN SUBSEQUENT FISCAL YEARS.—An eligible entity receiving an award under clause (i) may apply for additional funding for such project by submitting to the Director of the Center the information required under subparagraphs (B) and (C) of paragraph (2). The Director may fund a project of such eligible entity in an amount not to exceed $15,000,000 for a fiscal year subsequent to the initial award under clause (i).

(iii) MATCHING FUNDS.—As a condition for receiving an award under this subsection, an eligible entity shall contribute to the project non-Federal funds in the amount of $1 for every $3 awarded under clauses (i) and (ii), except that the Director of the Center may waive or modify such matching requirement in any case where the Director determines that the goals and

objectives of this section cannot adequately be carried out unless such requirement is waived.

(B) THE CURES ACCELERATION GRANT AWARDS.—

(i) INITIAL AWARD AMOUNT.—Each award under this subparagraph shall be not more than $15,000,000 per project for the first fiscal year for which the project is funded, which shall be payable in one payment.

(ii) FUNDING IN SUBSEQUENT FISCAL YEARS.—An eligible entity receiving an award under clause (i) may apply for additional funding for such project by submitting to the Board the information required under subparagraphs (B) and (C) of paragraph (2). The Director of the Center may fund a project of such eligible entity in an amount not to exceed $15,000,000 for a fiscal year subsequent to the initial award under clause (i).

(C) THE CURES ACCELERATION FLEXIBLE RESEARCH AWARDS.—If the Director of the Center determines that the goals and objectives of this section cannot adequately be carried out through a contract, grant, or cooperative agreement, the Director of the Center shall have flexible research authority to use other transactions to fund projects in accordance with the terms and conditions of this section. Awards made under such flexible research authority for a fiscal year shall not exceed 20 percent of the total funds appropriated under subsection (g)(1) for such fiscal year.

(4) SUSPENSION OF AWARDS FOR DEFAULTS, NONCOMPLIANCE WITH PROVISIONS AND PLANS, AND DIVERSION OF FUNDS; REPAYMENT OF FUNDS.—The Director of the Center may suspend the award to any entity upon noncompliance by such entity with provisions and plans under this section or diversion of funds.

(5) AUDITS.—The Director of the Center may enter into agreements with other entities to conduct periodic audits of the projects funded by grants or contracts awarded under this subsection.

(6) CLOSEOUT PROCEDURES.—At the end of a grant or contract period, a recipient shall follow the closeout procedures under section 74.71 of title 45, Code of Federal Regulations (or any successor regulation).

(7) REVIEW.—A determination by the Director of the Center as to whether a drug, device, or biological product is a high need cure (for purposes of subsection (a)(3)) shall not be subject to judicial review.

(f) COMPETITIVE BASIS OF AWARDS.—Any grant, cooperative agreement, or contract awarded under this section shall be awarded on a competitive basis.

(g) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—For purposes of carrying out this section, there are authorized to be appropriated $500,000,000 for fiscal year 2010, and such sums as may be necessary for subsequent

fiscal years. Funds appropriated under this section shall be available until expended.

(2) LIMITATION ON USE OF FUNDS OTHERWISE APPROPRIATED.—No funds appropriated under this Act, other than funds appropriated under paragraph (1), may be allocated to the Cures Acceleration Network.

OFFICE OF RARE DISEASES.

SEC. 481.[287a–1] (a) ESTABLISHMENT.—There is established within the Center an office to be known as the Office of Rare Diseases (in this section referred to as the "Office"), which shall be headed by a Director (in this section referred to as the "Director"), appointed by the Director of the Center.

(b) DUTIES.—

(1) IN GENERAL.—The Director of the Office shall carry out the following:

(A) The Director shall recommend an agenda for conducting and supporting research on rare diseases through the national research institutes and centers. The agenda shall provide for a broad range of research and education activities, including scientific workshops and symposia to identify research opportunities for rare diseases.

(B) The Director shall, with respect to rare diseases, promote coordination and cooperation among the national research institutes and centers and entities whose research is supported by such institutes.

(C) The Director, in collaboration with the directors of the other relevant institutes and centers of the National Institutes of Health, may enter into cooperative agreements with and make grants for regional centers of excellence on rare diseases in accordance with section 481A.

(D) The Director shall promote the sufficient allocation of the resources of the National Institutes of Health for conducting and supporting research on rare diseases.

(E) The Director shall promote and encourage the establishment of a centralized clearinghouse for rare and genetic disease information that will provide understandable information about these diseases to the public, medical professionals, patients and families.

(2) PRINCIPAL ADVISOR REGARDING ORPHAN DISEASES.—With respect to rare diseases, the Director shall serve as the principal advisor to the Director of NIH and shall provide advice to other relevant agencies. The Director shall provide liaison with national and international patient, health and scientific organizations concerned with rare diseases.

(c) DEFINITION.—For purposes of this section, the term "rare disease" means any disease or condition that affects less than 200,000 persons in the United States.

RARE DISEASE REGIONAL CENTERS OF EXCELLENCE.

SEC. 481A.[287a–2] (a) COOPERATIVE AGREEMENTS AND GRANTS.—

(1) IN GENERAL.—The Director of the Office of Rare Diseases (in this section referred to as the "Director"), in collaboration with the directors of the other relevant institutes and centers of the National Institutes of Health, may enter into cooperative agreements with and make grants to public or private nonprofit entities to pay all or part of the cost of planning, establishing, or strengthening, and providing basic operating support for regional centers of excellence for clinical research into, training in, and demonstration of diagnostic, prevention, control, and treatment methods for rare diseases.

(2) POLICIES.—A cooperative agreement or grant under paragraph (1) shall be entered into in accordance with policies established by the Director of NIH.

(b) COORDINATION WITH OTHER INSTITUTES.—The Director shall coordinate the activities under this section with similar activities conducted by other national research institutes, centers and agencies of the National Institutes of Health and by the Food and Drug Administration to the extent that such institutes, centers and agencies have responsibilities that are related to rare diseases.

(c) USES FOR FEDERAL PAYMENTS UNDER COOPERATIVE AGREEMENTS OR GRANTS.—Federal payments made under a cooperative agreement or grant under subsection (a) may be used for—

(1) staffing, administrative, and other basic operating costs, including such patient care costs as are required for research;

(2) clinical training, including training for allied health professionals, continuing education for health professionals and allied health professions personnel, and information programs for the public with respect to rare diseases; and

(3) clinical research and demonstration programs.

(d) PERIOD OF SUPPORT; ADDITIONAL PERIODS.—Support of a center under subsection (a) may be for a period of not to exceed 5 years. Such period may be extended by the Director for additional periods of not more than 5 years if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

SEC. 481B.[287a–3] GENERAL CLINICAL RESEARCH CENTERS.

(a) GRANTS.—The Director of the Center shall award grants for the establishment of general clinical research centers to provide the infrastructure for clinical research including clinical research training and career enhancement. Such centers shall support clinical studies and career development in all settings of the hospital or academic medical center involved.

(b) ACTIVITIES.—In carrying out subsection (a), the Director of National Institutes of Health shall expand the activities of the general clinical research centers through the increased use of telecommunications and telemedicine initiatives.

Subpart 2—John E. Fogarty International Center for Advanced Study in the Health Sciences

GENERAL PURPOSE.

SEC. 482.[287b] The general purpose of the John E. Fogarty International Center for Advanced Study in the Health Sciences is to—

(1) facilitate the assembly of scientists and others in the biomedical, behavioral, and related fields for discussion, study, and research relating to the development of health science internationally;

(2) provide research programs, conferences, and seminars to further international cooperation and collaboration in the life sciences;

(3) provide postdoctorate fellowships for research training in the United States and abroad and promote exchanges of senior scientists between the United States and other countries;

(4) coordinate the activities of the National Institutes of Health concerned with the health sciences internationally; and

(5) receive foreign visitors to the National Institutes of Health.

Subpart 4—Office of Dietary Supplements [55]

SEC. 485C.[287c–11] DIETARY SUPPLEMENTS.

(a) ESTABLISHMENT.—The Secretary shall establish an Office of Dietary Supplements within the National Institutes of Health.

(b) PURPOSE.—The purposes of the Office are—

(1) to explore more fully the potential role of dietary supplements as a significant part of the efforts of the United States to improve health care; and

(2) to promote scientific study of the benefits of dietary supplements in maintaining health and preventing chronic disease and other health-related conditions.

(c) DUTIES.—The Director of the Office of Dietary Supplements shall—

(1) conduct and coordinate scientific research within the National Institutes of Health relating to dietary supplements and the extent to which the use of dietary supplements can limit or reduce the risk of diseases such as heart disease, cancer, birth defects, osteoporosis, cataracts, or prostatism;

(2) collect and compile the results of scientific research relating to dietary supplements, including scientific data from foreign sources or the Office of Alternative Medicine;

(3) serve as the principal advisor to the Secretary and to the Assistant Secretary for Health and provide advice to the Director of the National Institutes of Health, the Director of the Centers for Disease Control and Prevention, and the Commissioner of Food and Drugs on issues relating to dietary supplements including—

[55] Subpart 3 of this part was transferred and redesignated as subpart 19 of part C by section 101(c) of Public Law 109–482.

(A) dietary intake regulations;

(B) the safety of dietary supplements;

(C) claims characterizing the relationship between—

(i) dietary supplements; and

(ii)(I) prevention of disease or other health-related conditions; and

(II) maintenance of health; and

(D) scientific issues arising in connection with the labeling and composition of dietary supplements;

(4) compile a database of scientific research on dietary supplements and individual nutrients; and

(5) coordinate funding relating to dietary supplements for the National Institutes of Health.

(d) DEFINITION.—As used in this section, the term "dietary supplement" has the meaning given the term in section 201(ff) of the Federal Food, Drug, and Cosmetic Act.

Subpart 5—National Center for Complementary and Alternative Medicine

SEC. 485D.[287c–21] PURPOSE OF CENTER.

(a) IN GENERAL.—The general purposes of the National Center for Complementary and Alternative Medicine (in this subpart referred to as the "Center") are the conduct and support of basic and applied research (including both intramural and extramural research), research training, the dissemination of health information, and other programs with respect to identifying, investigating, and validating complementary and alternative treatment, diagnostic and prevention modalities, disciplines and systems. The Center shall be headed by a director, who shall be appointed by the Secretary. The Director of the Center shall report directly to the Director of NIH.

(b) ADVISORY COUNCIL.—The Secretary shall establish an advisory council for the Center in accordance with section 406, except that at least half of the members of the advisory council who are not ex officio members shall include practitioners licensed in one or more of the major systems with which the Center is concerned, and at least 3 individuals representing the interests of individual consumers of complementary and alternative medicine.

(c) COMPLEMENT TO CONVENTIONAL MEDICINE.—In carrying out subsection (a), the Director of the Center shall, as appropriate, study the integration of alternative treatment, diagnostic and prevention systems, modalities, and disciplines with the practice of conventional medicine as a complement to such medicine and into health care delivery systems in the United States.

(d) APPROPRIATE SCIENTIFIC EXPERTISE AND COORDINATION WITH INSTITUTES AND FEDERAL AGENCIES.—The Director of the Center, after consultation with the advisory council for the Center and the division of research grants, shall ensure that scientists with appropriate expertise in research on complementary and alternative medicine are incorporated into the review, oversight, and management processes of all research projects and other activities funded by the Center. In carrying out this subsection, the Director of the Center, as necessary, may establish review groups with ap-

propriate scientific expertise. The Director of the Center shall coordinate efforts with other Institutes and Federal agencies to ensure appropriate scientific input and management.

(e) EVALUATION OF VARIOUS DISCIPLINES AND SYSTEMS.—In carrying out subsection (a), the Director of the Center shall identify and evaluate alternative and complementary medical treatment, diagnostic and prevention modalities in each of the disciplines and systems with which the Center is concerned, including each discipline and system in which accreditation, national certification, or a State license is available.

(f) ENSURING HIGH QUALITY, RIGOROUS SCIENTIFIC REVIEW.—In order to ensure high quality, rigorous scientific review of complementary and alternative, diagnostic and prevention modalities, disciplines and systems, the Director of the Center shall conduct or support the following activities:

(1) Outcomes research and investigations.

(2) Epidemiological studies.

(3) Health services research.

(4) Basic science research.

(5) Clinical trials.

(6) Other appropriate research and investigational activities.

The Director of NIH, in coordination with the Director of the Center, shall designate specific personnel in each Institute to serve as full-time liaisons with the Center in facilitating appropriate coordination and scientific input.

(g) DATA SYSTEM; INFORMATION CLEARINGHOUSE.—

(1) DATA SYSTEM.—The Director of the Center shall establish a bibliographic system for the collection, storage, and retrieval of worldwide research relating to complementary and alternative treatment, diagnostic and prevention modalities, disciplines and systems. Such a system shall be regularly updated and publicly accessible.

(2) CLEARINGHOUSE.—The Director of the Center shall establish an information clearinghouse to facilitate and enhance, through the effective dissemination of information, knowledge and understanding of alternative medical treatment, diagnostic and prevention practices by health professionals, patients, industry, and the public.

(h) RESEARCH CENTERS.—The Director of the Center, after consultation with the advisory council for the Center, shall provide support for the development and operation of multipurpose centers to conduct research and other activities described in subsection (a) with respect to complementary and alternative treatment, diagnostic and prevention modalities, disciplines and systems. The provision of support for the development and operation of such centers shall include accredited complementary and alternative medicine research and education facilities.

(i) AVAILABILITY OF RESOURCES.—After consultation with the Director of the Center, the Director of NIH shall ensure that resources of the National Institutes of Health, including laboratory and clinical facilities, fellowships (including research training fellowship and junior and senior clinical fellowships), and other resources are sufficiently available to enable the Center to appro-

priately and effectively carry out its duties as described in subsection (a). The Director of NIH, in coordination with the Director of the Center, shall designate specific personnel in each Institute to serve as full-time liaisons with the Center in facilitating appropriate coordination and scientific input.

(j) AVAILABILITY OF APPROPRIATIONS.—Amounts appropriated to carry out this section for fiscal year 1999 are available for obligation through September 30, 2001. Amounts appropriated to carry out this section for fiscal year 2000 are available for obligation through September 30, 2001.

PART F—RESEARCH ON WOMEN'S HEALTH

SEC. 486.[287d] OFFICE OF RESEARCH ON WOMEN'S HEALTH.

(a) ESTABLISHMENT.—There is established within the Office of the Director of NIH an office to be known as the Office of Research on Women's Health (in this part referred to as the "Office"). The Office shall be headed by a director, who shall be appointed by the Director of NIH and who shall report directly to the Director.

(b) PURPOSE.—The Director of the Office shall—

(1) identify projects of research on women's health that should be conducted or supported by the national research institutes;

(2) identify multidisciplinary research relating to research on women's health that should be so conducted or supported;

(3) carry out paragraphs (1) and (2) with respect to the aging process in women, with priority given to menopause;

(4) promote coordination and collaboration among entities conducting research identified under any of paragraphs (1) through (3);

(5) encourage the conduct of such research by entities receiving funds from the national research institutes;

(6) recommend an agenda for conducting and supporting such research;

(7) promote the sufficient allocation of the resources of the national research institutes for conducting and supporting such research;

(8) assist in the administration of section 492B with respect to the inclusion of women as subjects in clinical research; and

(9) prepare the report required in section 486B.

(c) COORDINATING COMMITTEE.—

(1) In carrying out subsection (b), the Director of the Office shall establish a committee to be known as the Coordinating Committee on Research on Women's Health (in this subsection referred to as the "Coordinating Committee").

(2) The Coordinating Committee shall be composed of the Directors of the national research institutes (or the designees of the Directors).

(3) The Director of the Office shall serve as the chair of the Coordinating Committee.

(4) With respect to research on women's health, the Coordinating Committee shall assist the Director of the Office in—

(A) identifying the need for such research, and making an estimate each fiscal year of the funds needed to adequately support the research;

(B) identifying needs regarding the coordination of research activities, including intramural and extramural multidisciplinary activities;

(C) supporting the development of methodologies to determine the circumstances in which obtaining data specific to women (including data relating to the age of women and the membership of women in ethnic or racial groups) is an appropriate function of clinical trials of treatments and therapies;

(D) supporting the development and expansion of clinical trials of treatments and therapies for which obtaining such data has been determined to be an appropriate function; and

(E) encouraging the national research institutes to conduct and support such research, including such clinical trials.

(d) ADVISORY COMMITTEE.—

(1) In carrying out subsection (b), the Director of the Office shall establish an advisory committee to be known as the Advisory Committee on Research on Women's Health (in this subsection referred to as the "Advisory Committee").

(2) The Advisory Committee shall be composed of no fewer than 12, and not more than 18 individuals, who are not officers or employees of the Federal Government. The Director of NIH shall make appointments to the Advisory Committee from among physicians, practitioners, scientists, and other health professionals, whose clinical practice, research specialization, or professional expertise includes a significant focus on research on women's health. A majority of the members of the Advisory Committee shall be women.

(3) The Director of the Office shall serve as the chair of the Advisory Committee.

(4) The Advisory Committee shall—

(A) advise the Director of the Office on appropriate research activities to be undertaken by the national research institutes with respect to—

(i) research on women's health;

(ii) research on gender differences in clinical drug trials, including responses to pharmacological drugs;

(iii) research on gender differences in disease etiology, course, and treatment;

(iv) research on obstetrical and gynecological health conditions, diseases, and treatments; and

(v) research on women's health conditions which require a multidisciplinary approach;

(B) report to the Director of the Office on such research;

(C) provide recommendations to such Director regarding activities of the Office (including recommendations on the development of the methodologies described in sub-

section (c)(4)(C) and recommendations on priorities in carrying out research described in subparagraph (A)); and

(D) assist in monitoring compliance with section 492B regarding the inclusion of women in clinical research.

(5)(A) The Advisory Committee shall prepare a biennial report describing the activities of the Committee, including findings made by the Committee regarding—

(i) compliance with section 492B;

(ii) the extent of expenditures made for research on women's health by the agencies of the National Institutes of Health; and

(iii) the level of funding needed for such research.

(B) The report required in subparagraph (A) shall be submitted to the Director of NIH for inclusion in the report required in section 403.

(e) REPRESENTATION OF WOMEN AMONG RESEARCHERS.—The Secretary, acting through the Assistant Secretary for Personnel and in collaboration with the Director of the Office, shall determine the extent to which women are represented among senior physicians and scientists of the national research institutes and among physicians and scientists conducting research with funds provided by such institutes, and as appropriate, carry out activities to increase the extent of such representation.

(f) DEFINITIONS.—For purposes of this part:

(1) The term "women's health conditions", with respect to women of all age, ethnic, and racial groups, means all diseases, disorders, and conditions (including with respect to mental health)—

(A) unique to, more serious, or more prevalent in women;

(B) for which the factors of medical risk or types of medical intervention are different for women, or for which it is unknown whether such factors or types are different for women; or

(C) with respect to which there has been insufficient clinical research involving women as subjects or insufficient clinical data on women.

(2) The term "research on women's health" means research on women's health conditions, including research on preventing such conditions.

SEC. 486A.[287d–1] NATIONAL DATA SYSTEM AND CLEARINGHOUSE ON RESEARCH ON WOMEN'S HEALTH.

(a) DATA SYSTEM.—

(1) The Director of NIH, in consultation with the Director of the Office and the Director of the National Library of Medicine, shall establish a data system for the collection, storage, analysis, retrieval, and dissemination of information regarding research on women's health that is conducted or supported by the national research institutes. Information from the data system shall be available through information systems available to health care professionals and providers, researchers, and members of the public.

(2) The data system established under paragraph (1) shall include a registry of clinical trials of experimental treatments

that have been developed for research on women's health. Such registry shall include information on subject eligibility criteria, sex, age, ethnicity or race, and the location of the trial site or sites. Principal investigators of such clinical trials shall provide this information to the registry within 30 days after it is available. Once a trial has been completed, the principal investigator shall provide the registry with information pertaining to the results, including potential toxicities or adverse effects associated with the experimental treatment or treatments evaluated.

(b) CLEARINGHOUSE.—The Director of NIH, in consultation with the Director of the Office and with the National Library of Medicine, shall establish, maintain, and operate a program to provide information on research and prevention activities of the national research institutes that relate to research on women's health.

SEC. 486B.[287d–2] BIENNIAL REPORT.

(a) IN GENERAL.—With respect to research on women's health, the Director of the Office shall, not later than February 1, 1994, and biennially thereafter, prepare a report—

(1) describing and evaluating the progress made during the preceding 2 fiscal years in research and treatment conducted or supported by the National Institutes of Health;

(2) describing and analyzing the professional status of women physicians and scientists of such Institutes, including the identification of problems and barriers regarding advancements;

(3) summarizing and analyzing expenditures made by the agencies of such Institutes (and by such Office) during the preceding 2 fiscal years; and

(4) making such recommendations for legislative and administrative initiatives as the Director of the Office determines to be appropriate.

(b) INCLUSION IN BIENNIAL REPORT OF DIRECTOR OF NIH.—The Director of the Office shall submit each report prepared under subsection (a) to the Director of NIH for inclusion in the report submitted to the President and the Congress under section 403.

PART G—AWARDS AND TRAINING

RUTH L. KIRSCHSTEIN NATIONAL RESEARCH SERVICE AWARDS[56].

SEC. 487.[288] (a)(1) The Secretary shall—

(A) provide Ruth L. Kirschstein National Research Service Awards[57] for—

(i) biomedical and behavioral research at the National Institutes of Health in matters relating to the cause, diagnosis, prevention, and treatment of the diseases or other

[56] The typeface is so in law. See section 804(b) of Public Law 107–206 (116 Stat. 874).

[57] Section 804(c) of Public Law 107–206 (116 Stat. 874) provides as follows:

"(c) Any reference in any law (other than this Act), regulation, document, record, map, or other paper of the United States to 'National Research Service Awards' shall be considered to be a reference to 'Ruth L. Kirschstein National Research Service Awards'".

health problems to which the activities of the National Institutes of Health and Administration[58] are directed;

(ii) training at the National Institutes of Health and at the Administration of individuals to undertake such research;

(iii) biomedical and behavioral research and health services research (including research in primary medical care) at public and nonprofit private entities; and

(iv) pre-doctoral and post-doctoral training at public and private institutions of individuals to undertake biomedical and behavioral research;

(B) make grants to public and nonprofit private institutions to enable such institutions to make Ruth L. Kirschstein National Research Service Awards for research (and training to undertake biomedical and behavioral research) in the matters described in subparagraph (A)(i) to individuals selected by such institutions; and

(C) provide contracts for scholarships and loan repayments in accordance with sections 487D and 487E, subject to providing not more than an aggregate 50 such contracts during the fiscal years 1994 through 1996.

A reference in this subsection to the National Institutes of Health shall be considered to include the institutes, agencies, divisions, and bureaus included in the National Institutes of Health or under the Administration, as the case may be.

(2) Ruth L. Kirschstein National Research Service Awards may not be used to support residency training of physicians and other health professionals.

(3) In awarding Ruth L. Kirschstein National Research Service Awards under this section, the Secretary shall take account of the Nation's overall need for biomedical research personnel by giving special consideration to physicians who agree to undertake a minimum of two years of biomedical research.

(4) The Secretary shall carry out paragraph (1) in a manner that will result in the recruitment of women, and individuals from disadvantaged backgrounds (including racial and ethnic minorities), into fields of biomedical or behavioral research and in the provision of research training to women and such individuals.

(b)(1) No Ruth L. Kirschstein National Research Service Award may be made by the Secretary to any individual unless—

(A) the individual has submitted to the Secretary an application therefor and the Secretary has approved the application;

(B) the individual provides, in such form and manner as the Secretary shall by regulation prescribe, assurances satisfactory to the Secretary that the individual will meet the service requirement of subsection (c); and

(C) in the case of a Ruth L. Kirschstein National Research Service Award for a purpose described in subsection (a)(1)(A)(iii), the individual has been sponsored (in such manner as the Secretary may by regulation require) by the institu-

[58] So in law. Section 163(b)(4)(B) of Public Law 102–321 (106 Stat. 376) struck a reference in paragraph (1) to the former Alcohol, Drug Abuse, and Mental Health Administration, but failed to conform related references.

tion at which the research or training under the award will be conducted.

An application for an award shall be in such form, submitted in such manner, and contain such information, as the Secretary may by regulation prescribe.

(2) The making of grants under subsection (a)(1)(B) for Ruth L. Kirschstein National Research Service Awards shall be subject to review and approval by the appropriate advisory councils within the Department of Health and Human Services (A) whose activities relate to the research or training under the awards, or (B) for the entity at which such research or training will be conducted.

(3) No grant may be made under subsection (a)(1)(B) unless an application therefor has been submitted to and approved by the Secretary. Such application shall be in such form, submitted in such manner, and contain such information, as the Secretary may by regulation prescribe. Subject to the provisions of this section (other than paragraph (1)), Ruth L. Kirschstein National Research Service Awards made under a grant under subsection (a)(1)(B) shall be made in accordance with such regulations as the Secretary shall prescribe.

(4) The period of any Ruth L. Kirschstein National Research Service Award made to any individual under subsection (a) may not exceed—

(A) five years in the aggregate for pre-doctoral training; and

(B) three years in the aggregate for post-doctoral training;

unless the Secretary for good cause shown waives the application of such limit to such individual.

(5) Ruth L. Kirschstein National Research Service Awards shall provide for such stipends, tuition, fees, and allowances (including travel and subsistence expenses and dependency allowances), adjusted periodically to reflect increases in the cost of living, for the recipients of the awards as the Secretary may deem necessary. A Ruth L. Kirschstein National Research Service Award made to an individual for research or research training at a non-Federal public or nonprofit private institution shall also provide for payments to be made to the institution for the cost of support services (including the cost of faculty salaries, supplies, equipment, general research support, and related items) provided such individual by such institution. The amount of any such payments to any institution shall be determined by the Secretary and shall bear a direct relationship to the reasonable costs of the institution for establishing and maintaining the quality of its biomedical and behavioral research and training programs.

(c)(1) Each individual who is awarded a Ruth L. Kirschstein National Research Service Award for postdoctoral research training shall, in accordance with paragraph (3), engage in research training, research, or teaching that is health-related (or any combination thereof) for the period specified in paragraph (2). Such period shall be served in accordance with the usual patterns of scientific employment.

(2)(A) The period referred to in paragraph (1) is 12 months, or one month for each month for which the individual involved re-

ceives a Ruth L. Kirschstein National Research Service Award for postdoctoral research training, whichever is less.

(B) With respect to postdoctoral research training, in any case in which an individual receives a Ruth L. Kirschstein National Research Service Award for more than 12 months, the 13th month and each subsequent month of performing activities under the Award shall be considered to be activities engaged in toward satisfaction of the requirement established in paragraph (1) regarding a period of service.

(3) The requirement of paragraph (1) shall be complied with by any individual to whom it applies within such reasonable period of time, after the completion of such individual's award, as the Secretary shall by regulation prescribe. The Secretary shall by regulation prescribe the type of research and teaching in which an individual may engage to comply with such requirement and such other requirements respecting research and teaching as the Secretary considers appropriate.

(4)(A) If any individual to whom the requirement of paragraph (1) is applicable fails, within the period prescribed by paragraph (3), to comply with such requirements, the United States shall be entitled to recover from such individual an amount determined in accordance with the formula—

$$A=\Phi \left(\frac{t-s}{t} \right)$$

in which "A" is the amount the United States is entitled to recover; "Φ" is the sum of the total amount paid under one or more Ruth L. Kirschstein National Research Service Awards to such individual; "t" is the total number of months in such individual's service obligation; and "s" is the number of months of such obligation served by such individual in accordance with paragraphs (1) and (2) of this subsection.

(B) Any amount which the United States is entitled to recover under subparagraph (A) shall, within the three-year period beginning on the date the United States becomes entitled to recover such amount, be paid to the United States. Until any amount due the United States under subparagraph (A) on account of any Ruth L. Kirschstein National Research Service Award is paid, there shall accrue to the United States interest on such amount at a rate fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing on the date the United States becomes entitled to such amount.

(5)(A) Any obligation of an individual under paragraph (1) shall be canceled upon the death of such individual.

(B) The Secretary shall by regulation provide for the waiver or suspension of any such obligation applicable to any individual whenever compliance by such individual is impossible or would involve substantial hardship to such individual or would be against equity and good conscience.

LOAN REPAYMENT PROGRAM FOR RESEARCH WITH RESPECT TO ACQUIRED IMMUNE DEFICIENCY SYNDROME.

SEC. 487A.[288–1] (a) IN GENERAL.—The Secretary shall carry out a program of entering into agreements with appropriately qualified health professionals under which such health professionals agree to conduct, as employees of the National Institutes of Health, research with respect to acquired immune deficiency syndrome in consideration of the Federal Government agreeing to repay, for each year of such service, not more than $35,000 of the principal and interest of the educational loans of such health professionals.

(b) APPLICABILITY OF CERTAIN PROVISIONS.—With respect to the National Health Service Corps Loan Repayment Program established in subpart III of part D of title III, the provisions of such subpart shall, except as inconsistent with subsection (a) of this section, apply to the program established in such subsection (a) in the same manner and to the same extent as such provisions apply to the National Health Service Corps Loan Repayment Program established in such subpart.

LOAN REPAYMENT PROGRAM FOR RESEARCH WITH RESPECT TO CONTRACEPTION AND INFERTILITY.

SEC. 487B.[288–2] (a) The Secretary, in consultation with the Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development, shall establish a program of entering into contracts with qualified health professionals (including graduate students) under which such health professionals agree to conduct research with respect to contraception, or with respect to infertility, in consideration of the Federal Government agreeing to repay, for each year of such service, not more than $35,000 of the principal and interest of the educational loans of such health professionals.

(b) The provisions of sections 338B, 338C, and 338E shall, except as inconsistent with subsection (a) of this section, apply to the program established in subsection (a) to the same extent and in the same manner as such provisions apply to the National Health Service Corps Loan Repayment Program established in subpart III of part D of title III.

(c) Amounts available for carrying out this section shall remain available until the expiration of the second fiscal year beginning after the fiscal year for which the amounts were made available.

LOAN REPAYMENT PROGRAM FOR RESEARCH GENERALLY.

SEC. 487C.[288–3] (a) IN GENERAL.—

(1) AUTHORITY FOR PROGRAM.—Subject to paragraph (2), the Secretary shall carry out a program of entering into contracts with appropriately qualified health professionals under which such health professionals agree to conduct research, as employees of the National Institutes of Health, in consideration of the Federal Government agreeing to repay, for each year of such service, not more than $35,000 of the principal

and interest of the educational loans of such health professionals.

(2) LIMITATION.—The Secretary may not enter into an agreement with a health professional pursuant to paragraph (1) unless such professional—

(A) has a substantial amount of educational loans relative to income; and

(B) agrees to serve as an employee of the National Institutes of Health for purposes of paragraph (1) for a period of not less than 3 years.

(b) APPLICABILITY OF CERTAIN PROVISIONS.—With respect to the National Health Service Corps Loan Repayment Program established in subpart III of part D of title III, the provisions of such subpart shall, except as inconsistent with subsection (a) of this section, apply to the program established in such subsection (a) in the same manner and to the same extent as such provisions apply to the National Health Service Corps Loan Repayment Program established in such subpart.

UNDERGRADUATE SCHOLARSHIP PROGRAM REGARDING PROFESSIONS NEEDED BY NATIONAL RESEARCH INSTITUTES.

SEC. 487D.[288–4] (a) ESTABLISHMENT OF PROGRAM.—

(1) IN GENERAL.—Subject to section 487(a)(1)(C), the Secretary, acting through the Director of NIH, may carry out a program of entering into contracts with individuals described in paragraph (2) under which—

(A) the Director of NIH agrees to provide to the individuals scholarships for pursuing, as undergraduates at accredited institutions of higher education, academic programs appropriate for careers in professions needed by the National Institutes of Health; and

(B) the individuals agree to serve as employees of the National Institutes of Health, for the period described in subsection (c), in positions that are needed by the National Institutes of Health and for which the individuals are qualified.

(2) INDIVIDUALS FROM DISADVANTAGED BACKGROUNDS.—The individuals referred to in paragraph (1) are individuals who—

(A) are enrolled or accepted for enrollment as full-time undergraduates at accredited institutions of higher education; and

(B) are from disadvantaged backgrounds.

(b) FACILITATION OF INTEREST OF STUDENTS IN CAREERS AT NATIONAL INSTITUTES OF HEALTH.—In providing employment to individuals pursuant to contracts under subsection (a)(1), the Director of NIH shall carry out activities to facilitate the interest of the individuals in pursuing careers as employees of the National Institutes of Health.

(c) PERIOD OF OBLIGATED SERVICE.—

(1) DURATION OF SERVICE.—For purposes of subparagraph (B) of subsection (a)(1), the period of service for which an individual is obligated to serve as an employee of the National In-

stitutes of Health is, subject to paragraph (2)(A), 12 months for each academic year for which the scholarship under such subsection is provided.

(2) SCHEDULE FOR SERVICE.—

(A) Subject to subparagraph (B), the Director of NIH may not provide a scholarship under subsection (a) unless the individual applying for the scholarship agrees that—

(i) the individual will serve as an employee of the National Institutes of Health full-time for not less than 10 consecutive weeks of each year during which the individual is attending the educational institution involved and receiving such a scholarship;

(ii) the period of service as such an employee that the individual is obligated to provide under clause (i) is in addition to the period of service as such an employee that the individual is obligated to provide under subsection (a)(1)(B); and

(iii) not later than 60 days after obtaining the educational degree involved, the individual will begin serving full-time as such an employee in satisfaction of the period of service that the individual is obligated to provide under subsection (a)(1)(B).

(B) The Director of NIH may defer the obligation of an individual to provide a period of service under subsection (a)(1)(B), if the Director determines that such a deferral is appropriate.

(3) APPLICABILITY OF CERTAIN PROVISIONS RELATING TO APPOINTMENT AND COMPENSATION.—For any period in which an individual provides service as an employee of the National Institutes of Health in satisfaction of the obligation of the individual under subsection (a)(1)(B) or paragraph (2)(A)(i), the individual may be appointed as such an employee without regard to the provisions of title 5, United States Code, relating to appointment and compensation.

(d) PROVISIONS REGARDING SCHOLARSHIP.—

(1) APPROVAL OF ACADEMIC PROGRAM.—The Director of NIH may not provide a scholarship under subsection (a) for an academic year unless—

(A) the individual applying for the scholarship has submitted to the Director a proposed academic program for the year and the Director has approved the program; and

(B) the individual agrees that the program will not be altered without the approval of the Director.

(2) ACADEMIC STANDING.—The Director of NIH may not provide a scholarship under subsection (a) for an academic year unless the individual applying for the scholarship agrees to maintain an acceptable level of academic standing, as determined by the educational institution involved in accordance with regulations issued by the Secretary.

(3) LIMITATION ON AMOUNT.—The Director of NIH may not provide a scholarship under subsection (a) for an academic year in an amount exceeding $20,000.

(4) AUTHORIZED USES.—A scholarship provided under subsection (a) may be expended only for tuition expenses, other

reasonable educational expenses, and reasonable living expenses incurred in attending the school involved.

(5) CONTRACT REGARDING DIRECT PAYMENTS TO INSTITUTION.—In the case of an institution of higher education with respect to which a scholarship under subsection (a) is provided, the Director of NIH may enter into a contract with the institution under which the amounts provided in the scholarship for tuition and other educational expenses are paid directly to the institution.

(e) PENALTIES FOR BREACH OF SCHOLARSHIP CONTRACT.—The provisions of section 338E shall apply to the program established in subsection (a) to the same extent and in the same manner as such provisions apply to the National Health Service Corps Loan Repayment Program established in section 338B.

(f) REQUIREMENT OF APPLICATION.—The Director of NIH may not provide a scholarship under subsection (a) unless an application for the scholarship is submitted to the Director and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Director determines to be necessary to carry out this section.

(g) AVAILABILITY OF AUTHORIZATION OF APPROPRIATIONS.—Amounts appropriated for a fiscal year for scholarships under this section shall remain available until the expiration of the second fiscal year beginning after the fiscal year for which the amounts were appropriated.

LOAN REPAYMENT PROGRAM REGARDING CLINICAL RESEARCHERS FROM DISADVANTAGED BACKGROUNDS.

SEC. 487E.[288–5] (a) IMPLEMENTATION OF PROGRAM.—

(1) IN GENERAL.—Subject to section 487(a)(1)(C), the Secretary, acting through the Director of NIH may, subject to paragraph (2), carry out a program of entering into contracts with appropriately qualified health professionals who are from disadvantaged backgrounds under which such health professionals agree to conduct clinical research in consideration of the Federal Government agreeing to pay, for each year of such service, not more than $35,000 of the principal and interest of the educational loans of the health professionals.

(2) LIMITATION.—The Director of NIH may not enter into a contract with a health professional pursuant to paragraph (1) unless such professional has a substantial amount of education loans relative to income.

(3) APPLICABILITY OF CERTAIN PROVISIONS REGARDING OBLIGATED SERVICE.—Except to the extent inconsistent with this section, the provisions of sections 338B, 338C[59] and 338E shall apply to the program established in paragraph (1) to the same extent and in the same manner as such provisions apply to the National Health Service Corps Loan Repayment Program established in section 338B.

(b) AVAILABILITY OF AUTHORIZATION OF APPROPRIATIONS.—Amounts appropriated for a fiscal year for contracts under subsection (a) shall remain available until the expiration of the second

[59] So in law. There is no comma after "338C".

fiscal year beginning after the fiscal year for which the amounts were appropriated.

SEC. 487F.[288–5a] LOAN REPAYMENT PROGRAM REGARDING CLINICAL RESEARCHERS.

(a) IN GENERAL.—The Secretary, acting through the Director of the National Institutes of Health, shall establish a program to enter into contracts with qualified health professionals under which such health professionals agree to conduct clinical research, in consideration of the Federal Government agreeing to repay, for each year of service conducting such research, not more than $35,000 of the principal and interest of the educational loans of such health professionals.

(b) APPLICATION OF PROVISIONS.—The provisions of sections 338B, 338C, and 338E shall, except as inconsistent with subsection (a) of this section, apply to the program established under subsection (a) to the same extent and in the same manner as such provisions apply to the National Health Service Corps Loan Repayment Program established in subpart III of part D of title III.

PEDIATRIC RESEARCH LOAN REPAYMENT PROGRAM.

SEC. 487F.[60][288–6] (a) IN GENERAL.—The Secretary, in consultation with the Director of NIH, may establish a pediatric research loan repayment program. Through such program—

(1) the Secretary shall enter into contracts with qualified health professionals under which such professionals will agree to conduct pediatric research, including pediatric pharmacological research, in consideration of the Federal Government agreeing to repay, for each year of such service, not more than $35,000 of the principal and interest of the educational loans of such professionals; and

(2) the Secretary shall, for the purpose of providing reimbursements for tax liability resulting from payments made under paragraph (1) on behalf of an individual, make payments, in addition to payments under such paragraph, to the individual in an amount equal to 39 percent of the total amount of loan repayments made for the taxable year involved.

(b) APPLICATION OF OTHER PROVISIONS.—The provisions of sections 338B, 338C, and 338E shall, except as inconsistent with paragraph (1), apply to the program established under such paragraph to the same extent and in the same manner as such provisions apply to the National Health Service Corps Loan Repayment Program established under subpart III of part D of title III.

(c) FUNDING.—

(1) IN GENERAL.—For the purpose of carrying out this section with respect to a national research institute the Secretary may reserve, from amounts appropriated for such institute for the fiscal year involved, such amounts as the Secretary determines to be appropriate.

[60] So in law. There are two sections 487F. Section 1002(b) of Public Law 106–310 (114 Stat. 1129) inserted section 487F above. Subsequently, section 205 of Public Law 106–505 (114 Stat. 2329), which relates to a loan repayment program regarding clinical researchers, inserted a section 487F after section 487E.

(2) AVAILABILITY OF FUNDS.—Amounts made available to carry out this section shall remain available until the expiration of the second fiscal year beginning after the fiscal year for which such amounts were made available.

VISITING SCIENTIST AWARDS.

SEC. 488.[288a] (a) The Secretary may make awards (hereafter in this section referred to as "Visiting Scientist Awards") to outstanding scientists who agree to serve as visiting scientists at institutions of postsecondary education which have significant enrollments of disadvantaged students. Visiting Scientist Awards shall be made by the Secretary to enable the faculty and students of such institutions to draw upon the special talents of scientists from other institutions for the purpose of receiving guidance, advice, and instruction with regard to research, teaching, and curriculum development in the biomedical and behavioral sciences and such other aspects of these sciences as the Secretary shall deem appropriate.

(b) The amount of each Visiting Scientist Award shall include such sum as shall be commensurate with the salary or remuneration which the individual receiving the award would have been entitled to receive from the institution with which the individual has, or had, a permanent or immediately prior affiliation. Eligibility for and terms of Visiting Scientist Awards shall be determined in accordance with regulations the Secretary shall prescribe.

STUDIES RESPECTING BIOMEDICAL AND BEHAVIORAL RESEARCH PERSONNEL.

SEC. 489.[288b] (a) The Secretary shall, in accordance with subsection (b), arrange for the conduct of a continuing study to—

(1) establish (A) the Nation's overall need for biomedical and behavioral research personnel, (B) the subject areas in which such personnel are needed and the number of such personnel needed in each such area, and (C) the kinds and extent of training which should be provided such personnel;

(2) assess (A) current training programs available for the training of biomedical and behavioral research personnel which are conducted under this Act, at or through national research institutes under the National Institutes of Health, and (B) other current training programs available for the training of such personnel;

(3) identify the kinds of research positions available to and held by individuals completing such programs;

(4) determine, to the extent feasible, whether the programs referred to in clause (B) of paragraph (2) would be adequate to meet the needs established under paragraph (1) if the programs referred to in clause (A) of paragraph (2) were terminated; and

(5) determine what modifications in the programs referred to in paragraph (2) are required to meet the needs established under paragraph (1).

(b)(1) The Secretary shall request the National Academy of Sciences to conduct the study required by subsection (a) under an

arrangement under which the actual expenses incurred by such Academy in conducting such study will be paid by the Secretary. If the National Academy of Sciences is willing to do so, the Secretary shall enter into such an arrangement with such Academy for the conduct of such study.

(2) If the National Academy of Sciences is unwilling to conduct such study under such an arrangement, then the Secretary shall enter into a similar arrangement with other appropriate nonprofit private groups or associations under which such groups or associations will conduct such study and prepare and submit the reports thereon as provided in subsection (c).

(3) The National Academy of Sciences or other group or association conducting the study required by subsection (a) shall conduct such study in consultation with the Director of NIH.

(c) A report on the results of the study required under subsection (a) shall be submitted by the Secretary to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate at least once every four years.

PART H—GENERAL PROVISIONS

INSTITUTIONAL REVIEW BOARDS; ETHICS GUIDANCE PROGRAM.

SEC. 491.**[**289**]** (a) The Secretary shall by regulation require that each entity which applies for a grant, contract, or cooperative agreement under this Act for any project or program which involves the conduct of biomedical or behavioral research involving human subjects submit in or with its application for such grant, contract, or cooperative agreement assurances satisfactory to the Secretary that it has established (in accordance with regulations which the Secretary shall prescribe) a board (to be known as an "Institutional Review Board") to review biomedical and behavioral research involving human subjects conducted at or supported by such entity in order to protect the rights of the human subjects of such research.

(b)(1) The Secretary shall establish a program within the Department of Health and Human Services under which requests for clarification and guidance with respect to ethical issues raised in connection with biomedical or behavioral research involving human subjects are responded to promptly and appropriately.

(2) The Secretary shall establish a process for the prompt and appropriate response to information provided to the Director of NIH respecting incidences of violations of the rights of human subjects of research for which funds have been made available under this Act. The process shall include procedures for the receiving of reports of such information from recipients of funds under this Act and taking appropriate action with respect to such violations.

PEER REVIEW REQUIREMENTS.

SEC. 492.**[**289a**]** (a)(1) The Secretary, acting through the Director of NIH, shall by regulation require appropriate technical and scientific peer review of—

(A) applications made for grants and cooperative agreements under this Act for biomedical and behavioral research; and

(B) applications made for biomedical and behavioral research and development contracts to be administered through the National Institutes of Health.

(2) Regulations promulgated under paragraph (1) shall require that the review of applications made for grants, contracts, and cooperative agreements required by the regulations be conducted—

(A) to the extent practical, in a manner consistent with the system for technical and scientific peer review applicable on the date of the date of enactment of the Health Research Extension Act of 1985 to grants under this Act for biomedical and behavioral research, and

(B) to the extent practical, by technical and scientific peer review groups performing such review on or before such date,

and shall authorize such review to be conducted by groups appointed under sections 402(b)(16) and 405(c)(3).

(b) The Director of NIH shall establish procedures for periodic technical and scientific peer review of research at the National Institutes of Health. Such procedures shall require that—

(1) the reviewing entity be provided a written description of the research to be reviewed, and

(2) the reviewing entity provide the advisory council of the national research institute involved with such description and the results of the review by the entity,

and shall authorize such review to be conducted by groups appointed under sections 402(b)(6) and 405(c)(3).

(c)(1) In technical and scientific peer review under this section of proposals for clinical research, the consideration of any such proposal (including the initial consideration) shall, except as provided in paragraph (2), include an evaluation of the technical and scientific merit of the proposal regarding compliance with section 492B.

(2) Paragraph (1) shall not apply to any proposal for clinical research that, pursuant to subsection (b) of section 492B, is not subject to the requirement of subsection (a) of such section regarding the inclusion of women and members of minority groups as subjects in clinical research.

CERTAIN PROVISIONS REGARDING REVIEW AND APPROVAL OF PROPOSALS FOR RESEARCH.

SEC. 492A.[289a–1] (a) REVIEW AS PRECONDITION TO RESEARCH.—

(1) PROTECTION OF HUMAN RESEARCH SUBJECTS.—

(A) In the case of any application submitted to the Secretary for financial assistance to conduct research, the Secretary may not approve or fund any application that is subject to review under section 491(a) by an Institutional Review Board unless the application has undergone review in accordance with such section and has been recommended for approval by a majority of the members of the Board conducting such review.

(B) In the case of research that is subject to review under procedures established by the Secretary for the protection of human subjects in clinical research conducted by the National Institutes of Health, the Secretary may not authorize the conduct of the research unless the research has, pursuant to such procedures, been recommended for approval.

(2) PEER REVIEW.—In the case of any proposal for the National Institutes of Health to conduct or support research, the Secretary may not approve or fund any proposal that is subject to technical and scientific peer review under section 492 unless the proposal has undergone such review in accordance with such section and has been recommended for approval by a majority of the members of the entity conducting such review, and unless a majority of the voting members of the appropriate advisory council under section 406, or as applicable, of the advisory council under section 402(k), has recommended the proposal for approval.

(b) ETHICAL REVIEW OF RESEARCH.—

(1) PROCEDURES REGARDING WITHHOLDING OF FUNDS.—If research has been recommended for approval for purposes of subsection (a), the Secretary may not withhold funds for the research because of ethical considerations unless—

(A) the Secretary convenes an advisory board in accordance with paragraph (5) to study such considerations; and

(B)(i) the majority of the advisory board recommends that, because of such considerations, the Secretary withhold funds for the research; or

(ii) the majority of such board recommends that the Secretary not withhold funds for the research because of such considerations, but the Secretary finds, on the basis of the report submitted under paragraph (5)(B)(ii), that the recommendation is arbitrary and capricious.

(2) RULES OF CONSTRUCTION.—Paragraph (1) may not be construed as prohibiting the Secretary from withholding funds for research on the basis of—

(A) the inadequacy of the qualifications of the entities that would be involved with the conduct of the research (including the entity that would directly receive the funds from the Secretary), subject to the condition that, with respect to the process of review through which the research was recommended for approval for purposes of subsection (a), all findings regarding such qualifications made in such process are conclusive; or

(B) the priorities established by the Secretary for the allocation of funds among projects of research that have been so recommended.

(3) APPLICABILITY.—The limitation established in paragraph (1) regarding the authority to withhold funds because of ethical considerations shall apply without regard to whether the withholding of funds on such basis is characterized as a disapproval, a moratorium, a prohibition, or other characterization.

(4) PRELIMINARY MATTERS REGARDING USE OF PROCEDURES.—

(A) If the Secretary makes a determination that an advisory board should be convened for purposes of paragraph (1), the Secretary shall, through a statement published in the Federal Register, announce the intention of the Secretary to convene such a board.

(B) A statement issued under subparagraph (A) shall include a request that interested individuals submit to the Secretary recommendations specifying the particular individuals who should be appointed to the advisory board involved. The Secretary shall consider such recommendations in making appointments to the board.

(C) The Secretary may not make appointments to an advisory board under paragraph (1) until the expiration of the 30-day period beginning on the date on which the statement required in subparagraph (A) is made with respect to the board.

(5) ETHICS ADVISORY BOARDS.—

(A) Any advisory board convened for purposes of paragraph (1) shall be known as an ethics advisory board (in this paragraph referred to as an "ethics board").

(B)(i) An ethics board shall advise, consult with, and make recommendations to the Secretary regarding the ethics of the project of biomedical or behavioral research with respect to which the board has been convened.

(ii) Not later than 180 days after the date on which the statement required in paragraph (4)(A) is made with respect to an ethics board, the board shall submit to the Secretary, and to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate, a report describing the findings of the board regarding the project of research involved and making a recommendation under clause (i) of whether the Secretary should or should not withhold funds for the project. The report shall include the information considered in making the findings.

(C) An ethics board shall be composed of no fewer than 14, and no more than 20, individuals who are not officers or employees of the United States. The Secretary shall make appointments to the board from among individuals with special qualifications and competence to provide advice and recommendations regarding ethical matters in biomedical and behavioral research. Of the members of the board—

(i) no fewer than 1 shall be an attorney;

(ii) no fewer than 1 shall be an ethicist;

(iii) no fewer than 1 shall be a practicing physician;

(iv) no fewer than 1 shall be a theologian; and

(v) no fewer than one-third, and no more than one-half, shall be scientists with substantial accomplishments in biomedical or behavioral research.

(D) The term of service as a member of an ethics board shall be for the life of the board. If such a member does not serve the full term of such service, the individual appointed to fill the resulting vacancy shall be appointed for the remainder of the term of the predecessor of the individual.

(E) A member of an ethics board shall be subject to removal from the board by the Secretary for neglect of duty or malfeasance or for other good cause shown.

(F) The Secretary shall designate an individual from among the members of an ethics board to serve as the chair of the board.

(G) In carrying out subparagraph (B)(i) with respect to a project of research, an ethics board shall conduct inquiries and hold public hearings.

(H) In carrying out subparagraph (B)(i) with respect to a project of research, an ethics board shall have access to all relevant information possessed by the Department of Health and Human Services, or available to the Secretary from other agencies.

(I) Members of an ethics board shall receive compensation for each day engaged in carrying out the duties of the board, including time engaged in traveling for purposes of such duties. Such compensation may not be provided in an amount in excess of the maximum rate of basic pay payable for GS–18 of the General Schedule.

(J) The Secretary, acting through the Director of the National Institutes of Health, shall provide to each ethics board reasonable staff and assistance to carry out the duties of the board.

(K) An ethics board shall terminate 30 days after the date on which the report required in subparagraph (B)(ii) is submitted to the Secretary and the congressional committees specified in such subparagraph.

(6) DEFINITION.—For purposes of this subsection, the term "ethical considerations" means considerations as to whether the nature of the research involved is such that it is unethical to conduct or support the research.

INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH.

SEC. 492B.[289a–2] (a) REQUIREMENT OF INCLUSION.—

(1) IN GENERAL.—In conducting or supporting clinical research for purposes of this title, the Director of NIH shall, subject to subsection (b), ensure that—

(A) women are included as subjects in each project of such research; and

(B) members of minority groups are included as subjects in such research.

(2) OUTREACH REGARDING PARTICIPATION AS SUBJECTS.—The Director of NIH, in consultation with the Director of the Office of Research on Women's Health and the Director of the Office of Research on Minority Health, shall conduct or support

outreach programs for the recruitment of women and members of minority groups as subjects in projects of clinical research.

(b) INAPPLICABILITY OF REQUIREMENT.—The requirement established in subsection (a) regarding women and members of minority groups shall not apply to a project of clinical research if the inclusion, as subjects in the project, of women and members of minority groups, respectively—

(1) is inappropriate with respect to the health of the subjects;

(2) is inappropriate with respect to the purpose of the research; or

(3) is inappropriate under such other circumstances as the Director of NIH may designate.

(c) DESIGN OF CLINICAL TRIALS.—In the case of any clinical trial in which women or members of minority groups will under subsection (a) be included as subjects, the Director of NIH shall ensure that the trial is designed and carried out in a manner sufficient to provide for a valid analysis of whether the variables being studied in the trial affect women or members of minority groups, as the case may be, differently than other subjects in the trial.

(d) GUIDELINES.—

(1) IN GENERAL.—Subject to paragraph (2), the Director of NIH, in consultation with the Director of the Office of Research on Women's Health and the Director of the Office of Research on Minority Health, shall establish guidelines regarding the requirements of this section. The guidelines shall include guidelines regarding—

(A) the circumstances under which the inclusion of women and minorities as subjects in projects of clinical research is inappropriate for purposes of subsection (b);

(B) the manner in which clinical trials are required to be designed and carried out for purposes of subsection (c); and

(C) the operation of outreach programs under subsection (a).

(2) CERTAIN PROVISIONS.—With respect to the circumstances under which the inclusion of women or members of minority groups (as the case may be) as subjects in a project of clinical research is inappropriate for purposes of subsection (b), the following applies to guidelines under paragraph (1):

(A)(i) In the case of a clinical trial, the guidelines shall provide that the costs of such inclusion in the trial is not a permissible consideration in determining whether such inclusion is inappropriate.

(ii) In the case of other projects of clinical research, the guidelines shall provide that the costs of such inclusion in the project is not a permissible consideration in determining whether such inclusion is inappropriate unless the data regarding women or members of minority groups, respectively, that would be obtained in such project (in the event that such inclusion were required) have been or are being obtained through other means that provide data of comparable quality.

(B) In the case of a clinical trial, the guidelines may provide that such inclusion in the trial is not required if there is substantial scientific data demonstrating that there is no significant difference between—

(i) the effects that the variables to be studied in the trial have on women or members of minority groups, respectively; and

(ii) the effects that the variables have on the individuals who would serve as subjects in the trial in the event that such inclusion were not required.

(e) DATE CERTAIN FOR GUIDELINES; APPLICABILITY.—

(1) DATE CERTAIN.—The guidelines required in subsection (d) shall be established and published in the Federal Register not later than 180 days after the date of the enactment of the National Institutes of Health Revitalization Act of 1993.

(2) APPLICABILITY.—For fiscal year 1995 and subsequent fiscal years, the Director of NIH may not approve any proposal of clinical research to be conducted or supported by any agency of the National Institutes of Health unless the proposal specifies the manner in which the research will comply with this section.

(f) REPORTS BY ADVISORY COUNCILS.—The advisory council of each national research institute shall prepare biennial reports describing the manner in which the institute has complied with this section. Each such report shall be submitted to the Director of the institute involved for inclusion in the biennial report under section 403.

(g) DEFINITIONS.—For purposes of this section:

(1) The term "project of clinical research" includes a clinical trial.

(2) The term "minority group" includes subpopulations of minority groups. The Director of NIH shall, through the guidelines established under subsection (d), define the terms "minority group" and "subpopulation" for purposes of the preceding sentence.

OFFICE OF RESEARCH INTEGRITY.

SEC. 493.[289b] (a) IN GENERAL.—

(1) ESTABLISHMENT OF OFFICE.—Not later than 90 days after the date of enactment of this section, the Secretary shall establish an office to be known as the Office of Research Integrity (referred to in this section as the "Office"), which shall be established as an independent entity in the Department of Health and Human Services.

(2) APPOINTMENT OF DIRECTOR.—The Office shall be headed by a Director, who shall be appointed by the Secretary, be experienced and specially trained in the conduct of research, and have experience in the conduct of investigations of research misconduct. The Secretary shall carry out this section acting through the Director of the Office. The Director shall report to the Secretary.

(3) DEFINITIONS.—

(A) The Secretary shall by regulation establish a definition for the term "research misconduct" for purposes of this section.

(B) For purposes of this section, the term "financial assistance" means a grant, contract, or cooperative agreement.

(b) EXISTENCE OF ADMINISTRATIVE PROCESSES AS CONDITION OF FUNDING FOR RESEARCH.—The Secretary shall by regulation require that each entity that applies for financial assistance under this Act for any project or program that involves the conduct of biomedical or behavioral research submit in or with its application for such assistance—

(1) assurances satisfactory to the Secretary that such entity has established and has in effect (in accordance with regulations which the Secretary shall prescribe) an administrative process to review reports of research misconduct in connection with biomedical and behavioral research conducted at or sponsored by such entity;

(2) an agreement that the entity will report to the Director any investigation of alleged research misconduct in connection with projects for which funds have been made available under this Act that appears substantial; and

(3) an agreement that the entity will comply with regulations issued under this section.

(c) PROCESS FOR RESPONSE OF DIRECTOR.—The Secretary shall by regulation establish a process to be followed by the Director for the prompt and appropriate—

(1) response to information provided to the Director respecting research misconduct in connection with projects for which funds have been made available under this Act;

(2) receipt of reports by the Director of such information from recipients of funds under this Act;

(3) conduct of investigations, when appropriate; and

(4) taking of other actions, including appropriate remedies, with respect to such misconduct.

(d) MONITORING BY DIRECTOR.—The Secretary shall by regulation establish procedures for the Director to monitor administrative processes and investigations that have been established or carried out under this section.

(e) PROTECTION OF WHISTLEBLOWERS.—

(1) IN GENERAL.—In the case of any entity required to establish administrative processes under subsection (b), the Secretary shall by regulation establish standards for preventing, and for responding to the occurrence of retaliation by such entity, its officials or agents, against an employee in the terms and conditions of employment in response to the employee having in good faith—

(A) made an allegation that the entity, its officials or agents, has engaged in or failed to adequately respond to an allegation of research misconduct; or

(B) cooperated with an investigation of such an allegation.

(2) MONITORING BY SECRETARY.—The Secretary shall by regulation establish procedures for the Director to monitor the

implementation of the standards established by an entity under paragraph (1) for the purpose of determining whether the procedures have been established, and are being utilized, in accordance with the standards established under such paragraph.

(3) NONCOMPLIANCE.—The Secretary shall by regulation establish remedies for noncompliance by an entity, its officials or agents, which has engaged in retaliation in violation of the standards established under paragraph (1). Such remedies may include termination of funding provided by the Secretary for such project or recovery of funding being provided by the Secretary for such project, or other actions as appropriate.

PROTECTION AGAINST FINANCIAL CONFLICTS OF INTEREST IN CERTAIN PROJECTS OF RESEARCH.

SEC. 493A.[289b–1] (a) ISSUANCE OF REGULATIONS.—The Secretary shall by regulation define the specific circumstances that constitute the existence of a financial interest in a project on the part of an entity or individual that will, or may be reasonably expected to, create a bias in favor of obtaining results in such project that are consistent with such financial interest. Such definition shall apply uniformly to each entity or individual conducting a research project under this Act. In the case of any entity or individual receiving assistance from the Secretary for a project of research described in subsection (b), the Secretary shall by regulation establish standards for responding to, including managing, reducing, or eliminating, the existence of such a financial interest. The entity may adopt individualized procedures for implementing the standards.

(b) RELEVANT PROJECTS.—A project of research referred to in subsection (a) is a project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment and for which such entity is receiving assistance from the Secretary.

(c) IDENTIFYING AND REPORTING TO SECRETARY.—The Secretary shall by regulation require that each entity described in subsection (a) that applies for assistance under this Act for any project described in subsection (b) submit in or with its application for such assistance—

(1) assurances satisfactory to the Secretary that such entity has established and has in effect an administrative process under subsection (a) to identify financial interests (as defined under subsection (a)) that exist regarding the project; and

(2) an agreement that the entity will report to the Secretary such interests identified by the entity and how any such interests identified by the entity will be managed or eliminated in order that the project in question will be protected from bias that may stem from such interests; and

(3) an agreement that the entity will comply with regulations issued under this section.

(d) MONITORING OF PROCESS.—The Secretary shall monitor the establishment and conduct of the administrative process established by an entity pursuant to subsection (a).

(e) RESPONSE.—In any case in which the Secretary determines that an entity has failed to comply with subsection (c) regarding a project of research described in subsection (b), the Secretary—

(1) shall require that, as a condition of receiving assistance, the entity disclose the existence of a financial interest (as defined under subsection (a)) in each public presentation of the results of such project; and

(2) may take such other actions as the Secretary determines to be appropriate.

(f) DEFINITIONS.—For purposes of this section:

(1) The term "financial interest" includes the receipt of consulting fees or honoraria and the ownership of stock or equity.

(2) The term "assistance", with respect to conducting a project of research, means a grant, contract, or cooperative agreement.

RESEARCH ON PUBLIC HEALTH EMERGENCIES.

SEC. 494.[289c] If the Secretary determines, after consultation with the Director of NIH, the Commissioner of the Food and Drug Administration, or the Director of the Centers for Disease Control and Prevention, that a disease or disorder constitutes a public health emergency, the Secretary, acting through the Director of NIH—

(1) shall expedite the review by advisory councils under section 406 and by peer review groups under section 492 of applications for grants for research on such disease or disorder or proposals for contracts for such research;

(2) shall exercise the authority in section 3709 of the Revised Statutes (41 U.S.C. 5) respecting public exigencies to waive the advertising requirements of such section in the case of proposals for contracts for such research;

(3) may provide administrative supplemental increases in existing grants and contracts to support new research relevant to such disease or disorder; and

(4) shall disseminate, to health professionals and the public, information on the cause, prevention, and treatment of such disease or disorder that has been developed in research assisted under this section.

The amount of an increase in a grant or contract provided under paragraph (3) may not exceed one-half the original amount of the grant or contract.

COLLABORATIVE USE OF CERTAIN HEALTH SERVICES RESEARCH FUNDS.

SEC. 494A.[289c–1] The Secretary shall ensure that amounts made available under subparts 14, 15 and 16 of part C for health services research relating to alcohol abuse and alcoholism, drug abuse and mental health be used collaboratively, as appropriate, and in consultation with the Agency for Health Care Policy Research.

ANIMALS IN RESEARCH.

SEC. 495.[289d] (a) The Secretary, acting through the Director of NIH, shall establish guidelines for the following:

(1) The proper care of animals to be used in biomedical and behavioral research.

(2) The proper treatment of animals while being used in such research. Guidelines under this paragraph shall require—

(A) the appropriate use of tranquilizers, analgesics, anesthetics, paralytics, and euthanasia for animals in such research; and

(B) appropriate pre-surgical and post-surgical veterinary medical and nursing care for animals in such research.

Such guidelines shall not be construed to prescribe methods of research.

(3) The organization and operation of animal care committees in accordance with subsection (b).

(b)(1) Guidelines of the Secretary under subsection (a)(3) shall require animal care committees at each entity which conducts biomedical and behavioral research with funds provided under this Act (including the National Institutes of Health and the national research institutes) to assure compliance with the guidelines established under subsection (a).

(2) Each animal care committee shall be appointed by the chief executive officer of the entity for which the committee is established, shall be composed of not fewer than three members, and shall include at least one individual who has no association with such entity and at least one doctor of veterinary medicine.

(3) Each animal care committee of a research entity shall—

(A) review the care and treatment of animals in all animal study areas and facilities of the research entity at least semiannually to evaluate compliance with applicable guidelines established under subsection (a) for appropriate animal care and treatment;

(B) keep appropriate records of reviews conducted under subparagraph (A); and

(C) for each review conducted under subparagraph (A), file with the Director of NIH at least annually (i) a certification that the review has been conducted, and (ii) reports of any violations of guidelines established under subsection (a) or assurances required under paragraph (1) which were observed in such review and which have continued after notice by the committee to the research entity involved of the violations.

Reports filed under subparagraph (C) shall include any minority views filed by members of the committee.

(c) The Director of NIH shall require each applicant for a grant, contract, or cooperative agreement involving research on animals which is administered by the National Institutes of Health or any national research institute to include in its application or contract proposal, submitted after the expiration of the twelve-month period beginning on the date of enactment of this section—

(1) assurances satisfactory to the Director of NIH that—

(A) the applicant meets the requirements of the guidelines established under paragraphs (1) and (2) of subsection (a) and has an animal care committee which meets the requirements of subsection (b); and

(B) scientists, animal technicians, and other personnel involved with animal care, treatment, and use by the applicant have available to them instruction or training in the humane practice of animal maintenance and experimentation, and the concept, availability, and use of research or testing methods that limit the use of animals or limit animal distress; and

(2) a statement of the reasons for the use of animals in the research to be conducted with funds provided under such grant or contract.

Notwithstanding subsection (a)(2) of section 553 of title 5, United States Code, regulations under this subsection shall be promulgated in accordance with the notice and comment requirements of such section.

(d) If the Director of NIH determines that—

(1) the conditions of animal care, treatment, or use in an entity which is receiving a grant, contract, or cooperative agreement involving research on animals under this title do not meet applicable guidelines established under subsection (a);

(2) the entity has been notified by the Director of NIH of such determination and has been given a reasonable opportunity to take corrective action; and

(3) no action has been taken by the entity to correct such conditions;

the Director of NIH shall suspend or revoke such grant or contract under such conditions as the Director determines appropriate.

(e) No guideline or regulation promulgated under subsection (a) or (c) may require a research entity to disclose publicly trade secrets or commercial or financial information which is privileged or confidential.

USE OF APPROPRIATIONS UNDER THIS TITLE.

SEC. 496.[289e] (a) Appropriations to carry out the purposes of this title, unless otherwise expressly provided, may be expended in the District of Columbia for—

(1) personal services;

(2) stenographic recording and translating services;

(3) travel expenses (including the expenses of attendance at meetings when specifically authorized by the Secretary);

(4) rental;

(5) supplies and equipment;

(6) purchase and exchange of medical books, books of reference, directories, periodicals, newspapers, and press clippings;

(7) purchase, operation, and maintenance of passenger motor vehicles;

(8) printing and binding (in addition to that otherwise provided by law); and

(9) all other necessary expenses in carrying out this title. Such appropriations may be expended by contract if deemed necessary, without regard to section 3709 of the Revised Statutes (41 U.S.C. 5).

(b)(1) None of the amounts appropriated under this Act for the purposes of this title may be obligated for the construction of facilities (including the acquisition of land) unless a provision of this title establishes express authority for such purpose and unless the Act making appropriations under such provision specifies that the amounts appropriated are available for such purpose.

(2) Any grants, cooperative agreements, or contracts authorized in this title for the construction of facilities may be awarded only on a competitive basis.

GIFTS.

SEC. 497.[289f] The Secretary may, in accordance with section 231, accept conditional gifts for the National Institutes of Health or a national research institute or for the acquisition of grounds or for the erection, equipment, or maintenance of facilities for the National Institutes of Health or a national research institute. Donations of $50,000 or over for the National Institutes of Health or a national research institute for carrying out the purposes of this title may be acknowledged by the establishment within the National Institutes of Health or a national research institute of suitable memorials to the donors.

FETAL RESEARCH.

SEC. 498.[289g] (a) The Secretary may not conduct or support any research or experimentation, in the United States or in any other country, on a nonviable living human fetus ex utero or a living human fetus ex utero for whom viability has not been ascertained unless the research or experimentation—

(1) may enhance the well-being or meet the health needs of the fetus or enhance the probability of its survival to viability; or

(2) will pose no added risk of suffering, injury, or death to the fetus and the purpose of the research or experimentation is the development of important biomedical knowledge which cannot be obtained by other means.

(b) In administering the regulations for the protection of human research subjects which—

(1) apply to research conducted or supported by the Secretary;

(2) involve living human fetuses in utero; and

(3) are published in section 46.208 of part 46 of title 45 of the Code of Federal Regulations;

or any successor to such regulations, the Secretary shall require that the risk standard (published in section 46.102(g) of such part 46 or any successor to such regulations) be the same for fetuses which are intended to be aborted and fetuses which are intended to be carried to term.

RESEARCH ON TRANSPLANTATION OF FETAL TISSUE.

SEC. 498A.[289g–1] (a) ESTABLISHMENT OF PROGRAM.—

(1) IN GENERAL.—The Secretary may conduct or support research on the transplantation of human fetal tissue for therapeutic purposes.

(2) SOURCE OF TISSUE.—Human fetal tissue may be used in research carried out under paragraph (1) regardless of whether the tissue is obtained pursuant to a spontaneous or induced abortion or pursuant to a stillbirth.

(b) INFORMED CONSENT OF DONOR.—

(1) IN GENERAL.—In research carried out under subsection (a), human fetal tissue may be used only if the woman providing the tissue makes a statement, made in writing and signed by the woman, declaring that—

(A) the woman donates the fetal tissue for use in research described in subsection (a);

(B) the donation is made without any restriction regarding the identity of individuals who may be the recipients of transplantations of the tissue; and

(C) the woman has not been informed of the identity of any such individuals.

(2) ADDITIONAL STATEMENT.—In research carried out under subsection (a), human fetal tissue may be used only if the attending physician with respect to obtaining the tissue from the woman involved makes a statement, made in writing and signed by the physician, declaring that—

(A) in the case of tissue obtained pursuant to an induced abortion—

(i) the consent of the woman for the abortion was obtained prior to requesting or obtaining consent for a donation of the tissue for use in such research;

(ii) no alteration of the timing, method, or procedures used to terminate the pregnancy was made solely for the purposes of obtaining the tissue; and

(iii) the abortion was performed in accordance with applicable State law;

(B) the tissue has been donated by the woman in accordance with paragraph (1); and

(C) full disclosure has been provided to the woman with regard to—

(i) such physician's interest, if any, in the research to be conducted with the tissue; and

(ii) any known medical risks to the woman or risks to her privacy that might be associated with the donation of the tissue and that are in addition to risks of such type that are associated with the woman's medical care.

(c) INFORMED CONSENT OF RESEARCHER AND DONEE.—In research carried out under subsection (a), human fetal tissue may be used only if the individual with the principal responsibility for conducting the research involved makes a statement, made in writing and signed by the individual, declaring that the individual—

(1) is aware that—

(A) the tissue is human fetal tissue;

(B) the tissue may have been obtained pursuant to a spontaneous or induced abortion or pursuant to a stillbirth; and

(C) the tissue was donated for research purposes;

(2) has provided such information to other individuals with responsibilities regarding the research;

(3) will require, prior to obtaining the consent of an individual to be a recipient of a transplantation of the tissue, written acknowledgment of receipt of such information by such recipient; and

(4) has had no part in any decisions as to the timing, method, or procedures used to terminate the pregnancy made solely for the purposes of the research.

(d) AVAILABILITY OF STATEMENTS FOR AUDIT.—

(1) IN GENERAL.—In research carried out under subsection (a), human fetal tissue may be used only if the head of the agency or other entity conducting the research involved certifies to the Secretary that the statements required under subsections (b)(2) and (c) will be available for audit by the Secretary.

(2) CONFIDENTIALITY OF AUDIT.—Any audit conducted by the Secretary pursuant to paragraph (1) shall be conducted in a confidential manner to protect the privacy rights of the individuals and entities involved in such research, including such individuals and entities involved in the donation, transfer, receipt, or transplantation of human fetal tissue. With respect to any material or information obtained pursuant to such audit, the Secretary shall—

(A) use such material or information only for the purposes of verifying compliance with the requirements of this section;

(B) not disclose or publish such material or information, except where required by Federal law, in which case such material or information shall be coded in a manner such that the identities of such individuals and entities are protected; and

(C) not maintain such material or information after completion of such audit, except where necessary for the purposes of such audit.

(e) APPLICABILITY OF STATE AND LOCAL LAW.—

(1) RESEARCH CONDUCTED BY RECIPIENTS OF ASSISTANCE.—The Secretary may not provide support for research under subsection (a) unless the applicant for the financial assistance involved agrees to conduct the research in accordance with applicable State law.

(2) RESEARCH CONDUCTED BY SECRETARY.—The Secretary may conduct research under subsection (a) only in accordance with applicable State and local law.

(f) REPORT.—The Secretary shall annually submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report describing the activities carried out under this section during the preceding fiscal year, including a description of whether

and to what extent research under subsection (a) has been conducted in accordance with this section.

(g) DEFINITION.—For purposes of this section, the term "human fetal tissue" means tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion, or after a stillbirth.

PROHIBITIONS REGARDING HUMAN FETAL TISSUE.

SEC. 498B.[289g–2] (a) PURCHASE OF TISSUE.—It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration if the transfer affects interstate commerce.

(b) SOLICITATION OR ACCEPTANCE OF TISSUE AS DIRECTED DONATION FOR USE IN TRANSPLANTATION.—It shall be unlawful for any person to solicit or knowingly acquire, receive, or accept a donation of human fetal tissue for the purpose of transplantation of such tissue into another person if the donation affects interstate commerce, the tissue will be or is obtained pursuant to an induced abortion, and—

(1) the donation will be or is made pursuant to a promise to the donating individual that the donated tissue will be transplanted into a recipient specified by such individual;

(2) the donated tissue will be transplanted into a relative of the donating individual; or

(3) the person who solicits or knowingly acquires, receives, or accepts the donation has provided valuable consideration for the costs associated with such abortion.

(c) SOLICITATION OR ACCEPTANCE OF TISSUE FROM FETUSES GESTATED FOR RESEARCH PURPOSES.—It shall be unlawful for any person or entity involved or engaged in interstate commerce to—

(1) solicit or knowingly acquire, receive, or accept a donation of human fetal tissue knowing that a human pregnancy was deliberately initiated to provide such tissue; or

(2) knowingly acquire, receive, or accept tissue or cells obtained from a human embryo or fetus that was gestated in the uterus of a nonhuman animal.

(d) CRIMINAL PENALTIES FOR VIOLATIONS.—

(1) IN GENERAL.—Any person who violates subsection (a), (b), or (c) shall be fined in accordance with title 18, United States Code, subject to paragraph (2), or imprisoned for not more than 10 years, or both.

(2) PENALTIES APPLICABLE TO PERSONS RECEIVING CONSIDERATION.—With respect to the imposition of a fine under paragraph (1), if the person involved violates subsection (a) or (b)(3), a fine shall be imposed in an amount not less than twice the amount of the valuable consideration received.

(e) DEFINITIONS.—For purposes of this section:

(1) The term "human fetal tissue" has the meaning given such term in section 498A(g).

(2) The term "interstate commerce" has the meaning given such term in section 201(b) of the Federal Food, Drug, and Cosmetic Act.

(3) The term "valuable consideration" does not include reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue.

SEC. 498C.[289g–3] BREAST IMPLANT RESEARCH.

(a) IN GENERAL.—The Director of NIH may conduct or support research to examine the long-term health implications of silicone breast implants, both gel and saline filled. Such research studies may include the following:

(1) Developing and examining techniques to measure concentrations of silicone in body fluids and tissues.

(2) Surveillance of recipients of silicone breast implants, including long-term outcomes and local complications.

(b) DEFINITION.—For purposes of this section, the term "breast implant" means a breast prosthesis that is implanted to augment or reconstruct the female breast.

SEC. 498D.[289g–4] SUPPORT FOR EMERGENCY MEDICINE RESEARCH.

(a) EMERGENCY MEDICAL RESEARCH.—The Secretary shall support Federal programs administered by the National Institutes of Health, the Agency for Healthcare Research and Quality, the Health Resources and Services Administration, the Centers for Disease Control and Prevention, and other agencies involved in improving the emergency care system to expand and accelerate research in emergency medical care systems and emergency medicine, including—

(1) the basic science of emergency medicine;

(2) the model of service delivery and the components of such models that contribute to enhanced patient health outcomes;

(3) the translation of basic scientific research into improved practice; and

(4) the development of timely and efficient delivery of health services.

(b) PEDIATRIC EMERGENCY MEDICAL RESEARCH.—The Secretary shall support Federal programs administered by the National Institutes of Health, the Agency for Healthcare Research and Quality, the Health Resources and Services Administration, the Centers for Disease Control and Prevention, and other agencies to coordinate and expand research in pediatric emergency medical care systems and pediatric emergency medicine, including—

(1) an examination of the gaps and opportunities in pediatric emergency care research and a strategy for the optimal organization and funding of such research;

(2) the role of pediatric emergency services as an integrated component of the overall health system;

(3) system-wide pediatric emergency care planning, preparedness, coordination, and funding;

(4) pediatric training in professional education; and

(5) research in pediatric emergency care, specifically on the efficacy, safety, and health outcomes of medications used for infants, children, and adolescents in emergency care settings in order to improve patient safety.

(c) IMPACT RESEARCH.—The Secretary shall support research to determine the estimated economic impact of, and savings that result from, the implementation of coordinated emergency care systems.

(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section such sums as may be necessary for each of fiscal years 2010 through 2014.

PART I—FOUNDATION FOR THE NATIONAL INSTITUTES OF HEALTH

SEC. 499.[290b] ESTABLISHMENT AND DUTIES OF FOUNDATION.

(a) IN GENERAL.—The Secretary shall, acting through the Director of NIH, establish a nonprofit corporation to be known as the Foundation for the National Institutes of Health (hereafter in this section referred to as the "Foundation"). The Foundation shall not be an agency or instrumentality of the United States Government.

(b) PURPOSE OF FOUNDATION.—The purpose of the Foundation shall be to support the National Institutes of Health in its mission (including collection of funds for pediatric pharmacologic research), and to advance collaboration with biomedical researchers from universities, industry, and nonprofit organizations.

(c) CERTAIN ACTIVITIES OF FOUNDATION.—

(1) IN GENERAL.—In carrying out subsection (b), the Foundation may solicit and accept gifts, grants, and other donations, establish accounts, and invest and expend funds in support of the following activities with respect to the purpose described in such subsection:

(A) A program to provide and administer endowed positions that are associated with the research program of the National Institutes of Health. Such endowments may be expended for the compensation of individuals holding the positions, for staff, equipment, quarters, travel, and other expenditures that are appropriate in supporting the endowed positions.

(B) A program to provide and administer fellowships and grants to research personnel in order to work and study in association with the National Institutes of Health. Such fellowships and grants may include stipends, travel, health insurance benefits and other appropriate expenses. The recipients of fellowships shall be selected by the donors and the Foundation upon the recommendation of the National Institutes of Health employees in the laboratory where the fellow would serve, and shall be subject to the agreement of the Director of the National Institutes of Health and the Executive Director of the Foundation.

(C) A program to collect funds for pediatric pharmacologic research and studies.

(D) Supplementary programs to provide for—

(i) scientists of other countries to serve in research capacities in the United States in association with the National Institutes of Health or elsewhere, or opportunities for employees of the National Institutes of

Health or other public health officials in the United States to serve in such capacities in other countries, or both;

(ii) the conduct and support of studies, projects, and research, which may include stipends, travel and other support for personnel in collaboration with national and international non-profit and for-profit organizations;

(iii) the conduct and support of forums, meetings, conferences, courses, and training workshops that may include undergraduate, graduate, post-graduate, and post-doctoral accredited courses and the maintenance of accreditation of such courses by the Foundation at the State and national level for college or continuing education credits or for degrees;

(iv) programs to support and encourage teachers and students of science at all levels of education and programs for the general public which promote the understanding of science;

(v) programs for writing, editing, printing, publishing, and vending of books and other materials; and

(vi) the conduct of other activities to carry out and support the purpose described in subsection (b).

(E) The Cures Acceleration Network described in section 480.

(2) FEES.—The Foundation may assess fees for the provision of professional, administrative and management services by the Foundation in amounts determined reasonable and appropriate by the Executive Director.

(3) AUTHORITY OF FOUNDATION.—The Foundation shall be the sole entity responsible for carrying out the activities described in this subsection.

(d) BOARD OF DIRECTORS.—

(1) COMPOSITION.—

(A) The Foundation shall have a Board of Directors (hereafter referred to in this section as the "Board"), which shall be composed of ex officio and appointed members in accordance with this subsection. All appointed members of the Board shall be voting members.

(B) The ex officio members of the Board shall be—

(i) the Chairman and ranking minority member of the Subcommittee on Health and the Environment (Committee on Energy and Commerce) or their designees, in the case of the House of Representatives;

(ii) the Chairman and ranking minority member of the Committee on Labor and Human Resources or their designees, in the case of the Senate;

(iii) the Director of the National Institutes of Health; and

(iv) the Commissioner of Food and Drugs.

(C) The ex officio members of the Board under subparagraph (B) shall appoint to the Board individuals from among a list of candidates to be provided by the National

Academy of Science. Such appointed members shall include—

(i) representatives of the general biomedical field;

(ii) representatives of experts in pediatric medicine and research;

(iii) representatives of the general biobehavioral field, which may include experts in biomedical ethics; and

(iv) representatives of the general public, which may include representatives of affected industries.

(D)(i) Not later than 30 days after the date of the enactment of the National Institutes of Health Revitalization Act of 1993, the Director of the National Institutes of Health shall convene a meeting of the ex officio members of the Board to—

(I) incorporate the Foundation and establish the general policies of the Foundation for carrying out the purposes of subsection (b), including the establishment of the bylaws of the Foundation; and

(II) appoint the members of the Board in accordance with subparagraph (C).

(ii) Upon the appointment of the appointed members of the Board under clause (i)(II), the terms of service as members of the Board of the ex officio members of the Board described in clauses (i) and (ii) of subparagraph (B) shall terminate. The ex officio members of the Board described in clauses (iii) and (iv) of subparagraph (B) shall continue to serve as ex officio members of the Board.

(E) The agreement of not less than three-fifths of the members of the ex officio members of the Board shall be required for the appointment of each member to the initial Board.

(F) No employee of the National Institutes of Health shall be appointed as a member of the Board.

(G) The Board may, through amendments to the bylaws of the Foundation, provide that the number of appointed members of the Board shall be greater than the number specified in subparagraph (C).

(2) CHAIR.—

(A) The ex officio members of the Board under paragraph (1)(B) shall designate an individual to serve as the initial Chair of the Board.

(B) Upon the termination of the term of service of the initial Chair of the Board, the appointed members of the Board shall elect a member of the Board to serve as the Chair of the Board.

(3) TERMS AND VACANCIES.—

(A) The term of office of each member of the Board appointed under paragraph (1)(C) shall be 5 years, except that the terms of offices for the initial appointed members of the Board shall expire as determined by the ex officio members and the Chair.

(B) Any vacancy in the membership of the appointed members of the Board shall be filled in accordance with the bylaws of the Foundation established in accordance with paragraph (6), and shall not affect the power of the remaining appointed members to execute the duties of the Board.

(C) If a member of the Board does not serve the full term applicable under subparagraph (A), the individual appointed to fill the resulting vacancy shall be appointed for the remainder of the term of the predecessor of the individual.

(D) A member of the Board may continue to serve after the expiration of the term of the member until a successor is appointed.

(4) COMPENSATION.—Members of the Board may not receive compensation for service on the Board. Such members may be reimbursed for travel, subsistence, and other necessary expenses incurred in carrying out the duties of the Board, as set forth in the bylaws issued by the Board.

(5) MEETINGS AND QUORUM.—A majority of the appointed members of the Board shall constitute a quorum for purposes of conducting the business of the Board.

(6) CERTAIN BYLAWS.—

(A) In establishing bylaws under this subsection, the Board shall ensure that the following are provided for:

(i) Policies for the selection of the officers, employees, agents, and contractors of the Foundation.

(ii) Policies, including ethical standards, for the acceptance, solicitation, and disposition of donations and grants to the Foundation and for the disposition of the assets of the Foundation. Policies with respect to ethical standards shall ensure that officers, employees and agents of the Foundation (including members of the Board) avoid encumbrances that would result in a conflict of interest, including a financial conflict of interest or a divided allegiance. Such policies shall include requirements for the provision of information concerning any ownership or controlling interest in entities related to the activities of the Foundation by such officers, employees and agents and their spouses and relatives.

(iii) Policies for the conduct of the general operations of the Foundation.

(iv) Policies for writing, editing, printing, publishing, and vending of books and other materials.

(B) In establishing bylaws under this subsection, the Board shall ensure that such bylaws (and activities carried out under the bylaws) do not—

(i) reflect unfavorably upon the ability of the Foundation or the National Institutes of Health to carry out its responsibilities or official duties in a fair and objective manner; or

(ii) compromise, or appear to compromise, the integrity of any governmental agency or program, or any officer or employee involved in such program.

(e) INCORPORATION.—The initial members of the Board shall serve as incorporators and shall take whatever actions necessary to incorporate the Foundation.

(f) NONPROFIT STATUS.—The Foundation shall be considered to be a corporation under section 501(c) of the Internal Revenue Code of 1986, and shall be subject to the provisions of such section.

(g) EXECUTIVE DIRECTOR.—

(1) IN GENERAL.—The Foundation shall have an Executive Director who shall be appointed by the Board and shall serve at the pleasure of the Board. The Executive Director shall be responsible for the day-to-day operations of the Foundation and shall have such specific duties and responsibilities as the Board shall prescribe.

(2) COMPENSATION.—The rate of compensation of the Executive Director shall be fixed by the Board.

(h) POWERS.—In carrying out subsection (b), the Foundation may—

(1) operate under the direction of its Board;

(2) adopt, alter, and use a corporate seal, which shall be judicially noticed;

(3) provide for 1 or more officers, employees, and agents, as may be necessary, define their duties, and require surety bonds or make other provisions against losses occasioned by acts of such persons;

(4) hire, promote, compensate, and discharge officers and employees of the Foundation, and define the duties of the officers and employees;

(5) with the consent of any executive department or independent agency, use the information, services, staff, and facilities of such in carrying out this section;

(6) sue and be sued in its corporate name, and complain and defend in courts of competent jurisdiction;

(7) modify or consent to the modification of any contract or agreement to which it is a party or in which it has an interest under this part;

(8) establish a process for the selection of candidates for positions under subsection (c);

(9) enter into contracts with public and private organizations for the writing, editing, printing, and publishing of books and other material;

(10) take such action as may be necessary to obtain patents and licenses for devices and procedures developed by the Foundation and its employees;

(11) solicit, accept, hold, administer, invest, and spend any gift, devise, or bequest of real or personal property made to the Foundation;

(12) enter into such other contracts, leases, cooperative agreements, and other transactions as the Executive Director considers appropriate to conduct the activities of the Foundation;

(13) appoint other groups of advisors as may be determined necessary from time to time to carry out the functions of the Foundation;

(14) enter into such other contracts, leases, cooperative agreements, and other transactions as the Executive Director considers appropriate to conduct the activities of the Foundation; and

(15) exercise other powers as set forth in this section, and such other incidental powers as are necessary to carry out its powers, duties, and functions in accordance with this part.

(i) ADMINISTRATIVE CONTROL.—No participant in the program established under this part shall exercise any administrative control over any Federal employee.

(7) in paragraphs (1) and (2) of subsection (j) (as so redesignated), by striking "(including those developed under subsection (d)(2)(B)(i)(II))" each place it appears.

(j) GENERAL PROVISIONS.—

(1) FOUNDATION INTEGRITY.—The members of the Board shall be accountable for the integrity of the operations of the Foundation and shall ensure such integrity through the development and enforcement of criteria and procedures relating to standards of conduct, financial disclosure statements, conflict of interest rules, recusal and waiver rules, audits and other matter determined appropriate by the Board.

(2) FINANCIAL CONFLICTS OF INTEREST.—Any individual who is an officer, employee, or member of the Board of the Foundation may not (in accordance with policies and requirements developed under subsection (d)(6))[61] personally or substantially participate in the consideration or determination by the Foundation of any matter that would directly or predictably affect any financial interest of the individual or a relative (as such term is defined in section 109(16) of the Ethics in Government Act of 1978) of the individual, of any business organization or other entity, or of which the individual is an officer or employee, or is negotiating for employment, or in which the individual has any other financial interest.

(3) AUDITS; AVAILABILITY OF RECORDS.—The Foundation shall—

(A) provide for annual audits of the financial condition of the Foundation; and

(B) make such audits, and all other records, documents, and other papers of the Foundation, available to the Secretary and the Comptroller General of the United States for examination or audit.

(4) REPORTS.—

(A) Not later than 5 months following the end of each fiscal year, the Foundation shall publish a report describing the activities of the Foundation during the preceding fiscal year. Each such report shall include for the fiscal year involved a comprehensive statement of the oper-

[61] Section 13(7) of Public Law 107–109 (115 Stat. 1419) provided that paragraphs (1) and (2) of section 499(j) are amended "by striking '(including those developed under subsection (d)(2)(B)(i)(II))' each place it appears". The term to be struck appeared in paragraph (1), but not in paragraph (2).

ations, activities, financial condition, and accomplishments of the Foundation, including an accounting of the use of amounts transferred under subsection (l).

(B) With respect to the financial condition of the Foundation, each report under subparagraph (A) shall include the source, and a description of, all gifts or grants to the Foundation of real or personal property, and the source and amount of all gifts or grants to the Foundation of money. Each such report shall include a specification of any restrictions on the purposes for which gifts or grants to the Foundation may be used.

(C) The Foundation shall make copies of each report submitted under subparagraph (A) available—

(i) for public inspection, and shall upon request provide a copy of the report to any individual for a charge that shall not exceed the cost of providing the copy; and

(ii) to the appropriate committees of Congress.

(D) The Board shall annually hold a public meeting to summarize the activities of the Foundation and distribute written reports concerning such activities and the scientific results derived from such activities.

(5) SERVICE OF FEDERAL EMPLOYEES.—Federal employees may serve on committees advisory to the Foundation and otherwise cooperate with and assist the Foundation in carrying out its function, so long as the employees do not direct or control Foundation activities.

(6) RELATIONSHIP WITH EXISTING ENTITIES.—The Foundation may, pursuant to appropriate agreements, merge with, acquire, or use the resources of existing nonprofit private corporations with missions similar to the purposes of the Foundation, such as the Foundation for Advanced Education in the Sciences.

(7) INTELLECTUAL PROPERTY RIGHTS.—The Board shall adopt written standards with respect to the ownership of any intellectual property rights derived from the collaborative efforts of the Foundation prior to the commencement of such efforts.

(8) NATIONAL INSTITUTES OF HEALTH AMENDMENTS OF 1990.—The activities conducted in support of the National Institutes of Health Amendments of 1990 (Public Law 101–613), and the amendments made by such Act, shall not be nullified by the enactment of this section.

(9) LIMITATION OF ACTIVITIES.—

(A) IN GENERAL.—The Foundation shall exist solely as an entity to work in collaboration with the research programs of the National Institutes of Health. The Foundation may not undertake activities (such as the operation of independent laboratories or competing for Federal research funds) that are independent of those of the National Institutes of Health research programs.

(B) GIFTS, GRANTS, AND OTHER DONATIONS.—

(i) IN GENERAL.—Gifts, grants, and other donations to the Foundation may be designated for pedi-

atric research and studies on drugs, and funds so designated shall be used solely for grants for research and studies under subsection (c)(1)(C).

(ii) OTHER GIFTS.—Other gifts, grants, or donations received by the Foundation and not described in clause (i) may also be used to support such pediatric research and studies.

(iii) REPORT.—The recipient of a grant for research and studies shall agree to provide the Director of the National Institutes of Health and the Commissioner of Food and Drugs, at the conclusion of the research and studies—

(I) a report describing the results of the research and studies; and

(II) all data generated in connection with the research and studies.

(iv) ACTION BY THE COMMISSIONER OF FOOD AND DRUGS.—The Commissioner of Food and Drugs shall take appropriate action in response to a report received under clause (iii) in accordance with paragraphs (7) through (12) of section 409I(c), including negotiating with the holders of approved applications for the drugs studied for any labeling changes that the Commissioner determines to be appropriate and requests the holders to make.

(C) APPLICABILITY.—Subparagraph (A) does not apply to the program described in subsection (c)(1)(C).

(10) TRANSFER OF FUNDS.—The Foundation may transfer funds to the National Institutes of Health and the National Institutes of Health may accept transfers of funds from the Foundation. Any funds transferred under this paragraph shall be subject to all Federal limitations relating to federally-funded research.

(k) DUTIES OF THE DIRECTOR.—

(1) APPLICABILITY OF CERTAIN STANDARDS TO NON-FEDERAL EMPLOYEES.—In the case of any individual who is not an employee of the Federal Government and who serves in association with the National Institutes of Health, with respect to financial assistance received from the Foundation, the Foundation may not provide the assistance of, or otherwise permit the work at the National Institutes of Health to begin until a memorandum of understanding between the individual and the Director of the National Institutes of Health, or the designee of such Director, has been executed specifying that the individual shall be subject to such ethical and procedural standards of conduct relating to duties performed at the National Institutes of Health, as the Director of the National Institutes of Health determines is appropriate.

(2) SUPPORT SERVICES.—The Director of the National Institutes of Health may provide facilities, utilities and support services to the Foundation if it is determined by the Director to be advantageous to the research programs of the National Institutes of Health.

(l) FUNDING.—From amounts appropriated to the National Institutes of Health, for each fiscal year, the Director of NIH shall transfer not less than $500,000 and not more than $1,250,000 to the Foundation.

December 13, 2013

PUBLIC HEALTH SERVICE ACT

As Amended Through P.L. 112–240, Enacted January 2, 2013

TITLE V—SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION

PART A—ORGANIZATION AND GENERAL AUTHORITIES

SEC. 501.[290aa] SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION.

(a) ESTABLISHMENT.—The Substance Abuse and Mental Health Services Administration (hereafter referred to in this title as the "Administration") is an agency of the Service.

(b) AGENCIES.—The following entities are agencies of the Administration:

(1) The Center for Substance Abuse Treatment.

(2) The Center for Substance Abuse Prevention.

(3) The Center for Mental Health Services.

(c) ADMINISTRATOR AND DEPUTY ADMINISTRATOR.—

(1) ADMINISTRATOR.—The Administration shall be headed by an Administrator (hereinafter in this title referred to as the "Administrator") who shall be appointed by the President, by and with the advice and consent of the Senate.

(2) DEPUTY ADMINISTRATOR.—The Administrator, with the approval of the Secretary, may appoint a Deputy Administrator and may employ and prescribe the functions of such officers and employees, including attorneys, as are necessary to administer the activities to be carried out through the Administration.

(d) AUTHORITIES.—The Secretary, acting through the Administrator, shall—

(1) supervise the functions of the agencies of the Administration in order to assure that the programs carried out through each such agency receive appropriate and equitable support and that there is cooperation among the agencies in the implementation of such programs;

(2) establish and implement, through the respective agencies, a comprehensive program to improve the provision of treatment and related services to individuals with respect to substance abuse and mental illness and to improve prevention services, promote mental health and protect the legal rights of individuals with mental illnesses and individuals who are substance abusers;

(3) carry out the administrative and financial management, policy development and planning, evaluation, knowledge dissemination, and public information functions that are required for the implementation of this title;

(4) assure that the Administration conduct and coordinate demonstration projects, evaluations, and service system assessments and other activities necessary to improve the availability and quality of treatment, prevention and related services;

(5) support activities that will improve the provision of treatment, prevention and related services, including the development of national mental health and substance abuse goals and model programs;

(6) in cooperation with the National Institutes of Health, the Centers for Disease Control and the Health Resources and Services Administration develop educational materials and intervention strategies to reduce the risks of HIV or tuberculosis among substance abusers and individuals with mental illness and to develop appropriate mental health services for individuals with such illnesses;

(7) coordinate Federal policy with respect to the provision of treatment services for substance abuse utilizing anti-addiction medications, including methadone;

(8) conduct programs, and assure the coordination of such programs with activities of the National Institutes of Health and the Agency for Health Care Policy Research[1], as appropriate, to evaluate the process, outcomes and community impact of treatment and prevention services and systems of care in order to identify the manner in which such services can most effectively be provided;

(9) collaborate with the Director of the National Institutes of Health in the development of a system by which the relevant research findings of the National Institute on Drug Abuse, the National Institute on Alcohol Abuse and Alcoholism, the National Institute of Mental Health, and, as appropriate, the Agency for Health Care Policy Research[2] are disseminated to service providers in a manner designed to improve the delivery and effectiveness of treatment and prevention services;

(10) encourage public and private entities that provide health insurance to provide benefits for substance abuse and mental health services;

(11) promote the integration of substance abuse and mental health services into the mainstream of the health care delivery system of the United States;

(12) monitor compliance by hospitals and other facilities with the requirements of sections 542 and 543;

(13) with respect to grant programs authorized under this title, assure that—

(A) all grants that are awarded for the provision of services are subject to performance and outcome evaluations; and

[1] So in law. See section 101(a) of Public Law 102–321 (106 Stat. 324). Probably should have been "Agency for Health Care Policy and Research". The Agency, however, was redesignated as the Agency for Health Care Policy and Research by Public Law 106–129 (see 113 Stat. 1653).

[2] So in law. See section 101(a) of Public Law 102–321 (106 Stat. 324). Probably should be "Administrator".

(B) all grants that are awarded to entities other than States are awarded only after the State in which the entity intends to provide services—

(i) is notified of the pendency of the grant application; and

(ii) is afforded an opportunity to comment on the merits of the application;

(14) assure that services provided with amounts appropriated under this title are provided bilingually, if appropriate;

(15) improve coordination among prevention programs, treatment facilities and nonhealth care systems such as employers, labor unions, and schools, and encourage the adoption of employee assistance programs and student assistance programs;

(16) maintain a clearinghouse for substance abuse and mental health information to assure the widespread dissemination of such information to States, political subdivisions, educational agencies and institutions, treatment providers, and the general public;

(17) in collaboration with the National Institute on Aging, and in consultation with the National Institute on Drug Abuse, the National Institute on Alcohol Abuse and Alcoholism and the National Institute of Mental Health, as appropriate, promote and evaluate substance abuse services for older Americans in need of such services, and mental health services for older Americans who are seriously mentally ill; and

(18) promote the coordination of service programs conducted by other departments, agencies, organizations and individuals that are or may be related to the problems of individuals suffering from mental illness or substance abuse, including liaisons with the Social Security Administration, Centers for Medicare & Medicaid Services, and other programs of the Department, as well as liaisons with the Department of Education, Department of Justice, and other Federal Departments and offices, as appropriate.

(e) ASSOCIATE ADMINISTRATOR FOR ALCOHOL PREVENTION AND TREATMENT POLICY.—

(1) IN GENERAL.—There may be in the Administration an Associate Administrator for Alcohol Prevention and Treatment Policy to whom the Administrator may delegate the functions of promoting, monitoring, and evaluating service programs for the prevention and treatment of alcoholism and alcohol abuse within the Center for Substance Abuse Prevention, the Center for Substance Abuse Treatment and the Center for Mental Health Services, and coordinating such programs among the Centers, and among the Centers and other public and private entities. The Associate Administrator also may ensure that alcohol prevention, education, and policy strategies are integrated into all programs of the Centers that address substance abuse prevention, education, and policy, and that the Center for Substance Abuse Prevention addresses the Healthy People 2010 goals and the National Dietary Guidelines of the Department of Health and Human Services and the Department of Agriculture related to alcohol consumption.

(2) PLAN.—

(A) The Administrator, acting through the Associate Administrator for Alcohol Prevention and Treatment Policy, shall develop, and periodically review and as appropriate revise, a plan for programs and policies to treat and prevent alcoholism and alcohol abuse. The plan shall be developed (and reviewed and revised) in collaboration with the Directors of the Centers of the Administration and in consultation with members of other Federal agencies and public and private entities.

(B) Not later than 1 year after the date of the enactment of the ADAMHA Reorganization Act, the Administrator shall submit to the Congress the first plan developed under subparagraph (A).

(3) REPORT.—

(A) Not less than once during each 2 years, the Administrator, acting through the Associate Administrator for Alcohol Prevention and Treatment Policy, shall prepare a report describing the alcoholism and alcohol abuse prevention and treatment programs undertaken by the Administration and its agencies, and the report shall include a detailed statement of the expenditures made for the activities reported on and the personnel used in connection with such activities.

(B) Each report under subparagraph (A) shall include a description of any revisions in the plan under paragraph (2) made during the preceding 2 years.

(C) Each report under subparagraph (A) shall be submitted to the Administrator for inclusion in the biennial report under subsection (k).

(f) ASSOCIATE ADMINISTRATOR FOR WOMEN'S SERVICES.—

(1) APPOINTMENT.—The Administrator, with the approval of the Secretary, shall appoint an Associate Administrator for Women's Services who shall report directly to the Administrator.

(2) DUTIES.—The Associate Administrator appointed under paragraph (1) shall—

(A) establish a committee to be known as the Coordinating Committee for Women's Services (hereafter in this subparagraph referred to as the "Coordinating Committee"), which shall be composed of the Directors of the agencies of the Administration (or the designees of the Directors);

(B) acting through the Coordinating Committee, with respect to women's substance abuse and mental health services—

(i) identify the need for such services, and make an estimate each fiscal year of the funds needed to adequately support the services;

(ii) identify needs regarding the coordination of services;

(iii) encourage the agencies of the Administration to support such services; and

(iv) assure that the unique needs of minority women, including Native American, Hispanic, African-American and Asian women, are recognized and addressed within the activities of the Administration; and

(C) establish an advisory committee to be known as the Advisory Committee for Women's Services, which shall be composed of not more than 10 individuals, a majority of whom shall be women, who are not officers or employees of the Federal Government, to be appointed by the Administrator from among physicians, practitioners, treatment providers, and other health professionals, whose clinical practice, specialization, or professional expertise includes a significant focus on women's substance abuse and mental health conditions, that shall—

(i) advise the Associate Administrator on appropriate activities to be undertaken by the agencies of the Administration with respect to women's substance abuse and mental health services, including services which require a multidisciplinary approach;

(ii) collect and review data, including information provided by the Secretary (including the material referred to in paragraph (3)), and report biannually to the Administrator regarding the extent to which women are represented among senior personnel, and make recommendations regarding improvement in the participation of women in the workforce of the Administration; and

(iii) prepare, for inclusion in the biennial report required pursuant to subsection (k), a description of activities of the Committee, including findings made by the Committee regarding—

(I) the extent of expenditures made for women's substance abuse and mental health services by the agencies of the Administration; and

(II) the estimated level of funding needed for substance abuse and mental health services to meet the needs of women;

(D) improve the collection of data on women's health by—

(i) reviewing the current data at the Administration to determine its uniformity and applicability;

(ii) developing standards for all programs funded by the Administration so that data are, to the extent practicable, collected and reported using common reporting formats, linkages and definitions; and

(iii) reporting to the Administrator a plan for incorporating the standards developed under clause (ii) in all Administration programs and a plan to assure that the data so collected are accessible to health professionals, providers, researchers, and members of the public; and

(E) shall establish, maintain, and operate a program to provide information on women's substance abuse and mental health services.

(3) STUDY.—

(A) The Secretary, acting through the Assistant Secretary for Personnel, shall conduct a study to evaluate the extent to which women are represented among senior personnel at the Administration.

(B) Not later than 90 days after the date of the enactment of the ADAMHA Reorganization Act, the Assistant Secretary for Personnel shall provide the Advisory Committee for Women's Services with a study plan, including the methodology of the study and any sampling frames. Not later than 180 days after such date of enactment, the Assistant Secretary shall prepare and submit directly to the Advisory Committee a report concerning the results of the study conducted under subparagraph (A).

(C) The Secretary shall prepare and provide to the Advisory Committee for Women's Services any additional data as requested.

(4) OFFICE.—Nothing in this subsection shall be construed to preclude the Secretary from establishing within the Substance Abuse and Mental Health Administration an Office of Women's Health.

(5) DEFINITION.—For purposes of this subsection, the term "women's substance abuse and mental health conditions", with respect to women of all age, ethnic, and racial groups, means all aspects of substance abuse and mental illness—

(A) unique to or more prevalent among women; or

(B) with respect to which there have been insufficient services involving women or insufficient data.

(g) SERVICES OF EXPERTS.—

(1) IN GENERAL.—The Administrator may obtain (in accordance with section 3109 of title 5, United States Code, but without regard to the limitation in such section on the number of days or the period of service) the services of not more than 20 experts or consultants who have professional qualifications. Such experts and consultants shall be obtained for the Administration and for each of its agencies.

(2) COMPENSATION AND EXPENSES.—

(A) Experts and consultants whose services are obtained under paragraph (1) shall be paid or reimbursed for their expenses associated with traveling to and from their assignment location in accordance with sections 5724, 5724a(a), 5724a(c), and 5726(c) of title 5, United States Code.

(B) Expenses specified in subparagraph (A) may not be allowed in connection with the assignment of an expert or consultant whose services are obtained under paragraph (1), unless and until the expert or consultant agrees in writing to complete the entire period of assignment or one year, whichever is shorter, unless separated or reassigned for reasons beyond the control of the expert or consultant that are acceptable to the Secretary. If the expert or con-

sultant violates the agreement, the money spent by the United States for the expenses specified in subparagraph (A) is recoverable from the expert or consultant as a debt of the United States. The Secretary may waive in whole or in part a right of recovery under this subparagraph.

(h) PEER REVIEW GROUPS.—The Administrator shall, without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title, relating to classification and General Schedule pay rates, establish such peer review groups and program advisory committees as are needed to carry out the requirements of this title and appoint and pay members of such groups, except that officers and employees of the United States shall not receive additional compensation for services as members of such groups. The Federal Advisory Committee Act shall not apply to the duration of a peer review group appointed under this subsection.

(i) VOLUNTARY SERVICES.—The Administrator may accept voluntary and uncompensated services.

(j) ADMINISTRATION.—The Administrator shall ensure that programs and activities assigned under this title to the Administration are fully administered by the respective Centers to which such programs and activities are assigned.

(k) REPORT CONCERNING ACTIVITIES AND PROGRESS.—Not later than February 10, 1994, and once every 2 years thereafter, the Administrator shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, the report containing—

(1) a description of the activities carried out by the Administration;

(2) a description of any measurable progress made in improving the availability and quality of substance abuse and mental health services;

(3) a description of the mechanisms by which relevant research findings of the National Institute on Drug Abuse, the National Institute on Alcohol Abuse and Alcoholism, and the National Institute of Mental Health have been disseminated to service providers or otherwise utilized by the Administration to further the purposes of this title; and

(4) any report required in this title to be submitted to the Adminstrator for inclusion in the report under this subsection.

(l) APPLICATIONS FOR GRANTS AND CONTRACTS.—With respect to awards of grants, cooperative agreements, and contracts under this title, the Administrator, or the Director of the Center involved, as the case may be, may not make such an award unless—

(1) an application for the award is submitted to the official involved;

(2) with respect to carrying out the purpose for which the award is to be provided, the application provides assurances of compliance satisfactory to such official; and

(3) the application is otherwise in such form, is made in such manner, and contains such agreements, assurances, and

information as the official determines to be necessary to carry out the purpose for which the award is to be provided.

(m) EMERGENCY RESPONSE.—

(1) IN GENERAL.—Notwithstanding section 504 and except as provided in paragraph (2), the Secretary may use not to exceed 2.5 percent of all amounts appropriated under this title for a fiscal year to make noncompetitive grants, contracts or cooperative agreements to public entities to enable such entities to address emergency substance abuse or mental health needs in local communities.

(2) EXCEPTIONS.—Amounts appropriated under part C shall not be subject to paragraph (1).

(3) EMERGENCIES.—The Secretary shall establish criteria for determining that a substance abuse or mental health emergency exists and publish such criteria in the Federal Register prior to providing funds under this subsection.

(n) LIMITATION ON THE USE OF CERTAIN INFORMATION.—No information, if an establishment or person supplying the information or described in it is identifiable, obtained in the course of activities undertaken or supported under section 505 may be used for any purpose other than the purpose for which it was supplied unless such establishment or person has consented (as determined under regulations of the Secretary) to its use for such other purpose. Such information may not be published or released in other form if the person who supplied the information or who is described in it is identifiable unless such person has consented (as determined under regulations of the Secretary) to its publication or release in other form.

(o) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of providing grants, cooperative agreements, and contracts under this section, there are authorized to be appropriated $25,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 and 2003.

ADVISORY COUNCILS.

SEC. 502.[290aa–1] (a) APPOINTMENT.—

(1) IN GENERAL.—The Secretary shall appoint an advisory council for—

(A) the Substance Abuse and Mental Health Services Administration;

(B) the Center for Substance Abuse Treatment;

(C) the Center for Substance Abuse Prevention; and

(D) the Center for Mental Health Services.

Each such advisory council shall advise, consult with, and make recommendations to the Secretary and the Administrator or Director of the Administration or Center for which the advisory council is established concerning matters relating to the activities carried out by and through the Administration or Center and the policies respecting such activities.

(2) FUNCTION AND ACTIVITIES.—An advisory council—

(A)(i) may on the basis of the materials provided by the organization respecting activities conducted at the organization, make recommendations to the Administrator or

Director of the Administration or Center for which it was established respecting such activities;

(ii) shall review applications submitted for grants and cooperative agreements for activities for which advisory council approval is required under section 504(d)(2) and recommend for approval applications for projects that show promise of making valuable contributions to the Administration's mission; and

(iii) may review any grant, contract, or cooperative agreement proposed to be made or entered into by the organization;

(B) may collect, by correspondence or by personal investigation, information as to studies and services that are being carried on in the United States or any other country as to the diseases, disorders, or other aspects of human health with respect to which the organization was established and with the approval of the Administrator or Director, whichever is appropriate, make such information available through appropriate publications for the benefit of public and private health entities and health professions personnel and for the information of the general public; and

(C) may appoint subcommittees and convene workshops and conferences.

(b) MEMBERSHIP.—

(1) IN GENERAL.—Each advisory council shall consist of nonvoting ex officio members and not more than 12 members to be appointed by the Secretary under paragraph (3).

(2) EX OFFICIO MEMBERS.—The ex officio members of an advisory council shall consist of—

(A) the Secretary;

(B) the Administrator;

(C) the Director of the Center for which the council is established;

(D) the Under Secretary for Health of the Department of Veterans Affairs;

(E) the Assistant Secretary for Defense for Health Affairs (or the designates of such officers); and

(F) such additional officers or employees of the United States as the Secretary determines necessary for the advisory council to effectively carry out its functions.

(3) APPOINTED MEMBERS.—Individuals shall be appointed to an advisory council under paragraph (1) as follows:

(A) Nine of the members shall be appointed by the Secretary from among the leading representatives of the health disciplines (including public health and behavioral and social sciences) relevant to the activities of the Administration or Center for which the advisory council is established.

(B) Three of the members shall be appointed by the Secretary from the general public and shall include leaders in fields of public policy, public relations, law, health policy economics, or management.

(4) COMPENSATION.—Members of an advisory council who are officers or employees of the United States shall not receive any compensation for service on the advisory council. The remaining members of an advisory council shall receive, for each day (including travel time) they are engaged in the performance of the functions of the advisory council, compensation at rates not to exceed the daily equivalent to the annual rate in effect for grade GS–18 of the General Schedule.

(c) TERMS OF OFFICE.—

(1) IN GENERAL.—The term of office of a member of an advisory council appointed under subsection (b) shall be 4 years, except that any member appointed to fill a vacancy for an unexpired term shall serve for the remainder of such term. The Secretary shall make appointments to an advisory council in such a manner as to ensure that the terms of the members not all expire in the same year. A member of an advisory council may serve after the expiration of such member's term until a successor has been appointed and taken office.

(2) REAPPOINTMENTS.—A member who has been appointed to an advisory council for a term of 4 years may not be reappointed to an advisory council during the 2-year period beginning on the date on which such 4-year term expired.

(3) TIME FOR APPOINTMENT.—If a vacancy occurs in an advisory council among the members under subsection (b), the Secretary shall make an appointment to fill such vacancy within 90 days from the date the vacancy occurs.

(d) CHAIR.—The Secretary shall select a member of an advisory council to serve as the chair of the council. The Secretary may so select an individual from among the appointed members, or may select the Administrator or the Director of the Center involved. The term of office of the chair shall be 2 years.

(e) MEETINGS.—An advisory council shall meet at the call of the chairperson or upon the request of the Administrator or Director of the Administration or Center for which the advisory council is established, but in no event less than 2 times during each fiscal year. The location of the meetings of each advisory council shall be subject to the approval of the Administrator or Director of Administration or Center for which the council was established.

(f) EXECUTIVE SECRETARY AND STAFF.—The Administrator or Director of the Administration or Center for which the advisory council is established shall designate a member of the staff of the Administration or Center for which the advisory council is established to serve as the Executive Secretary of the advisory council. The Administrator or Director shall make available to the advisory council such staff, information, and other assistance as it may require to carry out its functions. The Administrator or Director shall provide orientation and training for new members of the advisory council to provide for their effective participation in the functions of the advisory council.

REPORTS ON ALCOHOLISM, ALCOHOL ABUSE, AND DRUG ABUSE.

SEC. 503.[290aa–2] (a) The Secretary shall submit to Congress on or before January 15, 1984, and every three years thereafter a report—

(1) containing current information on the health consequences of using alcoholic beverages,

(2) containing a description of current research findings made with respect to alcohol abuse and alcoholism, and

(3) containing such recommendations for legislation and administrative action as the Secretary may deem appropriate.

(b) The Secretary shall submit to Congress on or before January 15, 1984, and every three years thereafter a report—

(1) describing the health consequences and extent of drug abuse in the United States;

(2) describing current research findings made with respect to drug abuse, including current findings on the health effects of marihuana and the addictive property of tobacco; and

(3) containing such recommendations for legislation and administrative action as the Secretary may deem appropriate.

SEC. 503A.[290aa–2a] REPORT ON INDIVIDUALS WITH CO-OCCURRING MENTAL ILLNESS AND SUBSTANCE ABUSE DISORDERS.

(a) IN GENERAL.—Not later than 2 years after the date of the enactment of this section, the Secretary shall, after consultation with organizations representing States, mental health and substance abuse treatment providers, prevention specialists, individuals receiving treatment services, and family members of such individuals, prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Commerce of the House of Representatives, a report on prevention and treatment services for individuals who have co-occurring mental illness and substance abuse disorders.

(b) REPORT CONTENT.—The report under subsection (a) shall be based on data collected from existing Federal and State surveys regarding the treatment of co-occurring mental illness and substance abuse disorders and shall include—

(1) a summary of the manner in which individuals with co-occurring disorders are receiving treatment, including the most up-to-date information available regarding the number of children and adults with co-occurring mental illness and substance abuse disorders and the manner in which funds provided under sections 1911 and 1921 are being utilized, including the number of such children and adults served with such funds;

(2) a summary of improvements necessary to ensure that individuals with co-occurring mental illness and substance abuse disorders receive the services they need;

(3) a summary of practices for preventing substance abuse among individuals who have a mental illness and are at risk of having or acquiring a substance abuse disorder; and

(4) a summary of evidenced-based practices for treating individuals with co-occurring mental illness and substance abuse disorders and recommendations for implementing such practices.

(c) FUNDS FOR REPORT.—The Secretary may obligate funds to carry out this section with such appropriations as are available.

SEC. 504.[3][290aa–3] PEER REVIEW.

(a) IN GENERAL.—The Secretary, after consultation with the Administrator, shall require appropriate peer review of grants, cooperative agreements, and contracts to be administered through the agency which exceed the simple acquisition threshold as defined in section 4(11) of the Office of Federal Procurement Policy Act.

(b) MEMBERS.—The members of any peer review group established under subsection (a) shall be individuals who by virtue of their training or experience are eminently qualified to perform the review functions of the group. Not more than one-fourth of the members of any such peer review group shall be officers or employees of the United States.

(c) ADVISORY COUNCIL REVIEW.—If the direct cost of a grant or cooperative agreement (described in subsection (a)) exceeds the simple acquisition threshold as defined by section 4(11) of the Office of Federal Procurement Policy Act, the Secretary may make such a grant or cooperative agreement only if such grant or cooperative agreement is recommended—

(1) after peer review required under subsection (a); and

(2) by the appropriate advisory council.

(d) CONDITIONS.—The Secretary may establish limited exceptions to the limitations contained in this section regarding participation of Federal employees and advisory council approval. The circumstances under which the Secretary may make such an exception shall be made public.

DATA COLLECTION[4].

SEC. 505.[290aa–4] (a) The Secretary, acting through the Administrator, shall collect data each year on—

(1) the national incidence and prevalence of the various forms of mental illness and substance abuse; and

(2) the incidence and prevalence of such various forms in major metropolitan areas selected by the Administrator.

(b) With respect to the activities of the Administrator under subsection (a) relating to mental health, the Administrator shall ensure that such activities include, at a minimum, the collection of data on—

(1) the number and variety of public and nonprofit private treatment programs;

(2) the number and demographic characteristics of individuals receiving treatment through such programs;

(3) the type of care received by such individuals; and

[3] Section 504 appears according to the probable intent of the Congress. Section 3401(b) of Public Law 106–310 (114 Stat. 1218) provides that the section "is amended as follows:". No amendatory instructions were then given, but a substitute text was provided. The amendment probably should have instructed that section 504 "is amended to read as follows:".

[4] Section 502 of Public Law 104–237 (110 Stat. 3112) provides as follows:

"The Secretary of Health and Human Services shall develop a public health monitoring program to monitor methamphetamine abuse in the United States. The program shall include the collection and dissemination of data related to methamphetamine abuse which can be used by public health officials in policy development.".

(4) such other data as may be appropriate.

(c)(1) With respect to the activities of the Administrator under subsection (a) relating to substance abuse, the Administrator shall ensure that such activities include, at a minimum, the collection of data on—

(A) the number of individuals admitted to the emergency rooms of hospitals as a result of the abuse of alcohol or other drugs;

(B) the number of deaths occurring as a result of substance abuse, as indicated in reports by coroners;

(C) the number and variety of public and private nonprofit treatment programs, including the number and type of patient slots available;

(D) the number of individuals seeking treatment through such programs, the number and demographic characteristics of individuals receiving such treatment, the percentage of individuals who complete such programs, and, with respect to individuals receiving such treatment, the length of time between an individual's request for treatment and the commencement of treatment;

(E) the number of such individuals who return for treatment after the completion of a prior treatment in such programs and the method of treatment utilized during the prior treatment;

(F) the number of individuals receiving public assistance for such treatment programs;

(G) the costs of the different types of treatment modalities for drug and alcohol abuse and the aggregate relative costs of each such treatment modality provided within a State in each fiscal year;

(H) to the extent of available information, the number of individuals receiving treatment for alcohol or drug abuse who have private insurance coverage for the costs of such treatment;

(I) the extent of alcohol and drug abuse among high school students and among the general population; and

(J) the number of alcohol and drug abuse counselors and other substance abuse treatment personnel employed in public and private treatment facilities.

(2) Annual surveys shall be carried out in the collection of data under this subsection. Summaries and analyses of the data collected shall be made available to the public.

(d) After consultation with the States and with appropriate national organizations, the Administrator shall develop uniform criteria for the collection of data, using the best available technology, pursuant to this section.

SEC. 506.[290aa–5] GRANTS FOR THE BENEFIT OF HOMELESS INDIVIDUALS.

(a) IN GENERAL.—The Secretary shall award grants, contracts and cooperative agreements to community-based public and private nonprofit entities for the purposes of providing mental health and substance abuse services for homeless individuals. In carrying out this section, the Secretary shall consult with the Interagency Coun-

cil on the Homeless, established under section 201 of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11311).

(b) PREFERENCES.—In awarding grants, contracts, and cooperative agreements under subsection (a), the Secretary shall give a preference to—

(1) entities that provide integrated primary health, substance abuse, and mental health services to homeless individuals;

(2) entities that demonstrate effectiveness in serving runaway, homeless, and street youth;

(3) entities that have experience in providing substance abuse and mental health services to homeless individuals;

(4) entities that demonstrate experience in providing housing for individuals in treatment for or in recovery from mental illness or substance abuse; and

(5) entities that demonstrate effectiveness in serving homeless veterans.

(c) SERVICES FOR CERTAIN INDIVIDUALS.—In awarding grants, contracts, and cooperative agreements under subsection (a), the Secretary shall not—

(1) prohibit the provision of services under such subsection to homeless individuals who are suffering from a substance abuse disorder and are not suffering from a mental health disorder; and

(2) make payments under subsection (a) to any entity that has a policy of—

(A) excluding individuals from mental health services due to the existence or suspicion of substance abuse; or

(B) has a policy of excluding individuals from substance abuse services due to the existence or suspicion of mental illness.

(d) TERM OF THE AWARDS.—No entity may receive a grant, contract, or cooperative agreement under subsection (a) for more than 5 years.

(e) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $50,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 and 2003.

SEC. 506A.[290aa–5a] ALCOHOL AND DRUG PREVENTION OR TREATMENT SERVICES FOR INDIANS AND NATIVE ALASKANS.[5].

(a) IN GENERAL.—The Secretary shall award grants, contracts, or cooperative agreements to public and private nonprofit entities, including Native Alaskan entities and Indian tribes and tribal organizations, for the purpose of providing alcohol and drug prevention or treatment services for Indians and Native Alaskans.

(b) PRIORITY.—In awarding grants, contracts, or cooperative agreements under subsection (a), the Secretary shall give priority to applicants that—

(1) propose to provide alcohol and drug prevention or treatment services on reservations;

[5] Section 3307 of Public Law 106–310 (114 Stat. 1216) establishes a Commission on Indian and Native Alaskan Health Care and provides that the Commission "shall examine the health concerns of Indians and Native Alaskans who reside on reservations and tribal lands".

(2) propose to employ culturally-appropriate approaches, as determined by the Secretary, in providing such services; and

(3) have provided prevention or treatment services to Native Alaskan entities and Indian tribes and tribal organizations for at least 1 year prior to applying for a grant under this section.

(c) DURATION.—The Secretary shall award grants, contracts, or cooperative agreements under subsection (a) for a period not to exceed 5 years.

(d) APPLICATION.—An entity desiring a grant, contract, or cooperative agreement under subsection (a) shall submit an application to the Secretary at such time, in such manner, and accompanied by such information as the Secretary may reasonably require.

(e) EVALUATION.—An entity that receives a grant, contract, or cooperative agreement under subsection (a) shall submit, in the application for such grant, a plan for the evaluation of any project undertaken with funds provided under this section. Such entity shall provide the Secretary with periodic evaluations of the progress of such project and such evaluation at the completion of such project as the Secretary determines to be appropriate. The final evaluation submitted by such entity shall include a recommendation as to whether such project shall continue.

(f) REPORT.—Not later than 3 years after the date of the enactment of this section and annually thereafter, the Secretary shall prepare and submit, to the Committee on Health, Education, Labor, and Pensions of the Senate, a report describing the services provided pursuant to this section.

(g) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, $15,000,000 for fiscal year 2001, and such sums as may be necessary for fiscal years 2002 and 2003.

SEC. 506B.[290aa–5b] GRANTS FOR ECSTASY AND OTHER CLUB DRUGS ABUSE PREVENTION.

(a) AUTHORITY.—The Administrator may make grants to, and enter into contracts and cooperative agreements with, public and nonprofit private entities to enable such entities—

(1) to carry out school-based programs concerning the dangers of the abuse of and addiction to 3,4-methylenedioxy methamphetamine, related drugs, and other drugs commonly referred to as "club drugs" using methods that are effective and science-based, including initiatives that give students the responsibility to create their own anti-drug abuse education programs for their schools; and

(2) to carry out community-based abuse and addiction prevention programs relating to 3,4-methylenedioxy methamphetamine, related drugs, and other club drugs that are effective and science-based.

(b) USE OF FUNDS.—Amounts made available under a grant, contract or cooperative agreement under subsection (a) shall be used for planning, establishing, or administering prevention programs relating to 3,4-methylenedioxy methamphetamine, related drugs, and other club drugs.

(c) USE OF FUNDS.—

(1) DISCRETIONARY FUNCTIONS.—Amounts provided to an entity under this section may be used—

(A) to carry out school-based programs that are focused on those districts with high or increasing rates of abuse and addiction to 3,4-methylenedioxy methamphetamine, related drugs, and other club drugs and targeted at populations that are most at risk to start abusing these drugs;

(B) to carry out community-based prevention programs that are focused on those populations within the community that are most at-risk for abuse of and addiction to 3,4-methylenedioxy methamphetamine, related drugs, and other club drugs;

(C) to assist local government entities to conduct appropriate prevention activities relating to 3,4-methylenedioxy methamphetamine, related drugs, and other club drugs;

(D) to train and educate State and local law enforcement officials, prevention and education officials, health professionals, members of community anti-drug coalitions and parents on the signs of abuse of and addiction to 3,4-methylenedioxy methamphetamine, related drugs, and other club drugs and the options for treatment and prevention;

(E) for planning, administration, and educational activities related to the prevention of abuse of and addiction to 3,4-methylenedioxy methamphetamine, related drugs, and other club drugs;

(F) for the monitoring and evaluation of prevention activities relating to 3,4-methylenedioxy methamphetamine, related drugs, and other club drugs and reporting and disseminating resulting information to the public; and

(G) for targeted pilot programs with evaluation components to encourage innovation and experimentation with new methodologies.

(2) PRIORITY.—The Administrator shall give priority in awarding grants under this section to rural and urban areas that are experiencing a high rate or rapid increases in abuse and addiction to 3,4-methylenedioxy methamphetamine, related drugs, and other club drugs.

(d) ALLOCATION AND REPORT.—

(1) PREVENTION PROGRAM ALLOCATION.—Not less than $500,000 of the amount appropriated in each fiscal year to carry out this section shall be made available to the Administrator, acting in consultation with other Federal agencies, to support and conduct periodic analyses and evaluations of effective prevention programs for abuse of and addiction to 3,4-methylenedioxy methamphetamine, related drugs, and other club drugs and the development of appropriate strategies for disseminating information about and implementing such programs.

(2) REPORT.—The Administrator shall annually prepare and submit to the Committee on Health, Education, Labor, and Pensions, the Committee on the Judiciary, and the Committee

on Appropriations of the Senate, and the Committee on Commerce, the Committee on the Judiciary, and the Committee on Appropriations of the House of Representatives, a report containing the results of the analyses and evaluations conducted under paragraph (1).

(e) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section—

(1) $10,000,000 for fiscal year 2001; and

(2) such sums as may be necessary for each succeeding fiscal year.

PART B—CENTERS AND PROGRAMS

Subpart 1—Center for Substance Abuse Treatment

CENTER FOR SUBSTANCE ABUSE TREATMENT[6].

SEC. 507.[290bb] (a) ESTABLISHMENT.—There is established in the Administration a Center for Substance Abuse Treatment (hereafter in this section referred to as the "Center"). The Center shall be headed by a Director (hereafter in this section referred to as the "Director") appointed by the Secretary from among individuals with extensive experience or academic qualifications in the treatment of substance abuse or in the evaluation of substance abuse treatment systems.

(b) DUTIES.—The Director of the Center shall—

(1) administer the substance abuse treatment block grant program authorized in section 1921;

(2) ensure that emphasis is placed on children and adolescents in the development of treatment programs;

(3) collaborate with the Attorney General to develop programs to provide substance abuse treatment services to individuals who have had contact with the Justice system, especially adolescents;

(4) collaborate with the Director of the Center for Substance Abuse Prevention in order to provide outreach services to identify individuals in need of treatment services, with emphasis on the provision of such services to pregnant and postpartum women and their infants and to individuals who abuse drugs intravenously;

(5) collaborate with the Director of the National Institute on Drug Abuse, with the Director of the National Institute on Alcohol Abuse and Alcoholism, and with the States to promote the study, dissemination, and implementation of research findings that will improve the delivery and effectiveness of treatment services;

(6) collaborate with the Administrator of the Health Resources and Services Administration and the Administrator of the Centers for Medicare & Medicaid Services to promote the

[6] Section 4 of Public Law 108–358 (118 Stat. 1664) authorizes the Secretary of Health and Human Services to "award grants to public and nonprofit private entities to enable such entities to carry out science-based education programs in elementary and secondary schools to highlight the harmful effects of anabolic steroids". Subsection (d) of such section provides that there is authorized to be appropriated to carry out the section $15,000,000 for each of the fiscal years 2005 through 2010.

increased integration into the mainstream of the health care system of the United States of programs for providing treatment services;

(7) evaluate plans submitted by the States pursuant to section 1932(a)(6) in order to determine whether the plans adequately provide for the availability, allocation, and effectiveness of treatment services;

(8) sponsor regional workshops on improving the quality and availability of treatment services;

(9) provide technical assistance to public and nonprofit private entities that provide treatment services, including technical assistance with respect to the process of submitting to the Director applications for any program of grants or contracts carried out by the Director;

(10) encourage the States to expand the availability (relative to fiscal year 1992) of programs providing treatment services through self-run, self-supported recovery based on the programs of housing operated pursuant to section 1925;

(11) carry out activities to educate individuals on the need for establishing treatment facilities within their communities;

(12) encourage public and private entities that provide health insurance to provide benefits for outpatient treatment services and other nonhospital-based treatment services;

(13) evaluate treatment programs to determine the quality and appropriateness of various forms of treatment, which shall be carried out through grants, contracts, or cooperative agreements provided to public or nonprofit private entities; and

(14) in carrying out paragraph (13), assess the quality, appropriateness, and costs of various treatment forms for specific patient groups.

(c) GRANTS AND CONTRACTS.—In carrying out the duties established in subsection (b), the Director may make grants to and enter into contracts and cooperative agreements with public and nonprofit private entities.

RESIDENTIAL TREATMENT PROGRAMS FOR PREGNANT AND POSTPARTUM WOMEN.

SEC. 508.[290bb–1] (a) IN GENERAL.—The Director of the Center for Substance Abuse Treatment shall provide awards of grants, cooperative agreement, or contracts to public and nonprofit private entities for the purpose of providing to pregnant and postpartum women treatment for substance abuse through programs in which, during the course of receiving treatment—

(1) the women reside in facilities provided by the programs;

(2) the minor children of the women reside with the women in such facilities, if the women so request; and

(3) the services described in subsection (d) are available to or on behalf of the women.

(b) AVAILABILITY OF SERVICES FOR EACH PARTICIPANT.—A funding agreement for an award under subsection (a) for an applicant is that, in the program operated pursuant to such subsection—

(1) treatment services and each supplemental service will be available through the applicant, either directly or through agreements with other public or nonprofit private entities; and

(2) the services will be made available to each woman admitted to the program.

(c) INDIVIDUALIZED PLAN OF SERVICES.—A funding agreement for an award under subsection (a) for an applicant is that—

(1) in providing authorized services for an eligible woman pursuant to such subsection, the applicant will, in consultation with the women, prepare an individualized plan for the provision to the woman of the services; and

(2) treatment services under the plan will include—

(A) individual, group, and family counseling, as appropriate, regarding substance abuse; and

(B) follow-up services to assist the woman in preventing a relapse into such abuse.

(d) REQUIRED SUPPLEMENTAL SERVICES.—In the case of an eligible woman, the services referred to in subsection (a)(3) are as follows:

(1) Prenatal and postpartum health care.

(2) Referrals for necessary hospital services.

(3) For the infants and children of the woman—

(A) pediatric health care, including treatment for any perinatal effects of maternal substance abuse and including screenings regarding the physical and mental development of the infants and children;

(B) counseling and other mental health services, in the case of children; and

(C) comprehensive social services.

(4) Providing supervision of children during periods in which the woman is engaged in therapy or in other necessary health or rehabilitative activities.

(5) Training in parenting.

(6) Counseling on the human immunodeficiency virus and on acquired immune deficiency syndrome.

(7) Counseling on domestic violence and sexual abuse.

(8) Counseling on obtaining employment, including the importance of graduating from a secondary school.

(9) Reasonable efforts to preserve and support the family units of the women, including promoting the appropriate involvement of parents and others, and counseling the children of the women.

(10) Planning for and counseling to assist reentry into society, both before and after discharge, including referrals to any public or nonprofit private entities in the community involved that provide services appropriate for the women and the children of the women.

(11) Case management services, including—

(A) assessing the extent to which authorized services are appropriate for the women and their children;

(B) in the case of the services that are appropriate, ensuring that the services are provided in a coordinated manner; and

(C) assistance in establishing eligibility for assistance under Federal, State, and local programs providing health services, mental health services, housing services, employment services, educational services, or social services.

(e) MINIMUM QUALIFICATIONS FOR RECEIPT OF AWARD.—

(1) CERTIFICATION BY RELEVANT STATE AGENCY.—With respect to the principal agency of the State involved that administers programs relating to substance abuse, the Director may make an award under subsection (a) to an applicant only if the agency has certified to the Director that—

(A) the applicant has the capacity to carry out a program described in subsection (a);

(B) the plans of the applicant for such a program are consistent with the policies of such agency regarding the treatment of substance abuse; and

(C) the applicant, or any entity through which the applicant will provide authorized services, meets all applicable State licensure or certification requirements regarding the provision of the services involved.

(2) STATUS AS MEDICAID PROVIDER.—

(A) Subject to subparagraphs (B) and (C), the Director may make an award under subsection (a) only if, in the case of any authorized service that is available pursuant to the State plan approved under title XIX of the Social Security Act for the State involved—

(i) the applicant for the award will provide the service directly, and the applicant has entered into a participation agreement under the State plan and is qualified to receive payments under such plan; or

(ii) the applicant will enter into an agreement with a public or nonprofit private entity under which the entity will provide the service, and the entity has entered into such a participation agreement plan and is qualified to receive such payments.

(B)(i) In the case of an entity making an agreement pursuant to subparagraph (A)(ii) regarding the provision of services, the requirement established in such subparagraph regarding a participation agreement shall be waived by the Director if the entity does not, in providing health care services, impose a charge or accept reimbursement available from any third-party payor, including reimbursement under any insurance policy or under any Federal or State health benefits plan.

(ii) A determination by the Director of whether an entity referred to in clause (i) meets the criteria for a waiver under such clause shall be made without regard to whether the entity accepts voluntary donations regarding the provision of services to the public.

(C) With respect to any authorized service that is available pursuant to the State plan described in subparagraph (A), the requirements established in such subparagraph shall not apply to the provision of any such service by an institution for mental diseases to an individual who has attained 21 years of age and who has not attained 65

years of age. For purposes of the preceding sentence, the term "institution for mental diseases" has the meaning given such term in section 1905(i) of the Social Security Act.

(f) REQUIREMENT OF MATCHING FUNDS.—

(1) IN GENERAL.—With respect to the costs of the program to be carried out by an applicant pursuant to subsection (a), a funding agreement for an award under such subsection is that the applicant will make available (directly or through donations from public or private entities) non-Federal contributions toward such costs in an amount that—

(A) for the first fiscal year for which the applicant receives payments under an award under such subsection, is not less than $1 for each $9 of Federal funds provided in the award;

(B) for any second such fiscal year, is not less than $1 for each $9 of Federal funds provided in the award; and

(C) for any subsequent such fiscal year, is not less than $1 for each $3 of Federal funds provided in the award.

(2) DETERMINATION OF AMOUNT CONTRIBUTED.—Non-Federal contributions required in paragraph (1) may be in cash or in kind, fairly evaluated, including plant, equipment, or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

(g) OUTREACH.—A funding agreement for an award under subsection (a) for an applicant is that the applicant will provide outreach services in the community involved to identify women who are engaging in substance abuse and to encourage the women to undergo treatment for such abuse.

(h) ACCESSIBILITY OF PROGRAM; CULTURAL CONTEXT OF SERVICES.—A funding agreement for an award under subsection (a) for an applicant is that—

(1) the program operated pursuant to such subsection will be operated at a location that is accessible to low-income pregnant and postpartum women; and

(2) authorized services will be provided in the language and the cultural context that is most appropriate.

(i) CONTINUING EDUCATION.—A funding agreement for an award under subsection (a) is that the applicant involved will provide for continuing education in treatment services for the individuals who will provide treatment in the program to be operated by the applicant pursuant to such subsection.

(j) IMPOSITION OF CHARGES.—A funding agreement for an award under subsection (a) for an applicant is that, if a charge is imposed for the provision of authorized services to on[7] behalf of an eligible woman, such charge—

(1) will be made according to a schedule of charges that is made available to the public;

[7] So in law. See section 108(a) of Public Law 102–321 (106 Stat. 336). Probably should be "to or on".

(2) will be adjusted to reflect the income of the woman involved; and

(3) will not be imposed on any such woman with an income of less than 185 percent of the official poverty line, as established by the Director of the Office for Management and Budget and revised by the Secretary in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1981.

(k) REPORTS TO DIRECTOR.—A funding agreement for an award under subsection (a) is that the applicant involved will submit to the Director a report—

(1) describing the utilization and costs of services provided under the award;

(2) specifying the number of women served, the number of infants served, and the type and costs of services provided; and

(3) providing such other information as the Director determines to be appropriate.

(l) REQUIREMENT OF APPLICATION.—The Director may make an award under subsection (a) only if an application for the award is submitted to the Director containing such agreements, and the application is in such form, is made in such manner, and contains such other agreements and such assurances and information as the Director determines to be necessary to carry out this section.

(m) EQUITABLE ALLOCATION OF AWARDS.—In making awards under subsection (a), the Director shall ensure that the awards are equitably allocated among the principal geographic regions of the United States, subject to the availability of qualified applicants for the awards.

(n) DURATION OF AWARD.—The period during which payments are made to an entity from an award under subsection (a) may not exceed 5 years. The provision of such payments shall be subject to annual approval by the Director of the payments and subject to the availability of appropriations for the fiscal year involved to make the payments. This subsection may not be construed to establish a limitation on the number of awards under such subsection that may be made to an entity.

(o) EVALUATIONS; DISSEMINATION OF FINDINGS.—The Director shall, directly or through contract, provide for the conduct of evaluations of programs carried out pursuant to subsection (a). The Director shall disseminate to the States the findings made as a result of the evaluations.

(p) REPORTS TO CONGRESS.—Not later than October 1, 1994, the Director shall submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report describing programs carried out pursuant to this section. Every 2 years thereafter, the Director shall prepare a report describing such programs carried out during the preceding 2 years, and shall submit the report to the Administrator for inclusion in the biennial report under section 501(k). Each report under this subsection shall include a summary of any evaluations conducted under subsection (m) during the period with respect to which the report is prepared.

(q) DEFINITIONS.—For purposes of this section:

(1) The term "authorized services" means treatment services and supplemental services.

(2) The term "eligible woman" means a woman who has been admitted to a program operated pursuant to subsection (a).

(3) The term "funding agreement under subsection (a)", with respect to an award under subsection (a), means that the Director may make the award only if the applicant makes the agreement involved.

(4) The term "treatment services" means treatment for substance abuse, including the counseling and services described in subsection (c)(2).

(5) The term "supplemental services" means the services described in subsection (d).

(r) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary to[8] fiscal years 2001 through 2003.

SEC. 509.[290bb–2] PRIORITY SUBSTANCE ABUSE TREATMENT NEEDS OF REGIONAL AND NATIONAL SIGNIFICANCE.

(a) PROJECTS.—The Secretary shall address priority substance abuse treatment needs of regional and national significance (as determined under subsection (b)) through the provision of or through assistance for—

(1) knowledge development and application projects for treatment and rehabilitation and the conduct or support of evaluations of such projects;

(2) training and technical assistance; and

(3) targeted capacity response programs.

The Secretary may carry out the activities described in this section directly or through grants or cooperative agreements with States, political subdivisions of States, Indian tribes and tribal organizations, other public or nonprofit private entities.

(b) PRIORITY SUBSTANCE ABUSE TREATMENT NEEDS.—

(1) IN GENERAL.—Priority substance abuse treatment needs of regional and national significance shall be determined by the Secretary after consultation with States and other interested groups. The Secretary shall meet with the States and interested groups on an annual basis to discuss program priorities.

(2) SPECIAL CONSIDERATION.—In developing program priorities under paragraph (1), the Secretary shall give special consideration to promoting the integration of substance abuse treatment services into primary health care systems.

(c) REQUIREMENTS.—

(1) IN GENERAL.—Recipients of grants, contracts, or cooperative agreements under this section shall comply with information and application requirements determined appropriate by the Secretary.

(2) DURATION OF AWARD.—With respect to a grant, contract, or cooperative agreement awarded under this section, the period during which payments under such award are made to the recipient may not exceed 5 years.

[8] So in law. Probably should be "for". See section 3301(a) of Public Law 106–310 (114 Stat. 1207).

(3) MATCHING FUNDS.—The Secretary may, for projects carried out under subsection (a), require that entities that apply for grants, contracts, or cooperative agreements under that project provide non-Federal matching funds, as determined appropriate by the Secretary, to ensure the institutional commitment of the entity to the projects funded under the grant, contract, or cooperative agreement. Such non-Federal matching funds may be provided directly or through donations from public or private entities and may be in cash or in kind, fairly evaluated, including plant, equipment, or services.

(4) MAINTENANCE OF EFFORT.—With respect to activities for which a grant, contract, or cooperative agreement is awarded under this section, the Secretary may require that recipients for specific projects under subsection (a) agree to maintain expenditures of non-Federal amounts for such activities at a level that is not less than the level of such expenditures maintained by the entity for the fiscal year preceding the fiscal year for which the entity receives such a grant, contract, or cooperative agreement.

(d) EVALUATION.—The Secretary shall evaluate each project carried out under subsection (a)(1) and shall disseminate the findings with respect to each such evaluation to appropriate public and private entities.

(e) INFORMATION AND EDUCATION.—The Secretary shall establish comprehensive information and education programs to disseminate and apply the findings of the knowledge development and application, training and technical assistance programs, and targeted capacity response programs under this section to the general public, to health professionals and other interested groups. The Secretary shall make every effort to provide linkages between the findings of supported projects and State agencies responsible for carrying out substance abuse prevention and treatment programs.

(f) AUTHORIZATION OF APPROPRIATION.—There are authorized to be appropriated to carry out this section, $300,000,000 for fiscal year 2001 and such sums as may be necessary for each of the fiscal years 2002 and 2003.

ACTION BY NATIONAL INSTITUTE ON DRUG ABUSE AND STATES CONCERNING MILITARY FACILITIES.

SEC. 513.[9] [290bb–6] (a) CENTER FOR SUBSTANCE ABUSE TREATMENT.—The Director of the Center for Substance Abuse Treatment shall—

(1) coordinate with the agencies represented on the Commission on Alternative Utilization of Military Facilities the utilization of military facilities or parts thereof, as identified by such Commission, established under the National Defense Authorization Act of 1989, that could be utilized or renovated to house nonviolent persons for drug treatment purposes;

(2) notify State agencies responsible for the oversight of drug abuse treatment entities and programs of the availability of space at the installations identified in paragraph (1); and

[9] Sections 510 through 512 were repealed by section 3301(c) of Public Law 106–310 (114 Stat. 1209).

(3) assist State agencies responsible for the oversight of drug abuse treatment entities and programs in developing methods for adapting the installations described in paragraph (1) into residential treatment centers.

(b) STATES.—With regard to military facilities or parts thereof, as identified by the Commission on Alternative Utilization of Military Facilities established under section 3042 of the Comprehensive Alcohol Abuse, Drug Abuse, and Mental Health Amendments Act of 1988, that could be utilized or renovated to house nonviolent persons for drug treatment purposes, State agencies responsible for the oversight of drug abuse treatment entities and programs shall—

(1) establish eligibility criteria for the treatment of individuals at such facilities;

(2) select treatment providers to provide drug abuse treatment at such facilities;

(3) provide assistance to treatment providers selected under paragraph (2) to assist such providers in securing financing to fund the cost of the programs at such facilities; and

(4) establish, regulate, and coordinate with the military official in charge of the facility, work programs for individuals receiving treatment at such facilities.

(c) RESERVATION OF SPACE.—Prior to notifying States of the availability of space at military facilities under subsection (a)(2), the Director may reserve space at such facilities to conduct research or demonstration projects.

SEC. 514.[290bb–7] SUBSTANCE ABUSE TREATMENT SERVICES FOR CHILDREN AND ADOLESCENTS.

(a) IN GENERAL.—The Secretary shall award grants, contracts, or cooperative agreements to public and private nonprofit entities, including Native Alaskan entities and Indian tribes and tribal organizations, for the purpose of providing substance abuse treatment services for children and adolescents.

(b) PRIORITY.—In awarding grants, contracts, or cooperative agreements under subsection (a), the Secretary shall give priority to applicants who propose to—

(1) apply evidenced-based and cost effective methods for the treatment of substance abuse among children and adolescents;

(2) coordinate the provision of treatment services with other social service agencies in the community, including educational, juvenile justice, child welfare, and mental health agencies;

(3) provide a continuum of integrated treatment services, including case management, for children and adolescents with substance abuse disorders and their families;

(4) provide treatment that is gender-specific and culturally appropriate;

(5) involve and work with families of children and adolescents receiving treatment;

(6) provide aftercare services for children and adolescents and their families after completion of substance abuse treatment; and

(7) address the relationship between substance abuse and violence.

(c) DURATION OF GRANTS.—The Secretary shall award grants, contracts, or cooperative agreements under subsection (a) for periods not to exceed 5 fiscal years.

(d) APPLICATION.—An entity desiring a grant, contract, or cooperative agreement under subsection (a) shall submit an application to the Secretary at such time, in such manner, and accompanied by such information as the Secretary may reasonably require.

(e) EVALUATION.—An entity that receives a grant, contract, or cooperative agreement under subsection (a) shall submit, in the application for such grant, contract, or cooperative agreement, a plan for the evaluation of any project undertaken with funds provided under this section. Such entity shall provide the Secretary with periodic evaluations of the progress of such project and such evaluation at the completion of such project as the Secretary determines to be appropriate.

(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, $40,000,000 for fiscal year 2001, and such sums as may be necessary for fiscal years 2002 and 2003.

SEC. 514A.[290bb–8] EARLY INTERVENTION SERVICES FOR CHILDREN AND ADOLESCENTS.

(a) IN GENERAL.—The Secretary shall award grants, contracts, or cooperative agreements to public and private nonprofit entities, including local educational agencies (as defined in section 14101 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 8801)), for the purpose of providing early intervention substance abuse services for children and adolescents.

(b) PRIORITY.—In awarding grants, contracts, or cooperative agreements under subsection (a), the Secretary shall give priority to applicants who demonstrate an ability to—

(1) screen for and assess substance use and abuse by children and adolescents;

(2) make appropriate referrals for children and adolescents who are in need of treatment for substance abuse;

(3) provide early intervention services, including counseling and ancillary services, that are designed to meet the developmental needs of children and adolescents who are at risk for substance abuse; and

(4) develop networks with the educational, juvenile justice, social services, and other agencies and organizations in the State or local community involved that will work to identify children and adolescents who are in need of substance abuse treatment services.

(c) CONDITION.—In awarding grants, contracts, or cooperative agreements under subsection (a), the Secretary shall ensure that such grants, contracts, or cooperative agreements are allocated, subject to the availability of qualified applicants, among the principal geographic regions of the United States, to Indian tribes and tribal organizations, and to urban and rural areas.

(d) DURATION OF GRANTS.—The Secretary shall award grants, contracts, or cooperative agreements under subsection (a) for periods not to exceed 5 fiscal years.

(e) APPLICATION.—An entity desiring a grant, contract, or cooperative agreement under subsection (a) shall submit an application to the Secretary at such time, in such manner, and accompanied by such information as the Secretary may reasonably require.

(f) EVALUATION.—An entity that receives a grant, contract, or cooperative agreement under subsection (a) shall submit, in the application for such grant, contract, or cooperative agreement, a plan for the evaluation of any project undertaken with funds provided under this section. Such entity shall provide the Secretary with periodic evaluations of the progress of such project and such evaluation at the completion of such project as the Secretary determines to be appropriate.

(g) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, $20,000,000 for fiscal year 2001, and such sums as may be necessary for fiscal years 2002 and 2003.

METHAMPHETAMINE AND AMPHETAMINE TREATMENT INITIATIVE.

SEC. 514.[10] **[**290bb–9**]** (a) GRANTS.—

(1) AUTHORITY TO MAKE GRANTS.—The Director of the Center for Substance Abuse Treatment may make grants to States and Indian tribes recognized by the United States that have a high rate, or have had a rapid increase, in methamphetamine or amphetamine abuse or addiction in order to permit such States and Indian tribes to expand activities in connection with the treatment of methamphetamine or amphetamine abuser or addiction in the specific geographical areas of such States or Indian tribes, as the case may be, where there is such a rate or has been such an increase.

(2) RECIPIENTS.—Any grants under paragraph (1) shall be directed to the substance abuse directors of the States, and of the appropriate tribal government authorities of the Indian tribes, selected by the Director to receive such grants.

(3) NATURE OF ACTIVITIES.—Any activities under a grant under paragraph (1) shall be based on reliable scientific evidence of their efficacy in the treatment of methamphetamine or amphetamine abuse or addiction.

(b) GEOGRAPHIC DISTRIBUTION.—The Director shall ensure that grants under subsection (a) are distributed equitably among the various regions of the country and among rural, urban, and suburban areas that are affected by methamphetamine or amphetamine abuse or addiction.

(c) ADDITIONAL ACTIVITIES.—The Director shall—

(1) evaluate the activities supported by grants under subsection (a);

(2) disseminate widely such significant information derived from the evaluation as the Director considers appropriate to assist States, Indian tribes, and private providers of treatment services for methamphetamine or amphetamine abuser or ad-

[10] So in law. There are two sections 514. The first was added at the end of this subpart (subpart 1 of part B) by section 3104(a) of Public Law 106–310 (114 Stat. 1171). That section also added section 514A. Section 3632 of such Public Law (114 Stat. 1236) then added at the end of this subpart section 514 above.

diction in the treatment of methamphetamine or amphetamine abuse or addiction; and

(3) provide States, Indian tribes, and such providers with technical assistance in connection with the provision of such treatment.

(d) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—There are authorized to be appropriated to carry out this section $10,000,000 for fiscal year 2000 and such sums as may be necessary for each of fiscal years 2001 and 2002.

(2) USE OF CERTAIN FUNDS.—Of the funds appropriated to carry out this section in any fiscal year, the lesser of 5 percent of such funds or $1,000,000 shall be available to the Director for purposes of carrying out subsection (c).

Subpart 2—Center for Substance Abuse Prevention

OFFICE FOR SUBSTANCE ABUSE PREVENTION.

SEC. 515.[290bb–21] (a) There is established in the Administration an Office for Substance Abuse Prevention (hereafter referred to in this part as the "Prevention Center"). The Office[11] shall be headed by a Director appointed by the Secretary from individuals with extensive experience or academic qualifications in the prevention of drug or alcohol abuse.

(b) The Director of the Prevention Center shall—

(1) sponsor regional workshops on the prevention of drug and alcohol abuse;

(2) coordinate the findings of research sponsored by agencies of the Service on the prevention of drug and alcohol abuse;

(3) develop effective drug and alcohol abuse prevention literature (including literature on the adverse effects of cocaine free base (known as crack));

(4) in cooperation with the Secretary of Education, assure the widespread dissemination of prevention materials among States, political subdivisions, and school systems;

(5) support clinical training programs for substance abuse counselors and other health professionals involved in drug abuse education, prevention,;[12]

(6) in cooperation with the Director of the Centers for Disease Control[13], develop educational materials to reduce the risks of acquired immune deficiency syndrome among intravenous drug abusers;

(7) conduct training, technical assistance, data collection, and evaluation activities of programs supported under the Drug Free Schools and Communities Act of 1986;

(8) support the development of model, innovative, community-based programs to discourage alcohol and drug abuse among young people;

[11] So in law. See subsections (a), (d), and (e) of section 113 of Public Law 102–321 (106 Stat. 345). Probably should be "Prevention Center".

[12] So in law. See section 113(c)(1) of Public Law 102-321 (106 Stat. 345).

[13] So in law. See section 113(b) of Public Law 102–321 (106 Stat. 345). Probably should be "Centers for Disease Control and Prevention". Section 515 formerly was section 508, and after such redesignation, section 312(d)(10) of Public Law 102–531 (106 Stat. 3505) attempted to amend "section 508(b)(6)" with respect to adding "and Prevention".

(9) collaborate with the Attorney General of the Department of Justice to develop programs to prevent drug abuse among high risk youth;

(10) prepare for distribution documentary films and public service announcements for television and radio to educate the public, especially adolescent audiences, concerning the dangers to health resulting from the consumption of alcohol and drugs and, to the extent feasible, use appropriate private organizations and business concerns in the preparation of such announcements; and

(11) develop and support innovative demonstration programs designed to identify and deter the improper use or abuse of anabolic steroids by students, especially students in secondary schools.

(c) The Director may make grants and enter into contracts and cooperative agreements in carrying out subsection (b).

(d) The Director of the Prevention Center shall establish a national data base providing information on programs for the prevention of substance abuse. The data base shall contain information appropriate for use by public entities and information appropriate for use by nonprofit private entities.

SEC. 516.[290bb–22] PRIORITY SUBSTANCE ABUSE PREVENTION NEEDS OF REGIONAL AND NATIONAL SIGNIFICANCE.

(a) PROJECTS.—The Secretary shall address priority substance abuse prevention needs of regional and national significance (as determined under subsection (b)) through the provision of or through assistance for—

(1) knowledge development and application projects for prevention and the conduct or support of evaluations of such projects;

(2) training and technical assistance; and

(3) targeted capacity response programs.

The Secretary may carry out the activities described in this section directly or through grants or cooperative agreements with States, political subdivisions of States, Indian tribes and tribal organizations, or other public or nonprofit private entities.

(b) PRIORITY SUBSTANCE ABUSE PREVENTION NEEDS.—

(1) IN GENERAL.—Priority substance abuse prevention needs of regional and national significance shall be determined by the Secretary in consultation with the States and other interested groups. The Secretary shall meet with the States and interested groups on an annual basis to discuss program priorities.

(2) SPECIAL CONSIDERATION.—In developing program priorities under paragraph (1), the Secretary shall give special consideration to—

(A) applying the most promising strategies and research-based primary prevention approaches; and

(B) promoting the integration of substance abuse prevention information and activities into primary health care systems.

(c) REQUIREMENTS.—

(1) IN GENERAL.—Recipients of grants, contracts, and cooperative agreements under this section shall comply with infor-

mation and application requirements determined appropriate by the Secretary.

(2) DURATION OF AWARD.—With respect to a grant, contract, or cooperative agreement awarded under this section, the period during which payments under such award are made to the recipient may not exceed 5 years.

(3) MATCHING FUNDS.—The Secretary may, for projects carried out under subsection (a), require that entities that apply for grants, contracts, or cooperative agreements under that project provide non-Federal matching funds, as determined appropriate by the Secretary, to ensure the institutional commitment of the entity to the projects funded under the grant, contract, or cooperative agreement. Such non-Federal matching funds may be provided directly or through donations from public or private entities and may be in cash or in kind, fairly evaluated, including plant, equipment, or services.

(4) MAINTENANCE OF EFFORT.—With respect to activities for which a grant, contract, or cooperative agreement is awarded under this section, the Secretary may require that recipients for specific projects under subsection (a) agree to maintain expenditures of non-Federal amounts for such activities at a level that is not less than the level of such expenditures maintained by the entity for the fiscal year preceding the fiscal year for which the entity receives such a grant, contract, or cooperative agreement.

(d) EVALUATION.—The Secretary shall evaluate each project carried out under subsection (a)(1) and shall disseminate the findings with respect to each such evaluation to appropriate public and private entities.

(e) INFORMATION AND EDUCATION.—The Secretary shall establish comprehensive information and education programs to disseminate the findings of the knowledge development and application, training and technical assistance programs, and targeted capacity response programs under this section to the general public and to health professionals. The Secretary shall make every effort to provide linkages between the findings of supported projects and State agencies responsible for carrying out substance abuse prevention and treatment programs.

(f) AUTHORIZATION OF APPROPRIATION.—There are authorized to be appropriated to carry out this section, $300,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 and 2003.

PREVENTION, TREATMENT, AND REHABILITATION MODEL PROJECTS FOR HIGH RISK YOUTH.

SEC. 517.[290bb–23] (a) The Secretary, through the Director of the Prevention Center, shall make grants to public and nonprofit private entities for projects to demonstrate effective models for the prevention, treatment, and rehabilitation of drug abuse and alcohol abuse among high risk youth.

(b)(1) In making grants for drug abuse and alcohol abuse prevention projects under this section, the Secretary shall give priority to applications for projects directed at children of substance abus-

ers, latchkey children, children at risk of abuse or neglect, preschool children eligible for services under the Head Start Act, children at risk of dropping out of school, children at risk of becoming adolescent parents, and children who do not attend school and who are at risk of being unemployed.

(2) In making grants for drug abuse and alcohol abuse treatment and rehabilitation projects under this section, the Secretary shall give priority to projects which address the relationship between drug abuse or alcohol abuse and physical child abuse, sexual child abuse, emotional child abuse, dropping out of school, unemployment, delinquency, pregnancy, violence, suicide, or mental health problems.

(3) In making grants under this section, the Secretary shall give priority to applications from community based organizations for projects to develop innovative models with multiple, coordinated services for the prevention or for the treatment and rehabilitation of drug abuse or alcohol abuse by high risk youth.

(4) In making grants under this section, the Secretary shall give priority to applications for projects to demonstrate effective models with multiple, coordinated services which may be replicated and which are for the prevention or for the treatment and rehabilitation of drug abuse or alcohol abuse by high risk youth.

(5) In making grants under this section, the Secretary shall give priority to applications that employ research designs adequate for evaluating the effectiveness of the program.

(c) The Secretary shall ensure that projects under subsection (a) include strategies for reducing the use of alcoholic beverages and tobacco products by individuals to whom it is unlawful to sell or distribute such beverages or products.

(d) To the extent feasible, the Secretary shall make grants under this section in all regions of the United States, and shall ensure the distribution of grants under this section among urban and rural areas.

(e) In order to receive a grant for a project under this section for a fiscal year, a public or nonprofit private entity shall submit an application to the Secretary, acting through the Office. The Secretary may provide to the Governor of the State the opportunity to review and comment on such application. Such application shall be in such form, shall contain such information, and shall be submitted at such time as the Secretary may by regulation prescribe.

(f) The Director[14] of the Office shall evaluate projects conducted with grants under this section.

(g) For purposes of this section, the term "high risk youth" means an individual who has not attained the age of 21 years, who is at high risk of becoming, or who has become, a drug abuser or an alcohol abuser, and who—

(1) is identified as a child of a substance abuser;

(2) is a victim of physical, sexual, or psychological abuse;

(3) has dropped out of school;

(4) has become pregnant;

(5) is economically disadvantaged;

[14] So in law. See section 114, and subsections (a), (d), and (e) of section 113, of Public Law 102–321 (106 Stat. 346, 345). Probably should be "Prevention Center".

(6) has committed a violent or delinquent act;

(7) has experienced mental health problems;

(8) has attempted suicide;

(9) has experienced long-term physical pain due to injury; or

(10) has experienced chronic failure in school.

(h) For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2003.

SEC. 519A.[15] [290bb–25a] GRANTS FOR STRENGTHENING FAMILIES.

(a) PROGRAM AUTHORIZED.—The Secretary, acting through the Director of the Prevention Center, may make grants to public and nonprofit private entities to develop and implement model substance abuse prevention programs to provide early intervention and substance abuse prevention services for individuals of high-risk families and the communities in which such individuals reside.

(b) PRIORITY.—In awarding grants under subsection (a), the Secretary shall give priority to applicants that—

(1) have proven experience in preventing substance abuse by individuals of high-risk families and reducing substance abuse in communities of such individuals;

(2) have demonstrated the capacity to implement community-based partnership initiatives that are sensitive to the diverse backgrounds of individuals of high-risk families and the communities of such individuals;

(3) have experience in providing technical assistance to support substance abuse prevention programs that are community-based;

(4) have demonstrated the capacity to implement research-based substance abuse prevention strategies; and

(5) have implemented programs that involve families, residents, community agencies, and institutions in the implementation and design of such programs.

(c) DURATION OF GRANTS.—The Secretary shall award grants under subsection (a) for a period not to exceed 5 years.

(d) USE OF FUNDS.—An applicant that is awarded a grant under subsection (a) shall—

(1) in the first fiscal year that such funds are received under the grant, use such funds to develop a model substance abuse prevention program; and

(2) in the fiscal year following the first fiscal year that such funds are received, use such funds to implement the program developed under paragraph (1) to provide early intervention and substance abuse prevention services to—

(A) strengthen the environment of children of high risk families by targeting interventions at the families of such children and the communities in which such children reside;

(B) strengthen protective factors, such as—

[15] The probable intent of the Congress is that section 399A of this Act appear before section 519A as a section 519. See footnote for section 399A. (Section 399A relates to grants for services for children of substance abusers.)

Section 518 was repealed by section 3202(b) of Public Law 106–310 (114 Stat. 1210).

(i) positive adult role models;

(ii) messages that oppose substance abuse;

(iii) community actions designed to reduce accessibility to and use of illegal substances; and

(iv) willingness of individuals of families in which substance abuse occurs to seek treatment for substance abuse;

(C) reduce family and community risks, such as family violence, alcohol or drug abuse, crime, and other behaviors that may effect healthy child development and increase the likelihood of substance abuse; and

(D) build collaborative and formal partnerships between community agencies, institutions, and businesses to ensure that comprehensive high quality services are provided, such as early childhood education, health care, family support programs, parent education programs, and home visits for infants.

(e) APPLICATION.—To be eligible to receive a grant under subsection (a), an applicant shall prepare and submit to the Secretary an application that—

(1) describes a model substance abuse prevention program that such applicant will establish;

(2) describes the manner in which the services described in subsection (d)(2) will be provided; and

(3) describe in as much detail as possible the results that the entity expects to achieve in implementing such a program.

(f) MATCHING FUNDING.—The Secretary may not make a grant to a entity under subsection (a) unless that entity agrees that, with respect to the costs to be incurred by the entity in carrying out the program for which the grant was awarded, the entity will make available non-Federal contributions in an amount that is not less than 40 percent of the amount provided under the grant.

(g) REPORT TO SECRETARY.—An applicant that is awarded a grant under subsection (a) shall prepare and submit to the Secretary a report in such form and containing such information as the Secretary may require, including an assessment of the efficacy of the model substance abuse prevention program implemented by the applicant and the short, intermediate, and long term results of such program.

(h) EVALUATIONS.—The Secretary shall conduct evaluations, based in part on the reports submitted under subsection (g), to determine the effectiveness of the programs funded under subsection (a) in reducing substance use in high-risk families and in making communities in which such families reside in stronger. The Secretary shall submit such evaluations to the appropriate committees of Congress.

(i) HIGH-RISK FAMILIES.—In this section, the term "high-risk family" means a family in which the individuals of such family are at a significant risk of using or abusing alcohol or any illegal substance.

(j) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $3,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 and 2003.

SEC. 519B.[290bb–25b] PROGRAMS TO REDUCE UNDERAGE DRINKING.

(a) DEFINITIONS.—For purposes of this section:

(1) The term "alcohol beverage industry" means the brewers, vintners, distillers, importers, distributors, and retail or online outlets that sell or serve beer, wine, and distilled spirits.

(2) The term "school-based prevention" means programs, which are institutionalized, and run by staff members or school-designated persons or organizations in any grade of school, kindergarten through 12th grade.

(3) The term "youth" means persons under the age of 21.

(4) The term "IOM report" means the report released in September 2003 by the National Research Council, Institute of Medicine, and entitled "Reducing Underage Drinking: A Collective Responsibility".

(b) SENSE OF CONGRESS.—It is the sense of the Congress that:

(1) A multi-faceted effort is needed to more successfully address the problem of underage drinking in the United States. A coordinated approach to prevention, intervention, treatment, enforcement, and research is key to making progress. This Act recognizes the need for a focused national effort, and addresses particulars of the Federal portion of that effort, as well as Federal support for State activities.

(2) The Secretary of Health and Human Services shall continue to conduct research and collect data on the short and long-range impact of alcohol use and abuse upon adolescent brain development and other organ systems.

(3) States and communities, including colleges and universities, are encouraged to adopt comprehensive prevention approaches, including—

(A) evidence-based screening, programs and curricula;

(B) brief intervention strategies;

(C) consistent policy enforcement; and

(D) environmental changes that limit underage access to alcohol.

(4) Public health groups, consumer groups, and the alcohol beverage industry should continue and expand evidence-based efforts to prevent and reduce underage drinking.

(5) The entertainment industries have a powerful impact on youth, and they should use rating systems and marketing codes to reduce the likelihood that underage audiences will be exposed to movies, recordings, or television programs with unsuitable alcohol content.

(6) The National Collegiate Athletic Association, its member colleges and universities, and athletic conferences should affirm a commitment to a policy of discouraging alcohol use among underage students and other young fans.

(7) Alcohol is a unique product and should be regulated differently than other products by the States and Federal Government. States have primary authority to regulate alcohol distribution and sale, and the Federal Government should support and supplement these State efforts. States also have a responsibility to fight youth access to alcohol and reduce underage drinking. Continued State regulation and licensing of the manufacture, importation, sale, distribution, transportation

and storage of alcoholic beverages are clearly in the public interest and are critical to promoting responsible consumption, preventing illegal access to alcohol by persons under 21 years of age from commercial and non-commercial sources, maintaining industry integrity and an orderly marketplace, and furthering effective State tax collection.

(c) INTERAGENCY COORDINATING COMMITTEE; ANNUAL REPORT ON STATE UNDERAGE DRINKING PREVENTION AND ENFORCEMENT ACTIVITIES.—

(1) INTERAGENCY COORDINATING COMMITTEE ON THE PREVENTION OF UNDERAGE DRINKING.—

(A) IN GENERAL.—The Secretary, in collaboration with the Federal officials specified in subparagraph (B), shall formally establish and enhance the efforts of the interagency coordinating committee, that began operating in 2004, focusing on underage drinking (referred to in this subsection as the "Committee").

(B) OTHER AGENCIES.—The officials referred to in paragraph (1) are the Secretary of Education, the Attorney General, the Secretary of Transportation, the Secretary of the Treasury, the Secretary of Defense, the Surgeon General, the Director of the Centers for Disease Control and Prevention, the Director of the National Institute on Alcohol Abuse and Alcoholism, the Administrator of the Substance Abuse and Mental Health Services Administration, the Director of the National Institute on Drug Abuse, the Assistant Secretary for Children and Families, the Director of the Office of National Drug Control Policy, the Administrator of the National Highway Traffic Safety Administration, the Administrator of the Office of Juvenile Justice and Delinquency Prevention, the Chairman of the Federal Trade Commission, and such other Federal officials as the Secretary of Health and Human Services determines to be appropriate.

(C) CHAIR.—The Secretary of Health and Human Services shall serve as the chair of the Committee.

(D) DUTIES.—The Committee shall guide policy and program development across the Federal Government with respect to underage drinking, provided, however, that nothing in this section shall be construed as transferring regulatory or program authority from an Agency to the Coordinating Committee.

(E) CONSULTATIONS.—The Committee shall actively seek the input of and shall consult with all appropriate and interested parties, including States, public health research and interest groups, foundations, and alcohol beverage industry trade associations and companies.

(F) ANNUAL REPORT.—

(i) IN GENERAL.—The Secretary, on behalf of the Committee, shall annually submit to the Congress a report that summarizes—

(I) all programs and policies of Federal agencies designed to prevent and reduce underage drinking;

(II) the extent of progress in preventing and reducing underage drinking nationally;

(III) data that the Secretary shall collect with respect to the information specified in clause (ii); and

(IV) such other information regarding underage drinking as the Secretary determines to be appropriate.

(ii) CERTAIN INFORMATION.—The report under clause (i) shall include information on the following:

(I) Patterns and consequences of underage drinking as reported in research and surveys such as, but not limited to Monitoring the Future, Youth Risk Behavior Surveillance System, the National Survey on Drug Use and Health, and the Fatality Analysis Reporting System.

(II) Measures of the availability of alcohol from commercial and non-commercial sources to underage populations.

(III) Measures of the exposure of underage populations to messages regarding alcohol in advertising and the entertainment media as reported by the Federal Trade Commission.

(IV) Surveillance data, including information on the onset and prevalence of underage drinking, consumption patterns and the means of underage access. The Secretary shall develop a plan to improve the collection, measurement and consistency of reporting Federal underage alcohol data.

(V) Any additional findings resulting from research conducted or supported under subsection (f).

(VI) Evidence-based best practices to prevent and reduce underage drinking and provide treatment services to those youth who need them.

(2) ANNUAL REPORT ON STATE UNDERAGE DRINKING PREVENTION AND ENFORCEMENT ACTIVITIES.—

(A) IN GENERAL.—The Secretary shall, with input and collaboration from other appropriate Federal agencies, States, Indian tribes, territories, and public health, consumer, and alcohol beverage industry groups, annually issue a report on each State's performance in enacting, enforcing, and creating laws, regulations, and programs to prevent or reduce underage drinking.

(B) STATE PERFORMANCE MEASURES.—

(i) IN GENERAL.—The Secretary shall develop, in consultation with the Committee, a set of measures to be used in preparing the report on best practices.

(ii) CATEGORIES.—In developing these measures, the Secretary shall consider categories including, but not limited to:

(I) Whether or not the State has comprehensive anti-underage drinking laws such as for the illegal sale, purchase, attempt to purchase, con-

sumption, or possession of alcohol; illegal use of fraudulent ID; illegal furnishing or obtaining of alcohol for an individual under 21 years; the degree of strictness of the penalties for such offenses; and the prevalence of the enforcement of each of these infractions.

(II) Whether or not the State has comprehensive liability statutes pertaining to underage access to alcohol such as dram shop, social host, and house party laws, and the prevalence of enforcement of each of these laws.

(III) Whether or not the State encourages and conducts comprehensive enforcement efforts to prevent underage access to alcohol at retail outlets, such as random compliance checks and shoulder tap programs, and the number of compliance checks within alcohol retail outlets measured against the number of total alcohol retail outlets in each State, and the result of such checks.

(IV) Whether or not the State encourages training on the proper selling and serving of alcohol for all sellers and servers of alcohol as a condition of employment.

(V) Whether or not the State has policies and regulations with regard to direct sales to consumers and home delivery of alcoholic beverages.

(VI) Whether or not the State has programs or laws to deter adults from purchasing alcohol for minors; and the number of adults targeted by these programs.

(VII) Whether or not the State has programs targeted to youths, parents, and caregivers to deter underage drinking; and the number of individuals served by these programs.

(VIII) Whether or not the State has enacted graduated drivers licenses and the extent of those provisions.

(IX) The amount that the State invests, per youth capita, on the prevention of underage drinking, further broken down by the amount spent on—

(aa) compliance check programs in retail outlets, including providing technology to prevent and detect the use of false identification by minors to make alcohol purchases;

(bb) checkpoints and saturation patrols that include the goal of reducing and deterring underage drinking;

(cc) community-based, school-based, and higher-education-based programs to prevent underage drinking;

(dd) underage drinking prevention programs that target youth within the juvenile justice and child welfare systems; and

(ee) other State efforts or programs as deemed appropriate.

(3) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this subsection $1,000,000 for fiscal year 2007, and $1,000,000 for each of the fiscal years 2008 through 2010.

(d) NATIONAL MEDIA CAMPAIGN TO PREVENT UNDERAGE DRINKING.—

(1) SCOPE OF THE CAMPAIGN.—The Secretary shall continue to fund and oversee the production, broadcasting, and evaluation of the national adult-oriented media public service campaign if the Secretary determines that such campaign is effective in achieving the media campaign's measurable objectives.

(2) REPORT.—The Secretary shall provide a report to the Congress annually detailing the production, broadcasting, and evaluation of the campaign referred to in paragraph (1), and to detail in the report the effectiveness of the campaign in reducing underage drinking, the need for and likely effectiveness of an expanded adult-oriented media campaign, and the feasibility and the likely effectiveness of a national youth-focused media campaign to combat underage drinking.

(3) CONSULTATION REQUIREMENT.—In carrying out the media campaign, the Secretary shall direct the entity carrying out the national adult-oriented media public service campaign to consult with interested parties including both the alcohol beverage industry and public health and consumer groups. The progress of this consultative process is to be covered in the report under paragraph (2).

(4) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this subsection, $1,000,000 for fiscal year 2007 and $1,000,000 for each of the fiscal years 2008 through 2010.

(e) INTERVENTIONS.—

(1) COMMUNITY-BASED COALITION ENHANCEMENT GRANTS TO PREVENT UNDERAGE DRINKING.—

(A) AUTHORIZATION OF PROGRAM.—The Administrator of the Substance Abuse and Mental Health Services Administration, in consultation with the Director of the Office of National Drug Control Policy, shall award, if the Administrator determines that the Department of Health and Human Services is not currently conducting activities that duplicate activities of the type described in this subsection, "enhancement grants" to eligible entities to design, test, evaluate and disseminate effective strategies to maximize the effectiveness of community-wide approaches to preventing and reducing underage drinking. This subsection is subject to the availability of appropriations.

(B) PURPOSES.—The purposes of this paragraph are to—

(i) prevent and reduce alcohol use among youth in communities throughout the United States;

(ii) strengthen collaboration among communities, the Federal Government, and State, local, and tribal governments;

(iii) enhance intergovernmental cooperation and coordination on the issue of alcohol use among youth;

(iv) serve as a catalyst for increased citizen participation and greater collaboration among all sectors and organizations of a community that first demonstrates a long-term commitment to reducing alcohol use among youth;

(v) disseminate to communities timely information regarding state-of-the-art practices and initiatives that have proven to be effective in preventing and reducing alcohol use among youth; and

(vi) enhance, not supplant, effective local community initiatives for preventing and reducing alcohol use among youth.

(C) APPLICATION.—An eligible entity desiring an enhancement grant under this paragraph shall submit an application to the Administrator at such time, and in such manner, and accompanied by such information as the Administrator may require. Each application shall include—

(i) a complete description of the entity's current underage alcohol use prevention initiatives and how the grant will appropriately enhance the focus on underage drinking issues; or

(ii) a complete description of the entity's current initiatives, and how it will use this grant to enhance those initiatives by adding a focus on underage drinking prevention.

(D) USES OF FUNDS.—Each eligible entity that receives a grant under this paragraph shall use the grant funds to carry out the activities described in such entity's application submitted pursuant to subparagraph (C). Grants under this paragraph shall not exceed $50,000 per year and may not exceed four years.

(E) SUPPLEMENT NOT SUPPLANT.—Grant funds provided under this paragraph shall be used to supplement, not supplant, Federal and non-Federal funds available for carrying out the activities described in this paragraph.

(F) EVALUATION.—Grants under this paragraph shall be subject to the same evaluation requirements and procedures as the evaluation requirements and procedures imposed on recipients of drug free community grants.

(G) DEFINITIONS.—For purposes of this paragraph, the term "eligible entity" means an organization that is currently receiving or has received grant funds under the Drug-Free Communities Act of 1997 (21 U.S.C. 1521 et seq.).

(H) ADMINISTRATIVE EXPENSES.—Not more than 6 percent of a grant under this paragraph may be expended for administrative expenses.

(I) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this paragraph $5,000,000 for fiscal year 2007, and $5,000,000 for each of the fiscal years 2008 through 2010.

(2) GRANTS DIRECTED AT PREVENTING AND REDUCING ALCOHOL ABUSE AT INSTITUTIONS OF HIGHER EDUCATION.—

(A) AUTHORIZATION OF PROGRAM.—The Secretary shall award grants to eligible entities to enable the entities to prevent and reduce the rate of underage alcohol consumption including binge drinking among students at institutions of higher education.

(B) APPLICATIONS.—An eligible entity that desires to receive a grant under this paragraph shall submit an application to the Secretary at such time, in such manner, and accompanied by such information as the Secretary may require. Each application shall include—

(i) a description of how the eligible entity will work to enhance an existing, or where none exists to build a, statewide coalition;

(ii) a description of how the eligible entity will target underage students in the State;

(iii) a description of how the eligible entity intends to ensure that the statewide coalition is actually implementing the purpose of this section and moving toward indicators described in subparagraph (D);

(iv) a list of the members of the statewide coalition or interested parties involved in the work of the eligible entity;

(v) a description of how the eligible entity intends to work with State agencies on substance abuse prevention and education;

(vi) the anticipated impact of funds provided under this paragraph in preventing and reducing the rates of underage alcohol use;

(vii) outreach strategies, including ways in which the eligible entity proposes to—

(I) reach out to students and community stakeholders;

(II) promote the purpose of this paragraph;

(III) address the range of needs of the students and the surrounding communities; and

(IV) address community norms for underage students regarding alcohol use; and

(viii) such additional information as required by the Secretary.

(C) USES OF FUNDS.—Each eligible entity that receives a grant under this paragraph shall use the grant funds to carry out the activities described in such entity's application submitted pursuant to subparagraph (B).

(D) ACCOUNTABILITY.—On the date on which the Secretary first publishes a notice in the Federal Register soliciting applications for grants under this paragraph, the Secretary shall include in the notice achievement indicators for the program authorized under this paragraph. The achievement indicators shall be designed—

(i) to measure the impact that the statewide coalitions assisted under this paragraph are having on the institutions of higher education and the surrounding

communities, including changes in the number of incidents of any kind in which students have abused alcohol or consumed alcohol while under the age of 21 (including violations, physical assaults, sexual assaults, reports of intimidation, disruptions of school functions, disruptions of student studies, mental health referrals, illnesses, or deaths);

(ii) to measure the quality and accessibility of the programs or information offered by the eligible entity; and

(iii) to provide such other measures of program impact as the Secretary determines appropriate.

(E) SUPPLEMENT NOT SUPPLANT.—Grant funds provided under this paragraph shall be used to supplement, and not supplant, Federal and non-Federal funds available for carrying out the activities described in this paragraph.

(F) DEFINITIONS.—For purposes of this paragraph:

(i) ELIGIBLE ENTITY.—The term "eligible entity" means a State, institution of higher education, or nonprofit entity.

(ii) INSTITUTION OF HIGHER EDUCATION.—The term "institution of higher education" has the meaning given the term in section 101(a) of the Higher Education Act of 1965 (20 U.S.C. 1001(a)).

(iii) SECRETARY.—The term "Secretary" means the Secretary of Education.

(iv) STATE.—The term "State" means each of the 50 States, the District of Columbia, and the Commonwealth of Puerto Rico.

(v) STATEWIDE COALITION.—The term "statewide coalition" means a coalition that—

(I) includes, but is not limited to—

(aa) institutions of higher education within a State; and

(bb) a nonprofit group, a community underage drinking prevention coalition, or another substance abuse prevention group within a State; and

(II) works toward lowering the alcohol abuse rate by targeting underage students at institutions of higher education throughout the State and in the surrounding communities.

(vi) SURROUNDING COMMUNITY.—The term "surrounding community" means the community—

(I) that surrounds an institution of higher education participating in a statewide coalition;

(II) where the students from the institution of higher education take part in the community; and

(III) where students from the institution of higher education live in off-campus housing.

(G) ADMINISTRATIVE EXPENSES.—Not more than 5 percent of a grant under this paragraph may be expended for administrative expenses.

(H) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this paragraph $5,000,000 for fiscal year 2007, and $5,000,000 for each of the fiscal years 2008 through 2010.

(f) ADDITIONAL RESEARCH.—

(1) ADDITIONAL RESEARCH ON UNDERAGE DRINKING.—

(A) IN GENERAL.—The Secretary shall, subject to the availability of appropriations, collect data, and conduct or support research that is not duplicative of research currently being conducted or supported by the Department of Health and Human Services, on underage drinking, with respect to the following:

(i) Comprehensive community-based programs or strategies and statewide systems to prevent and reduce underage drinking, across the underage years from early childhood to age 21, including programs funded and implemented by government entities, public health interest groups and foundations, and alcohol beverage companies and trade associations.

(ii) Annually obtain and report more precise information than is currently collected on the scope of the underage drinking problem and patterns of underage alcohol consumption, including improved knowledge about the problem and progress in preventing, reducing and treating underage drinking; as well as information on the rate of exposure of youth to advertising and other media messages encouraging and discouraging alcohol consumption.

(iii) Compiling information on the involvement of alcohol in unnatural deaths of persons ages 12 to 20 in the United States, including suicides, homicides, and unintentional injuries such as falls, drownings, burns, poisonings, and motor vehicle crash deaths.

(B) CERTAIN MATTERS.—The Secretary shall carry out activities toward the following objectives with respect to underage drinking:

(i) Obtaining new epidemiological data within the national or targeted surveys that identify alcohol use and attitudes about alcohol use during pre- and early adolescence, including harm caused to self or others as a result of adolescent alcohol use such as violence, date rape, risky sexual behavior, and prenatal alcohol exposure.

(ii) Developing or identifying successful clinical treatments for youth with alcohol problems.

(C) PEER REVIEW.—Research under subparagraph (A) shall meet current Federal standards for scientific peer review.

(2) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this subsection $6,000,000 for fiscal year 2007, and $6,000,000 for each of the fiscal years 2008 through 2010.

SEC. 519C.[290bb–25c] SERVICES FOR INDIVIDUALS WITH FETAL ALCOHOL SYNDROME.

(a) IN GENERAL.—The Secretary shall make awards of grants, cooperative agreements, or contracts to public and nonprofit private entities, including Indian tribes and tribal organizations, to provide services to individuals diagnosed with fetal alcohol syndrome or alcohol-related birth defects.

(b) USE OF FUNDS.—An award under subsection (a) may, subject to subsection (d), be used to—

(1) screen and test individuals to determine the type and level of services needed;

(2) develop a comprehensive plan for providing services to the individual;

(3) provide mental health counseling;

(4) provide substance abuse prevention services and treatment, if needed;

(5) coordinate services with other social programs including social services, justice system, educational services, health services, mental health and substance abuse services, financial assistance programs, vocational services and housing assistance programs;

(6) provide vocational services;

(7) provide health counseling;

(8) provide housing assistance;

(9) parenting skills training;

(10) overall case management;

(11) supportive services for families of individuals with Fetal Alcohol Syndrome; and

(12) provide other services and programs, to the extent authorized by the Secretary after consideration of recommendations made by the National Task Force on Fetal Alcohol Syndrome.

(c) REQUIREMENTS.—To be eligible to receive an award under subsection (a), an applicant shall—

(1) demonstrate that the program will be part of a coordinated, comprehensive system of care for such individuals;

(2) demonstrate an established communication with other social programs in the community including social services, justice system, financial assistance programs, health services, educational services, mental health and substance abuse services, vocational services and housing assistance services;

(3) show a history of working with individuals with fetal alcohol syndrome or alcohol-related birth defects;

(4) provide assurance that the services will be provided in a culturally and linguistically appropriate manner; and

(5) provide assurance that at the end of the 5-year award period, other mechanisms will be identified to meet the needs of the individuals and families served under such award.

(d) RELATIONSHIP TO PAYMENTS UNDER OTHER PROGRAMS.—An award may be made under subsection (a) only if the applicant involved agrees that the award will not be expended to pay the expenses of providing any service under this section to an individual to the extent that payment has been made, or can reasonably be expected to be made, with respect to such expenses—

(1) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program; or

(2) by an entity that provides health services on a prepaid basis.

(e) DURATION OF AWARDS.—With respect to an award under subsection (a), the period during which payments under such award are made to the recipient may not exceed 5 years.

(f) EVALUATION.—The Secretary shall evaluate each project carried out under subsection (a) and shall disseminate the findings with respect to each such evaluation to appropriate public and private entities.

(g) FUNDING.—

(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $25,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 and 2003.

(2) ALLOCATION.—Of the amounts appropriated under paragraph (1) for a fiscal year, not less than $300,000 shall, for purposes relating to fetal alcohol syndrome and alcohol-related birth defects, be made available for collaborative, coordinated interagency efforts with the National Institute on Alcohol Abuse and Alcoholism, the Eunice Kennedy Shriver National Institute of Child Health and Human Development, the Health Resources and Services Administration, the Agency for Healthcare Research and Quality, the Centers for Disease Control and Prevention, the Department of Education, and the Department of Justice.

SEC. 519D.[290bb–25d] CENTERS OF EXCELLENCE ON SERVICES FOR INDIVIDUALS WITH FETAL ALCOHOL SYNDROME AND ALCOHOL-RELATED BIRTH DEFECTS AND TREATMENT FOR INDIVIDUALS WITH SUCH CONDITIONS AND THEIR FAMILIES.

(a) IN GENERAL.—The Secretary shall make awards of grants, cooperative agreements, or contracts to public or nonprofit private entities for the purposes of establishing not more than four centers of excellence to study techniques for the prevention of fetal alcohol syndrome and alcohol-related birth defects and adaptations of innovative clinical interventions and service delivery improvements for the provision of comprehensive services to individuals with fetal alcohol syndrome or alcohol-related birth defects and their families and for providing training on such conditions.

(b) USE OF FUNDS.—An award under subsection (a) may be used to—

(1) study adaptations of innovative clinical interventions and service delivery improvements strategies for children and adults with fetal alcohol syndrome or alcohol-related birth defects and their families;

(2) identify communities which have an exemplary comprehensive system of care for such individuals so that they can provide technical assistance to other communities attempting to set up such a system of care;

(3) provide technical assistance to communities who do not have a comprehensive system of care for such individuals and their families;

(4) train community leaders, mental health and substance abuse professionals, families, law enforcement personnel, judges, health professionals, persons working in financial assistance programs, social service personnel, child welfare professionals, and other service providers on the implications of fetal alcohol syndrome and alcohol-related birth defects, the early identification of and referral for such conditions;

(5) develop innovative techniques for preventing alcohol use by women in child bearing years;[16]

(6) perform other functions, to the extent authorized by the Secretary after consideration of recommendations made by the National Task Force on Fetal Alcohol Syndrome.

(c) REPORT.—

(1) IN GENERAL.—A recipient of an award under subsection (a) shall at the end of the period of funding report to the Secretary on any innovative techniques that have been discovered for preventing alcohol use among women of child bearing years.

(2) DISSEMINATION OF FINDINGS.—The Secretary shall upon receiving a report under paragraph (1) disseminate the findings to appropriate public and private entities.

(d) DURATION OF AWARDS.—With respect to an award under subsection (a), the period during which payments under such award are made to the recipient may not exceed 5 years.

(e) EVALUATION.—The Secretary shall evaluate each project carried out under subsection (a) and shall disseminate the findings with respect to each such evaluation to appropriate public and private entities.

(f) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $5,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 and 2003.

SEC. 519E.[17] [290bb–25e] PREVENTION OF METHAMPHETAMINE AND INHALANT ABUSE AND ADDICTION.

(a) GRANTS.—The Director of the Center for Substance Abuse Prevention (referred to in this section as the "Director") may make grants to and enter into contracts and cooperative agreements with public and nonprofit private entities to enable such entities—

(1) to carry out school-based programs concerning the dangers of methamphetamine or inhalant abuse and addiction, using methods that are effective and evidence-based, including initiatives that give students the responsibility to create their own anti-drug abuse education programs for their schools; and

(2) to carry out community-based methamphetamine or inhalant abuse and addiction prevention programs that are effective and evidence-based.

[16] So in law. Probably should read "; and". See section 3110 of Public Law 106–310 (114 Stat. 1185).

[17] The placement of section 519E is according to the probable intent of the Congress. Section 3104(c) of Public Law 106–310 (114 Stat. 1173) added the section to this subpart, but did not specify the specific placement of the section.

(b) USE OF FUNDS.—Amounts made available under a grant, contract or cooperative agreement under subsection (a) shall be used for planning, establishing, or administering methamphetamine or inhalant prevention programs in accordance with subsection (c).

(c) PREVENTION PROGRAMS AND ACTIVITIES.—

(1) IN GENERAL.—Amounts provided under this section may be used—

(A) to carry out school-based programs that are focused on those districts with high or increasing rates of methamphetamine or inhalant abuse and addiction and targeted at populations which are most at risk to start methamphetamine or inhalant abuse;

(B) to carry out community-based prevention programs that are focused on those populations within the community that are most at-risk for methamphetamine or inhalant abuse and addiction;

(C) to assist local government entities to conduct appropriate methamphetamine or inhalant prevention activities;

(D) to train and educate State and local law enforcement officials, prevention and education officials, members of community anti-drug coalitions and parents on the signs of methamphetamine or inhalant abuse and addiction and the options for treatment and prevention;

(E) for planning, administration, and educational activities related to the prevention of methamphetamine or inhalant abuse and addiction;

(F) for the monitoring and evaluation of methamphetamine or inhalant prevention activities, and reporting and disseminating resulting information to the public; and

(G) for targeted pilot programs with evaluation components to encourage innovation and experimentation with new methodologies.

(2) PRIORITY.—The Director shall give priority in making grants under this section to rural and urban areas that are experiencing a high rate or rapid increases in methamphetamine or inhalant abuse and addiction.

(d) ANALYSES AND EVALUATION.—

(1) IN GENERAL.—Up to $500,000 of the amount available in each fiscal year to carry out this section shall be made available to the Director, acting in consultation with other Federal agencies, to support and conduct periodic analyses and evaluations of effective prevention programs for methamphetamine or inhalant abuse and addiction and the development of appropriate strategies for disseminating information about and implementing these programs.

(2) ANNUAL REPORTS.—The Director shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Commerce and Committee on Appropriations of the House of Representatives, an annual report with the results of the analyses and evaluation under paragraph (1).

(e) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out subsection (a), $10,000,000 for fiscal year 2001, and such sums as may be necessary for each of fiscal years 2002 and 2003.

Subpart 3—Center for Mental Health Services

CENTER FOR MENTAL HEALTH SERVICES.

SEC. 520.[290bb–31] (a) ESTABLISHMENT.—There is established in the Administration a Center for Mental Health Services (hereafter in this section referred to as the "Center"). The Center shall be headed by a Director (hereafter in this section referred to as the "Director") appointed by the Secretary from among individuals with extensive experience or academic qualifications in the provision of mental health services or in the evaluation of mental health service systems.

(b) DUTIES.—The Director of the Center shall—

(1) design national goals and establish national priorities for—

(A) the prevention of mental illness; and

(B) the promotion of mental health;

(2) encourage and assist local entities and State agencies to achieve the goals and priorities described in paragraph (1);

(3) collaborate with the Department of Education and the Department of Justice to develop programs to assist local communities in addressing violence among children and adolescents;

(4) develop and coordinate Federal prevention policies and programs and to assure increased focus on the prevention of mental illness and the promotion of mental health;

(5) develop improved methods of treating individuals with mental health problems and improved methods of assisting the families of such individuals;

(6) administer the mental health services block grant program authorized in section 1911;

(7) promote policies and programs at Federal, State, and local levels and in the private sector that foster independence and protect the legal rights of persons with mental illness, including carrying out the provisions of the Protection and Advocacy of Mentally Ill Individuals Act;

(8) carry out the programs under part C;

(9) carry out responsibilities for the Human Resource Development program, and programs of clinical training for professional and paraprofessional personnel pursuant to section 303 [18];

(10) conduct services-related assessments, including evaluations of the organization and financing of care, self-help and consumer-run programs, mental health economics, mental

[18] The probable intent of the Congress is that the paragraph read "(9) carry out responsibilities for the Human Resource Development Program;". See section 3112(c)(4) of Public Law 106–310 (114 Stat. 1188), which provides that paragraph (9) is amended "by striking 'program and programs' and all that follows through '303' and inserting 'programs'". The amendment cannot be executed because the term to be struck does not appear in paragraph (9). (Compare "program and programs" and "program, and programs".)

health service systems, rural mental health, and improve the capacity of State to conduct evaluations of publicly funded mental health programs;

(11) establish a clearinghouse for mental health information to assure the widespread dissemination of such information to States, political subdivisions, educational agencies and institutions, treatment and prevention service providers, and the general public, including information concerning the practical application of research supported by the National Institute of Mental Health that is applicable to improving the delivery of services;

(12) provide technical assistance to public and private entities that are providers of mental health services;

(13) monitor and enforce obligations incurred by community mental health centers pursuant to the Community Mental Health Centers Act (as in effect prior to the repeal of such Act on August 13, 1981, by section 902(e)(2)(B) of Public Law 97–35 (95 Stat. 560));

(14) conduct surveys with respect to mental health, such as the National Reporting Program; and

(15) assist States in improving their mental health data collection.

(c) GRANTS AND CONTRACTS.—In carrying out the duties established in subsection (b), the Director may make grants to and enter into contracts and cooperative agreements with public and nonprofit private entities.

SEC. 520A.[290bb–32] PRIORITY MENTAL HEALTH NEEDS OF REGIONAL AND NATIONAL SIGNIFICANCE.

(a) PROJECTS.—The Secretary shall address priority mental health needs of regional and national significance (as determined under subsection (b)) through the provision of or through assistance for—

(1) knowledge development and application projects for prevention, treatment, and rehabilitation, and the conduct or support of evaluations of such projects;

(2) training and technical assistance programs;

(3) targeted capacity response programs; and

(4) systems change grants including statewide family network grants and client-oriented and consumer run self-help activities.

The Secretary may carry out the activities described in this subsection directly or through grants or cooperative agreements with States, political subdivisions of States, Indian tribes and tribal organizations, other public or private nonprofit entities.

(b) PRIORITY MENTAL HEALTH NEEDS.—

(1) DETERMINATION OF NEEDS.—Priority mental health needs of regional and national significance shall be determined by the Secretary in consultation with States and other interested groups. The Secretary shall meet with the States and interested groups on an annual basis to discuss program priorities.

(2) SPECIAL CONSIDERATION.—In developing program priorities described in paragraph (1), the Secretary shall give spe-

cial consideration to promoting the integration of mental health services into primary health care systems.

(c) REQUIREMENTS.—

(1) IN GENERAL.—Recipients of grants, contracts, and cooperative agreements under this section shall comply with information and application requirements determined appropriate by the Secretary.

(2) DURATION OF AWARD.—With respect to a grant, contract, or cooperative agreement awarded under this section, the period during which payments under such award are made to the recipient may not exceed 5 years.

(3) MATCHING FUNDS.—The Secretary may, for projects carried out under subsection (a), require that entities that apply for grants, contracts, or cooperative agreements under this section provide non-Federal matching funds, as determined appropriate by the Secretary, to ensure the institutional commitment of the entity to the projects funded under the grant, contract, or cooperative agreement. Such non-Federal matching funds may be provided directly or through donations from public or private entities and may be in cash or in kind, fairly evaluated, including plant, equipment, or services.

(4) MAINTENANCE OF EFFORT.—With respect to activities for which a grant, contract or cooperative agreement is awarded under this section, the Secretary may require that recipients for specific projects under subsection (a) agree to maintain expenditures of non-Federal amounts for such activities at a level that is not less than the level of such expenditures maintained by the entity for the fiscal year preceding the fiscal year for which the entity receives such a grant, contract, or cooperative agreement.

(d) EVALUATION.—The Secretary shall evaluate each project carried out under subsection (a)(1) and shall disseminate the findings with respect to each such evaluation to appropriate public and private entities.

(e) INFORMATION AND EDUCATION.—

(1) IN GENERAL.—The Secretary shall establish information and education programs to disseminate and apply the findings of the knowledge development and application, training, and technical assistance programs, and targeted capacity response programs, under this section to the general public, to health care professionals, and to interested groups. The Secretary shall make every effort to provide linkages between the findings of supported projects and State agencies responsible for carrying out mental health services.

(2) RURAL AND UNDERSERVED AREAS.—In disseminating information on evidence-based practices in the provision of children's mental health services under this subsection, the Secretary shall ensure that such information is distributed to rural and medically underserved areas.

(f) AUTHORIZATION OF APPROPRIATION.—

(1) IN GENERAL.—There are authorized to be appropriated to carry out this section, $300,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 and 2003.

(2) DATA INFRASTRUCTURE.—If amounts are not appropriated for a fiscal year to carry out section 1971 with respect to mental health, then the Secretary shall make available, from the amounts appropriated for such fiscal year under paragraph (1), an amount equal to the sum of $6,000,000 and 10 percent of all amounts appropriated for such fiscal year under such paragraph in excess of $100,000,000, to carry out such section 1971.

SEC. 520B.[290bb–33] NATIONAL CENTERS OF EXCELLENCE FOR DEPRESSION.

(a) DEPRESSIVE DISORDER DEFINED.—In this section, the term "depressive disorder" means a mental or brain disorder relating to depression, including major depression, bipolar disorder, and related mood disorders.

(b) GRANT PROGRAM.—

(1) IN GENERAL.—The Secretary, acting through the Administrator, shall award grants on a competitive basis to eligible entities to establish national centers of excellence for depression (referred to in this section as "Centers"), which shall engage in activities related to the treatment of depressive disorders.

(2) ALLOCATION OF AWARDS.—If the funds authorized under subsection (f) are appropriated in the amounts provided for under such subsection, the Secretary shall allocate such amounts so that—

(A) not later than 1 year after the date of enactment of the ENHANCED Act of 2009, not more than 20 Centers may be established; and

(B) not later than September 30, 2016, not more than 30 Centers may be established.

(3) GRANT PERIOD.—

(A) IN GENERAL.—A grant awarded under this section shall be for a period of 5 years.

(B) RENEWAL.—A grant awarded under subparagraph (A) may be renewed, on a competitive basis, for 1 additional 5-year period, at the discretion of the Secretary. In determining whether to renew a grant, the Secretary shall consider the report cards issued under subsection (e)(2).

(4) USE OF FUNDS.—Grant funds awarded under this subsection shall be used for the establishment and ongoing activities of the recipient of such funds.

(5) ELIGIBLE ENTITIES.—

(A) REQUIREMENTS.—To be eligible to receive a grant under this section, an entity shall—

(i) be an institution of higher education or a public or private nonprofit research institution; and

(ii) submit an application to the Secretary at such time and in such manner as the Secretary may require, as described in subparagraph (B).

(B) APPLICATION.—An application described in subparagraph (A)(ii) shall include—

(i) evidence that such entity—

(I) provides, or is capable of coordinating with other entities to provide, comprehensive health

services with a focus on mental health services and subspecialty expertise for depressive disorders;

(II) collaborates with other mental health providers, as necessary, to address co-occurring mental illnesses;

(III) is capable of training health professionals about mental health; and

(ii) such other information, as the Secretary may require.

(C) PRIORITIES.—In awarding grants under this section, the Secretary shall give priority to eligible entities that meet 1 or more of the following criteria:

(i) Demonstrated capacity and expertise to serve the targeted population.

(ii) Existing infrastructure or expertise to provide appropriate, evidence-based and culturally and linguistically competent services.

(iii) A location in a geographic area with disproportionate numbers of underserved and at-risk populations in medically underserved areas and health professional shortage areas.

(iv) Proposed innovative approaches for outreach to initiate or expand services.

(v) Use of the most up-to-date science, practices, and interventions available.

(vi) Demonstrated capacity to establish cooperative and collaborative agreements with community mental health centers and other community entities to provide mental health, social, and human services to individuals with depressive disorders.

(6) NATIONAL COORDINATING CENTER.—

(A) IN GENERAL.—The Secretary, acting through the Administrator, shall designate 1 recipient of a grant under this section to be the coordinating center of excellence for depression (referred to in this section as the "coordinating center"). The Secretary shall select such coordinating center on a competitive basis, based upon the demonstrated capacity of such center to perform the duties described in subparagraph (C).

(B) APPLICATION.—A Center that has been awarded a grant under paragraph (1) may apply for designation as the coordinating center by submitting an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require.

(C) DUTIES.—The coordinating center shall—

(i) develop, administer, and coordinate the network of Centers under this section;

(ii) oversee and coordinate the national database described in subsection (d);

(iii) lead a strategy to disseminate the findings and activities of the Centers through such database; and

(iv) serve as a liaison with the Administration, the National Registry of Evidence-based Programs and Practices of the Administration, and any Federal interagency or interagency forum on mental health.

(7) MATCHING FUNDS.—The Secretary may not award a grant or contract under this section to an entity unless the entity agrees that it will make available (directly or through contributions from other public or private entities) non-Federal contributions toward the activities to be carried out under the grant or contract in an amount equal to $1 for each $5 of Federal funds provided under the grant or contract. Such non-Federal matching funds may be provided directly or through donations from public or private entities and may be in cash or in-kind, fairly evaluated, including plant, equipment, or services.

(c) ACTIVITIES OF THE CENTERS.—Each Center shall carry out the following activities:

(1) GENERAL ACTIVITIES.—Each Center shall—

(A) integrate basic, clinical, or health services interdisciplinary research and practice in the development, implementation, and dissemination of evidence-based interventions;

(B) involve a broad cross-section of stakeholders, such as researchers, clinicians, consumers, families of consumers, and voluntary health organizations, to develop a research agenda and disseminate findings, and to provide support in the implementation of evidence-based practices;

(C) provide training and technical assistance to mental health professionals, and engage in and disseminate translational research with a focus on meeting the needs of individuals with depressive disorders; and

(D) educate policy makers, employers, community leaders, and the public about depressive disorders to reduce stigma and raise awareness of treatments.

(2) IMPROVED TREATMENT STANDARDS, CLINICAL GUIDELINES, DIAGNOSTIC PROTOCOLS, AND CARE COORDINATION PRACTICE.—Each Center shall collaborate with other Centers in the network to—

(A) develop and implement treatment standards, clinical guidelines, and protocols that emphasize primary prevention, early intervention, treatment for, and recovery from, depressive disorders;

(B) foster communication with other providers attending to co-occurring physical health conditions such as cardiovascular, diabetes, cancer, and substance abuse disorders;

(C) leverage available community resources, develop and implement improved self-management programs, and, when appropriate, involve family and other providers of social support in the development and implementation of care plans; and

(D) use electronic health records and telehealth technology to better coordinate and manage, and improve access to, care, as determined by the coordinating center.

(3) TRANSLATIONAL RESEARCH THROUGH COLLABORATION OF CENTERS AND COMMUNITY-BASED ORGANIZATIONS.—Each Center shall—

(A) demonstrate effective use of a public-private partnership to foster collaborations among members of the network and community-based organizations such as community mental health centers and other social and human services providers;

(B) expand interdisciplinary, translational, and patient-oriented research and treatment; and

(C) coordinate with accredited academic programs to provide ongoing opportunities for the professional and continuing education of mental health providers.

(d) NATIONAL DATABASE.—

(1) IN GENERAL.—The coordinating center shall establish and maintain a national, publicly available database to improve prevention programs, evidence-based interventions, and disease management programs for depressive disorders, using data collected from the Centers, as described in paragraph (2).

(2) DATA COLLECTION.—Each Center shall submit data gathered at such center, as appropriate, to the coordinating center regarding—

(A) the prevalence and incidence of depressive disorders;

(B) the health and social outcomes of individuals with depressive disorders;

(C) the effectiveness of interventions designed, tested, and evaluated;

(D) other information, as the Secretary may require.

(3) SUBMISSION OF DATA TO THE ADMINISTRATOR.—The coordinating center shall submit to the Administrator the data and financial information gathered under paragraph (2).

(4) PUBLICATION USING DATA FROM THE DATABASE.—A Center, or an individual affiliated with a Center, may publish findings using the data described in paragraph (2) only if such center submits such data to the coordinating center, as required under such paragraph.

(e) ESTABLISHMENT OF STANDARDS; REPORT CARDS AND RECOMMENDATIONS; THIRD PARTY REVIEW.—

(1) ESTABLISHMENT OF STANDARDS.—The Secretary, acting through the Administrator, shall establish performance standards for—

(A) each Center; and

(B) the network of Centers as a whole.

(2) REPORT CARDS.—The Secretary, acting through the Administrator, shall—

(A) for each Center, not later than 3 years after the date on which such center of excellence is established and annually thereafter, issue a report card to the coordinating center to rate the performance of such Center; and

(B) not later than 3 years after the date on which the first grant is awarded under subsection (b)(1) and annually thereafter, issue a report card to Congress to rate the per-

formance of the network of centers of excellence as a whole.

(3) RECOMMENDATIONS.—Based upon the report cards described in paragraph (2), the Secretary shall, not later than September 30, 2015—

(A) make recommendations to the Centers regarding improvements such centers shall make; and

(B) make recommendations to Congress for expanding the Centers to serve individuals with other types of mental disorders.

(4) THIRD PARTY REVIEW.—Not later than 3 years after the date on which the first grant is awarded under subsection (b)(1) and annually thereafter, the Secretary shall arrange for an independent third party to conduct an evaluation of the network of Centers to ensure that such centers are meeting the goals of this section.

(f) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—To carry out this section, there are authorized to be appropriated—

(A) $100,000,000 for each of the fiscal years 2011 through 2015; and

(B) $150,000,000 for each of the fiscal years 2016 through 2020.

(2) ALLOCATION OF FUNDS AUTHORIZED.—Of the amount appropriated under paragraph (1) for a fiscal year, the Secretary shall determine the allocation of each Center receiving a grant under this section, but in no case may the allocation be more than $5,000,000, except that the Secretary may allocate not more than $10,000,000 to the coordinating center.

SEC. 520C.[290bb–34] YOUTH INTERAGENCY RESEARCH, TRAINING, AND TECHNICAL ASSISTANCE CENTERS.

(a) PROGRAM AUTHORIZED.—The Secretary, acting through the Administrator of the Substance Abuse and Mental Health Services Administration, and in consultation with the Administrator of the Office of Juvenile Justice and Delinquency Prevention, the Director of the Bureau of Justice Assistance and the Director of the National Institutes of Health—

(1) shall award grants or contracts to public or nonprofit private entities to establish not more than four research, training, and technical assistance centers to carry out the activities described in subsection (c); and

(2) shall award a competitive grant to 1 additional research, training, and technical assistance center to carry out the activities described in subsection (d).

(b) APPLICATION.—A public or private nonprofit entity desiring a grant or contract under subsection (a) shall prepare and submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require.

(c) AUTHORIZED ACTIVITIES.—A center established under a grant or contract under subsection (a)(1) shall—

(1) provide training with respect to state-of-the-art mental health and justice-related services and successful mental health and substance abuse-justice collaborations that focus on children and adolescents, to public policymakers, law enforce-

ment administrators, public defenders, police, probation officers, judges, parole officials, jail administrators and mental health and substance abuse providers and administrators;

(2) engage in research and evaluations concerning State and local justice and mental health systems, including system redesign initiatives, and disseminate information concerning the results of such evaluations;

(3) provide direct technical assistance, including assistance provided through toll-free telephone numbers, concerning issues such as how to accommodate individuals who are being processed through the courts under the Americans with Disabilities Act of 1990 (42 U.S.C. 12101 et seq.), what types of mental health or substance abuse service approaches are effective within the judicial system, and how community-based mental health or substance abuse services can be more effective, including relevant regional, ethnic, and gender-related considerations; and

(4) provide information, training, and technical assistance to State and local governmental officials to enhance the capacity of such officials to provide appropriate services relating to mental health or substance abuse.

(d) ADDITIONAL CENTER.—The additional research, training, and technical assistance center established under subsection (a)(2) shall provide appropriate information, training, and technical assistance to States, political subdivisions of a State, Federally recognized Indian tribes, tribal organizations, institutions of higher education, public organizations, or private nonprofit organizations for—

(1) the development or continuation of statewide or tribal youth suicide early intervention and prevention strategies;

(2) ensuring the surveillance of youth suicide early intervention and prevention strategies;

(3) studying the costs and effectiveness of statewide youth suicide early intervention and prevention strategies in order to provide information concerning relevant issues of importance to State, tribal, and national policymakers;

(4) further identifying and understanding causes and associated risk factors for youth suicide;

(5) analyzing the efficacy of new and existing youth suicide early intervention techniques and technology;

(6) ensuring the surveillance of suicidal behaviors and nonfatal suicidal attempts;

(7) studying the effectiveness of State-sponsored statewide and tribal youth suicide early intervention and prevention strategies on the overall wellness and health promotion strategies related to suicide attempts;

(8) promoting the sharing of data regarding youth suicide with Federal agencies involved with youth suicide early intervention and prevention, and State-sponsored statewide or tribal youth suicide early intervention and prevention strategies for the purpose of identifying previously unknown mental health causes and associated risk factors for suicide in youth;

(9) evaluating and disseminating outcomes and best practices of mental and behavioral health services at institutions of higher education; and

(10) other activities determined appropriate by the Secretary.

(e) AUTHORIZATION OF APPROPRIATIONS.—

(1) For the purpose of awarding grants or contracts under subsection (a)(1), there is authorized to be appropriated $4,000,000 for fiscal year 2001, and such sums as may be necessary for fiscal years 2002 and 2003.

(2) For the purpose of awarding a grant under subsection (a)(2), there are authorized to be appropriated $3,000,000 for fiscal year 2005, $4,000,000 for fiscal year 2006, and $5,000,000 for fiscal year 2007.

SEC. 520D.[290bb–35] SERVICES FOR YOUTH OFFENDERS.

(a) IN GENERAL.—The Secretary, acting through the Director of the Center for Mental Health Services, and in consultation with the Director of the Center for Substance Abuse Treatment, the Administrator of the Office of Juvenile Justice and Delinquency Prevention, and the Director of the Special Education Programs, shall award grants on a competitive basis to State or local juvenile justice agencies to enable such agencies to provide aftercare services for youth offenders who have been discharged from facilities in the juvenile or criminal justice system and have serious emotional disturbances or are at risk of developing such disturbances.

(b) USE OF FUNDS.—A State or local juvenile justice agency receiving a grant under subsection (a) shall use the amounts provided under the grant—

(1) to develop a plan describing the manner in which the agency will provide services for each youth offender who has a serious emotional disturbance and has been detained or incarcerated in facilities within the juvenile or criminal justice system;

(2) to provide a network of core or aftercare services or access to such services for each youth offender, including diagnostic and evaluation services, substance abuse treatment services, outpatient mental health care services, medication management services, intensive home-based therapy, intensive day treatment services, respite care, and therapeutic foster care;

(3) to establish a program that coordinates with other State and local agencies providing recreational, social, educational, vocational, or operational services for youth, to enable the agency receiving a grant under this section to provide community-based system of care services for each youth offender that addresses the special needs of the youth and helps the youth access all of the aforementioned services; and

(4) using not more than 20 percent of funds received, to provide planning and transition services as described in paragraph (3) for youth offenders while such youth are incarcerated or detained.

(c) APPLICATION.—A State or local juvenile justice agency that desires a grant under subsection (a) shall submit an application to

the Secretary at such time, in such manner, and accompanied by such information as the Secretary may reasonably require.

(d) REPORT.—Not later than 3 years after the date of the enactment of this section and annually thereafter, the Secretary shall prepare and submit, to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Commerce of the House of Representatives, a report that describes the services provided pursuant to this section.

(e) DEFINITIONS.—In this section:

(1) SERIOUS EMOTIONAL DISTURBANCE.—The term "serious emotional disturbance" with respect to a youth offender means an offender who currently, or at any time within the 1-year period ending on the day on which services are sought under this section, has a diagnosable mental, behavioral, or emotional disorder that functionally impairs the offender's life by substantially limiting the offender's role in family, school, or community activities, and interfering with the offender's ability to achieve or maintain one or more developmentally-appropriate social, behavior, cognitive, communicative, or adaptive skills.

(2) COMMUNITY-BASED SYSTEM OF CARE.—The term "community-based system of care" means the provision of services for the youth offender by various State or local agencies that in an interagency fashion or operating as a network addresses the recreational, social, educational, vocational, mental health, substance abuse, and operational needs of the youth offender.

(3) YOUTH OFFENDER.—The term "youth offender" means an individual who is 21 years of age or younger who has been discharged from a State or local juvenile or criminal justice system, except that if the individual is between the ages of 18 and 21 years, such individual has had contact with the State or local juvenile or criminal justice system prior to attaining 18 years of age and is under the jurisdiction of such a system at the time services are sought.

(f) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $40,000,000 for fiscal year 2001, and such sums as may be necessary for each of fiscal years 2002 and 2003.

SEC. 520E.[290bb–36] YOUTH SUICIDE EARLY INTERVENTION AND PREVENTION STRATEGIES.

(a) IN GENERAL.—The Secretary, acting through the Administrator of the Substance Abuse and Mental Health Services Administration, shall award grants or cooperative agreements to eligible entities to—

(1) develop and implement State-sponsored statewide or tribal youth suicide early intervention and prevention strategies in schools, educational institutions, juvenile justice systems, substance abuse programs, mental health programs, foster care systems, and other child and youth support organizations;

(2) support public organizations and private nonprofit organizations actively involved in State-sponsored statewide or tribal youth suicide early intervention and prevention strategies and in the development and continuation of State-spon-

sored statewide youth suicide early intervention and prevention strategies;

(3) provide grants to institutions of higher education to coordinate the implementation of State-sponsored statewide or tribal youth suicide early intervention and prevention strategies;

(4) collect and analyze data on State-sponsored statewide or tribal youth suicide early intervention and prevention services that can be used to monitor the effectiveness of such services and for research, technical assistance, and policy development; and

(5) assist eligible entities, through State-sponsored statewide or tribal youth suicide early intervention and prevention strategies, in achieving targets for youth suicide reductions under title V of the Social Security Act.

(b) ELIGIBLE ENTITY.—

(1) DEFINITION.—In this section, the term "eligible entity" means—

(A) a State;

(B) a public organization or private nonprofit organization designated by a State to develop or direct the State-sponsored statewide youth suicide early intervention and prevention strategy; or

(C) a Federally recognized Indian tribe or tribal organization (as defined in the Indian Self-Determination and Education Assistance Act) or an urban Indian organization (as defined in the Indian Health Care Improvement Act) that is actively involved in the development and continuation of a tribal youth suicide early intervention and prevention strategy.

(2) LIMITATION.—In carrying out this section, the Secretary shall ensure that each State is awarded only 1 grant or cooperative agreement under this section. For purposes of the preceding sentence, a State shall be considered to have been awarded a grant or cooperative agreement if the eligible entity involved is the State or an entity designated by the State under paragraph (1)(B). Nothing in this paragraph shall be construed to apply to entities described in paragraph (1)(C).

(c) PREFERENCE.—In providing assistance under a grant or cooperative agreement under this section, an eligible entity shall give preference to public organizations, private nonprofit organizations, political subdivisions, institutions of higher education, and tribal organizations actively involved with the State-sponsored statewide or tribal youth suicide early intervention and prevention strategy that—

(1) provide early intervention and assessment services, including screening programs, to youth who are at risk for mental or emotional disorders that may lead to a suicide attempt, and that are integrated with school systems, educational institutions, juvenile justice systems, substance abuse programs, mental health programs, foster care systems, and other child and youth support organizations;

(2) demonstrate collaboration among early intervention and prevention services or certify that entities will engage in future collaboration;

(3) employ or include in their applications a commitment to evaluate youth suicide early intervention and prevention practices and strategies adapted to the local community;

(4) provide timely referrals for appropriate community-based mental health care and treatment of youth who are at risk for suicide in child-serving settings and agencies;

(5) provide immediate support and information resources to families of youth who are at risk for suicide;

(6) offer access to services and care to youth with diverse linguistic and cultural backgrounds;

(7) offer appropriate postsuicide intervention services, care, and information to families, friends, schools, educational institutions, juvenile justice systems, substance abuse programs, mental health programs, foster care systems, and other child and youth support organizations of youth who recently completed suicide;

(8) offer continuous and up-to-date information and awareness campaigns that target parents, family members, child care professionals, community care providers, and the general public and highlight the risk factors associated with youth suicide and the life-saving help and care available from early intervention and prevention services;

(9) ensure that information and awareness campaigns on youth suicide risk factors, and early intervention and prevention services, use effective communication mechanisms that are targeted to and reach youth, families, schools, educational institutions, and youth organizations;

(10) provide a timely response system to ensure that child-serving professionals and providers are properly trained in youth suicide early intervention and prevention strategies and that child-serving professionals and providers involved in early intervention and prevention services are properly trained in effectively identifying youth who are at risk for suicide;

(11) provide continuous training activities for child care professionals and community care providers on the latest youth suicide early intervention and prevention services practices and strategies;

(12) conduct annual self-evaluations of outcomes and activities, including consulting with interested families and advocacy organizations;

(13) provide services in areas or regions with rates of youth suicide that exceed the national average as determined by the Centers for Disease Control and Prevention; and

(14) obtain informed written consent from a parent or legal guardian of an at-risk child before involving the child in a youth suicide early intervention and prevention program.

(d) REQUIREMENT FOR DIRECT SERVICES.—Not less than 85 percent of grant funds received under this section shall be used to provide direct services, of which not less than 5 percent shall be used for activities authorized under subsection (a)(3).

(e) COORDINATION AND COLLABORATION.—

(1) IN GENERAL.—In carrying out this section, the Secretary shall collaborate with relevant Federal agencies and suicide working groups responsible for early intervention and prevention services relating to youth suicide.

(2) CONSULTATION.—In carrying out this section, the Secretary shall consult with—

(A) State and local agencies, including agencies responsible for early intervention and prevention services under title XIX of the Social Security Act, the State Children's Health Insurance Program under title XXI of the Social Security Act, and programs funded by grants under title V of the Social Security Act;

(B) local and national organizations that serve youth at risk for suicide and their families;

(C) relevant national medical and other health and education specialty organizations;

(D) youth who are at risk for suicide, who have survived suicide attempts, or who are currently receiving care from early intervention services;

(E) families and friends of youth who are at risk for suicide, who have survived suicide attempts, who are currently receiving care from early intervention and prevention services, or who have completed suicide;

(F) qualified professionals who possess the specialized knowledge, skills, experience, and relevant attributes needed to serve youth at risk for suicide and their families; and

(G) third-party payers, managed care organizations, and related commercial industries.

(3) POLICY DEVELOPMENT.—In carrying out this section, the Secretary shall—

(A) coordinate and collaborate on policy development at the Federal level with the relevant Department of Health and Human Services agencies and suicide working groups; and

(B) consult on policy development at the Federal level with the private sector, including consumer, medical, suicide prevention advocacy groups, and other health and education professional-based organizations, with respect to State-sponsored statewide or tribal youth suicide early intervention and prevention strategies.

(f) RULE OF CONSTRUCTION; RELIGIOUS AND MORAL ACCOMMODATION.—Nothing in this section shall be construed to require suicide assessment, early intervention, or treatment services for youth whose parents or legal guardians object based on the parents' or legal guardians' religious beliefs or moral objections.

(g) EVALUATIONS AND REPORT.—

(1) EVALUATIONS BY ELIGIBLE ENTITIES.—Not later than 18 months after receiving a grant or cooperative agreement under this section, an eligible entity shall submit to the Secretary the results of an evaluation to be conducted by the entity concerning the effectiveness of the activities carried out under the grant or agreement.

(2) REPORT.—Not later than 2 years after the date of enactment of this section, the Secretary shall submit to the appropriate committees of Congress a report concerning the results of—

(A) the evaluations conducted under paragraph (1); and

(B) an evaluation conducted by the Secretary to analyze the effectiveness and efficacy of the activities conducted with grants, collaborations, and consultations under this section.

(h) RULE OF CONSTRUCTION; STUDENT MEDICATION.—Nothing in this section or section 520E–1 shall be construed to allow school personnel to require that a student obtain any medication as a condition of attending school or receiving services.

(i) PROHIBITION.—Funds appropriated to carry out this section, section 520C, section 520E–1, or section 520E–2 shall not be used to pay for or refer for abortion.

(j) PARENTAL CONSENT.—States and entities receiving funding under this section and section 520E–1 shall obtain prior written, informed consent from the child's parent or legal guardian for assessment services, school-sponsored programs, and treatment involving medication related to youth suicide conducted in elementary and secondary schools. The requirement of the preceding sentence does not apply in the following cases:

(1) In an emergency, where it is necessary to protect the immediate health and safety of the student or other students.

(2) Other instances, as defined by the State, where parental consent cannot reasonably be obtained.

(k) RELATION TO EDUCATION PROVISIONS.—Nothing in this section or section 520E–1 shall be construed to supersede section 444 of the General Education Provisions Act, including the requirement of prior parental consent for the disclosure of any education records. Nothing in this section or section 520E–1 shall be construed to modify or affect parental notification requirements for programs authorized under the Elementary and Secondary Education Act of 1965 (as amended by the No Child Left Behind Act of 2001; Public Law 107–110).

(l) DEFINITIONS.—In this section:

(1) EARLY INTERVENTION.—The term "early intervention" means a strategy or approach that is intended to prevent an outcome or to alter the course of an existing condition.

(2) EDUCATIONAL INSTITUTION; INSTITUTION OF HIGHER EDUCATION; SCHOOL.—The term—

(A) "educational institution" means a school or institution of higher education;

(B) "institution of higher education" has the meaning given such term in section 101 of the Higher Education Act of 1965; and

(C) "school" means an elementary or secondary school (as such terms are defined in section 9101 of the Elementary and Secondary Education Act of 1965).

(3) PREVENTION.—The term "prevention" means a strategy or approach that reduces the likelihood or risk of onset, or

delays the onset, of adverse health problems that have been known to lead to suicide.

(4) YOUTH.—The term "youth" means individuals who are between 10 and 24 years of age.

(m) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—For the purpose of carrying out this section, there are authorized to be appropriated $7,000,000 for fiscal year 2005, $18,000,000 for fiscal year 2006, and $30,000,000 for fiscal year 2007.

(2) PREFERENCE.—If less than $3,500,000 is appropriated for any fiscal year to carry out this section, in awarding grants and cooperative agreements under this section during the fiscal year, the Secretary shall give preference to States that have rates of suicide that significantly exceed the national average as determined by the Centers for Disease Control and Prevention.

SEC. 520E–1.[290bb–36a] SUICIDE PREVENTION FOR CHILDREN AND ADOLESCENTS[19].

(a) IN GENERAL.—The Secretary shall award grants or cooperative agreements to public organizations, private nonprofit organizations, political subdivisions, consortia of political subdivisions, consortia of States, or Federally recognized Indian tribes or tribal organizations to design early intervention and prevention strategies that will complement the State-sponsored statewide or tribal youth suicide early intervention and prevention strategies developed pursuant to section 520E.

(b) COLLABORATION.—In carrying out subsection (a), the Secretary shall ensure that activities under this section are coordinated with the relevant Department of Health and Human Services agencies and suicide working groups.

(c) REQUIREMENTS.—A public organization, private nonprofit organization, political subdivision, consortium of political subdivisions, consortium of States, or federally recognized Indian tribe or tribal organization desiring a grant, contract, or cooperative agreement under this section shall demonstrate that the suicide prevention program such entity proposes will—

(1)(A) comply with the State-sponsored statewide early intervention and prevention strategy as developed under section 520E; and

(B) in the case of a consortium of States, receive the support of all States involved;

(2) provide for the timely assessment, treatment, or referral for mental health or substance abuse services of youth at risk for suicide;

(3) be based on suicide prevention practices and strategies that are adapted to the local community;

(4) integrate its suicide prevention program into the existing health care system in the community including general,

[19] The probable intent of the Congress is that the heading be "SUICIDE PREVENTION FOR YOUTH". See the amendment described in section 3(b)(1)(A) of Public Law 108–355 (118 Stat. 1407). The amendment cannot be executed because the matter in the heading to be struck does not appear, as the amendatory instruction used the wrong font. The amendment referred to "CHILDREN AND ADOLESCENTS" rather than "CHILDREN AND ADOLESCENTS". (The amendment is directed to section "520E". Section 520E–1 above formerly was section 520E, and was redesignated by section 3(b)(2) of such Public Law.)

mental, and behavioral health services, and substance abuse services;

(5) be integrated into other systems in the community that address the needs of youth including the school systems, educational institutions, juvenile justice system, substance abuse programs, mental health programs, foster care systems, and community child and youth support organizations;

(6) use primary prevention methods to educate and raise awareness in the local community by disseminating evidence-based information about suicide prevention;

(7) include suicide prevention, mental health, and related information and services for the families and friends of those who completed suicide, as needed;

(8) offer access to services and care to youth with diverse linguistic and cultural backgrounds;

(9) conduct annual self-evaluations of outcomes and activities, including consulting with interested families and advocacy organizations;[20]

(10) ensure that staff used in the program are trained in suicide prevention and that professionals involved in the system of care have received training in identifying persons at risk of suicide.

(d) USE OF FUNDS.—Amounts provided under a grant or cooperative agreement under this section shall be used to supplement, and not supplant, Federal and non-Federal funds available for carrying out the activities described in this section. Applicants shall provide financial information to demonstrate compliance with this section.

(e) CONDITION.—An applicant for a grant or cooperative agreement under subsection (a) shall demonstrate to the Secretary that the application complies with the State-sponsored statewide early intervention and prevention strategy as developed under section 520E and the applicant has the support of the local community and relevant public health officials.

(f) SPECIAL POPULATIONS.—In awarding grants and cooperative agreements under subsection (a), the Secretary shall ensure that such awards are made in a manner that will focus on the needs of communities or groups that experience high or rapidly rising rates of suicide.

(g) APPLICATION.—A public organization, private nonprofit organization, political subdivision, consortium of political subdivisions, consortium of States, or Federally recognized Indian tribe or tribal organization receiving a grant or cooperative agreement under subsection (a) shall prepare and submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may reasonably require. Such application shall include a plan for the rigorous evaluation of activities funded under the grant or cooperative agreement, including a process and outcome evaluation.

(h) DISTRIBUTION OF AWARDS.—In awarding grants and cooperative agreements under subsection (a), the Secretary shall ensure

[20] So in law. Probably should include "and" after the semicolon at the end of paragraph (9). See section 3(b)(1)(D)(ix) of Public Law 108–355 (118 Stat. 1408).

that such awards are distributed among the geographical regions of the United States and between urban and rural settings.

(i) EVALUATION.—A public organization, private nonprofit organization, political subdivision, consortium of political subdivisions, consortium of States, or Federally recognized Indian tribe or tribal organization receiving a grant or cooperative agreement under subsection (a) shall prepare and submit to the Secretary at the end of the program period, an evaluation of all activities funded under this section.

(j) DISSEMINATION AND EDUCATION.—The Secretary shall ensure that findings derived from activities carried out under this section are disseminated to State, county and local governmental agencies and public and private nonprofit organizations active in promoting suicide prevention and family support activities.

(k) DURATION OF PROJECTS.—With respect to a grant, contract, or cooperative agreement[21] awarded under this section, the period during which payments under such award may be made to the recipient may not exceed 3 years.

(l) STUDY.—Within 1 year after the date of the enactment of this section, the Secretary shall, directly or by grant or contract, initiate a study to assemble and analyze data to identify—

(1) unique profiles of children under 13 who attempt or complete suicide;

(2) unique profiles of youths between ages 13 and 24 who attempt or complete suicide; and

(3) a profile of services available to these groups and the use of these services by children and youths from paragraphs (1) and (2).

(m) DEFINITIONS.—In this section, the terms "early intervention", "educational institution", "institution of higher education", "prevention", "school", and "youth" have the meanings given to those terms in section 520E.

(n) AUTHORIZATION OF APPROPRIATION.—For purposes of carrying out this section, there is authorized to be appropriated $75,000,000 for fiscal year 2001 and such sums as may be necessary for each of the fiscal years 2002 through 2003.

SEC. 520E–2.[290bb–36b] MENTAL AND BEHAVIORAL HEALTH SERVICES ON CAMPUS.

(a) IN GENERAL.—The Secretary, acting through the Director of the Center for Mental Health Services, in consultation with the Secretary of Education, may award grants on a competitive basis to institutions of higher education to enhance services for students with mental and behavioral health problems that can lead to school failure, such as depression, substance abuse, and suicide attempts, so that students will successfully complete their studies.

(b) USE OF FUNDS.—The Secretary may not make a grant to an institution of higher education under this section unless the institution agrees to use the grant only for—

(1) educational seminars;

(2) the operation of hot lines;

(3) preparation of informational material;

[21] So in law. Probably should be "grant or cooperative agreement". See the amendments made by section 3(b) of Public Law 108–355 (118 Stat. 1407).

(4) preparation of educational materials for families of students to increase awareness of potential mental and behavioral health issues of students enrolled at the institution of higher education;

(5) training programs for students and campus personnel to respond effectively to students with mental and behavioral health problems that can lead to school failure, such as depression, substance abuse, and suicide attempts; or

(6) the creation of a networking infrastructure to link colleges and universities that do not have mental health services with health care providers who can treat mental and behavioral health problems.

(c) ELIGIBLE GRANT RECIPIENTS.—Any institution of higher education receiving a grant under this section may carry out activities under the grant through—

(1) college counseling centers;

(2) college and university psychological service centers;

(3) mental health centers;

(4) psychology training clinics; or

(5) institution of higher education supported, evidence-based, mental health and substance abuse programs.

(d) APPLICATION.—An institution of higher education desiring a grant under this section shall prepare and submit an application to the Secretary at such time and in such manner as the Secretary may require. At a minimum, the application shall include the following:

(1) A description of identified mental and behavioral health needs of students at the institution of higher education.

(2) A description of Federal, State, local, private, and institutional resources currently available to address the needs described in paragraph (1) at the institution of higher education.

(3) A description of the outreach strategies of the institution of higher education for promoting access to services, including a proposed plan for reaching those students most in need of mental health services.

(4) A plan to evaluate program outcomes, including a description of the proposed use of funds, the program objectives, and how the objectives will be met.

(5) An assurance that the institution will submit a report to the Secretary each fiscal year on the activities carried out with the grant and the results achieved through those activities.

(e) REQUIREMENT OF MATCHING FUNDS.—

(1) IN GENERAL.—The Secretary may make a grant under this section to an institution of higher education only if the institution agrees to make available (directly or through donations from public or private entities) non-Federal contributions in an amount that is not less than $1 for each $1 of Federal funds provided in the grant, toward the costs of activities carried out with the grant (as described in subsection (b)) and other activities by the institution to reduce student mental and behavioral health problems.

(2) DETERMINATION OF AMOUNT CONTRIBUTED.—Non-Federal contributions required under paragraph (1) may be in cash

or in kind. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

(3) WAIVER.—The Secretary may waive the requirement established in paragraph (1) with respect to an institution of higher education if the Secretary determines that extraordinary need at the institution justifies the waiver.

(f) REPORTS.—For each fiscal year that grants are awarded under this section, the Secretary shall conduct a study on the results of the grants and submit to the Congress a report on such results that includes the following:

(1) An evaluation of the grant program outcomes, including a summary of activities carried out with the grant and the results achieved through those activities.

(2) Recommendations on how to improve access to mental and behavioral health services at institutions of higher education, including efforts to reduce the incidence of suicide and substance abuse.

(g) DEFINITION.—In this section, the term "institution of higher education" has the meaning given such term in section 101 of the Higher Education Act of 1965.

(h) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $5,000,000 for fiscal year 2005, $5,000,000 for fiscal year 2006, and $5,000,000 for fiscal year 2007.

SEC. 520F.[290bb–37] GRANTS FOR EMERGENCY MENTAL HEALTH CENTERS.

(a) PROGRAM AUTHORIZED.—The Secretary shall award grants to States, political subdivisions of States, Indian tribes, and tribal organizations to support the designation of hospitals and health centers as Emergency Mental Health Centers.

(b) HEALTH CENTER.—In this section, the term "health center" has the meaning given such term in section 330, and includes community health centers and community mental health centers.

(c) DISTRIBUTION OF AWARDS.—The Secretary shall ensure that such grants awarded under subsection (a) are equitably distributed among the geographical regions of the United States, between urban and rural populations, and between different settings of care including health centers, mental health centers, hospitals, and other psychiatric units or facilities.

(d) APPLICATION.—A State, political subdivision of a State, Indian tribe, or tribal organization that desires a grant under subsection (a) shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require, including a plan for the rigorous evaluation of activities carried out with funds received under this section.

(e) USE OF FUNDS.—

(1) IN GENERAL.—A State, political subdivision of a State, Indian tribe, or tribal organization receiving a grant under subsection (a) shall use funds from such grant to establish or designate hospitals and health centers as Emergency Mental Health Centers.

(2) EMERGENCY MENTAL HEALTH CENTERS.—Such Emergency Mental Health Centers described in paragraph (1)—

(A) shall—

(i) serve as a central receiving point in the community for individuals who may be in need of emergency mental health services;

(ii) purchase, if needed, any equipment necessary to evaluate, diagnose and stabilize an individual with a mental illness;

(iii) provide training, if needed, to the medical personnel staffing the Emergency Mental Health Center to evaluate, diagnose, stabilize, and treat an individual with a mental illness; and

(iv) provide any treatment that is necessary for an individual with a mental illness or a referral for such individual to another facility where such treatment may be received; and

(B) may establish and train a mobile crisis intervention team to respond to mental health emergencies within the community.

(f) EVALUATION.—A State, political subdivision of a State, Indian tribe, or tribal organization that receives a grant under subsection (a) shall prepare and submit an evaluation to the Secretary at such time, in such manner, and containing such information as the Secretary may reasonably require, including an evaluation of activities carried out with funds received under this section and a process and outcomes evaluation.

(g) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $25,000,000 for fiscal year 2001 and such sums as may be necessary for each of the fiscal years 2002 through 2003.

SEC. 520G.[290bb–38] GRANTS FOR JAIL DIVERSION PROGRAMS.

(a) PROGRAM AUTHORIZED.—The Secretary shall make up to 125 grants to States, political subdivisions of States, Indian tribes, and tribal organizations, acting directly or through agreements with other public or nonprofit entities, to develop and implement programs to divert individuals with a mental illness from the criminal justice system to community-based services.

(b) ADMINISTRATION.—

(1) CONSULTATION.—The Secretary shall consult with the Attorney General and any other appropriate officials in carrying out this section.

(2) REGULATORY AUTHORITY.—The Secretary shall issue regulations and guidelines necessary to carry out this section, including methodologies and outcome measures for evaluating programs carried out by States, political subdivisions of States, Indian tribes, and tribal organizations receiving grants under subsection (a).

(c) APPLICATIONS.—

(1) IN GENERAL.—To receive a grant under subsection (a), the chief executive of a State, chief executive of a subdivision of a State, Indian tribe or tribal organization shall prepare and submit an application to the Secretary at such time, in such

manner, and containing such information as the Secretary shall reasonably require.

(2) CONTENT.—Such application shall—

(A) contain an assurance that—

(i) community-based mental health services will be available for the individuals who are diverted from the criminal justice system, and that such services are based on the best known practices, reflect current research findings, include case management, assertive community treatment, medication management and access, integrated mental health and co-occurring substance abuse treatment, and psychiatric rehabilitation, and will be coordinated with social services, including life skills training, housing placement, vocational training, education job placement, and health care;

(ii) there has been relevant interagency collaboration between the appropriate criminal justice, mental health, and substance abuse systems; and

(iii) the Federal support provided will be used to supplement, and not supplant, State, local, Indian tribe, or tribal organization sources of funding that would otherwise be available;

(B) demonstrate that the diversion program will be integrated with an existing system of care for those with mental illness;

(C) explain the applicant's inability to fund the program adequately without Federal assistance;

(D) specify plans for obtaining necessary support and continuing the proposed program following the conclusion of Federal support; and

(E) describe methodology and outcome measures that will be used in evaluating the program.

(d) USE OF FUNDS.—A State, political subdivision of a State, Indian tribe, or tribal organization that receives a grant under subsection (a) may use funds received under such grant to—

(1) integrate the diversion program into the existing system of care;

(2) create or expand community-based mental health and co-occurring mental illness and substance abuse services to accommodate the diversion program;

(3) train professionals involved in the system of care, and law enforcement officers, attorneys, and judges; and

(4) provide community outreach and crisis intervention.

(e) FEDERAL SHARE.—

(1) IN GENERAL.—The Secretary shall pay to a State, political subdivision of a State, Indian tribe, or tribal organization receiving a grant under subsection (a) the Federal share of the cost of activities described in the application.

(2) FEDERAL SHARE.—The Federal share of a grant made under this section shall not exceed 75 percent of the total cost of the program carried out by the State, political subdivision of a State, Indian tribe, or tribal organization. Such share shall be used for new expenses of the program carried out by such

State, political subdivision of a State, Indian tribe, or tribal organization.

(3) NON-FEDERAL SHARE.—The non-Federal share of payments made under this section may be made in cash or in kind fairly evaluated, including planned equipment or services. The Secretary may waive the requirement of matching contributions.

(f) GEOGRAPHIC DISTRIBUTION.—The Secretary shall ensure that such grants awarded under subsection (a) are equitably distributed among the geographical regions of the United States and between urban and rural populations.

(g) TRAINING AND TECHNICAL ASSISTANCE.—Training and technical assistance may be provided by the Secretary to assist a State, political subdivision of a State, Indian tribe, or tribal organization receiving a grant under subsection (a) in establishing and operating a diversion program.

(h) EVALUATIONS.—The programs described in subsection (a) shall be evaluated not less than one time in every 12-month period using the methodology and outcome measures identified in the grant application.

(i) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $10,000,000 for fiscal year 2001, and such sums as may be necessary for fiscal years 2002 through 2003.

SEC. 520H.[290bb–39] IMPROVING OUTCOMES FOR CHILDREN AND ADOLESCENTS THROUGH SERVICES INTEGRATION BETWEEN CHILD WELFARE AND MENTAL HEALTH SERVICES.

(a) IN GENERAL.—The Secretary shall award grants, contracts or cooperative agreements to States, political subdivisions of States, Indian tribes, and tribal organizations to provide integrated child welfare and mental health services for children and adolescents under 19 years of age in the child welfare system or at risk for becoming part of the system, and parents or caregivers with a mental illness or a mental illness and a co-occurring substance abuse disorder.

(b) DURATION.—With respect to a grant, contract or cooperative agreement awarded under this section, the period during which payments under such award are made to the recipient may not exceed 5 years.

(c) APPLICATION.—

(1) IN GENERAL.—To be eligible to receive an award under subsection (a), a State, political subdivision of a State, Indian tribe, or tribal organization shall submit an application to the Secretary at such time, in such manner, and accompanied by such information as the Secretary may reasonably require.

(2) CONTENT.—An application submitted under paragraph (1) shall—

(A) describe the program to be funded under the grant, contract or cooperative agreement;

(B) explain how such program reflects best practices in the provision of child welfare and mental health services; and

(C) provide assurances that—

(i) persons providing services under the grant, contract or cooperative agreement are adequately trained to provide such services; and

(ii) the services will be provided in accordance with subsection (d).

(d) USE OF FUNDS.—A State, political subdivision of a State, Indian tribe, or tribal organization that receives a grant, contract, or cooperative agreement under subsection (a) shall use amounts made available through such grant, contract or cooperative agreement to—

(1) provide family-centered, comprehensive, and coordinated child welfare and mental health services, including prevention, early intervention and treatment services for children and adolescents, and for their parents or caregivers;

(2) ensure a single point of access for such coordinated services;

(3) provide integrated mental health and substance abuse treatment for children, adolescents, and parents or caregivers with a mental illness and a co-occurring substance abuse disorder;

(4) provide training for the child welfare, mental health and substance abuse professionals who will participate in the program carried out under this section;

(5) provide technical assistance to child welfare and mental health agencies;

(6) develop cooperative efforts with other service entities in the community, including education, social services, juvenile justice, and primary health care agencies;

(7) coordinate services with services provided under the Medicaid program and the State Children's Health Insurance Program under titles XIX and XXI of the Social Security Act;

(8) provide linguistically appropriate and culturally competent services; and

(9) evaluate the effectiveness and cost-efficiency of the integrated services that measure the level of coordination, outcome measures for parents or caregivers with a mental illness or a mental illness and a co-occurring substance abuse disorder, and outcome measures for children.

(e) DISTRIBUTION OF AWARDS.—The Secretary shall ensure that grants, contracts, and cooperative agreements awarded under subsection (a) are equitably distributed among the geographical regions of the United States and between urban and rural populations.

(f) EVALUATION.—The Secretary shall evaluate each program carried out by a State, political subdivision of a State, Indian tribe, or tribal organization under subsection (a) and shall disseminate the findings with respect to each such evaluation to appropriate public and private entities.

(g) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $10,000,000 for fiscal year 2001, and such sums as may be necessary for each of fiscal years 2002 and 2003.

SEC. 520I.[290bb–40] GRANTS FOR THE INTEGRATED TREATMENT OF SERIOUS MENTAL ILLNESS AND CO-OCCURRING SUBSTANCE ABUSE.

(a) IN GENERAL.—The Secretary shall award grants, contracts, or cooperative agreements to States, political subdivisions of States, Indian tribes, tribal organizations, and private nonprofit organizations for the development or expansion of programs to provide integrated treatment services for individuals with a serious mental illness and a co-occurring substance abuse disorder.

(b) PRIORITY.—In awarding grants, contracts, and cooperative agreements under subsection (a), the Secretary shall give priority to applicants that emphasize the provision of services for individuals with a serious mental illness and a co-occurring substance abuse disorder who—

(1) have a history of interactions with law enforcement or the criminal justice system;

(2) have recently been released from incarceration;

(3) have a history of unsuccessful treatment in either an inpatient or outpatient setting;

(4) have never followed through with outpatient services despite repeated referrals; or

(5) are homeless.

(c) USE OF FUNDS.—A State, political subdivision of a State, Indian tribe, tribal organization, or private nonprofit organization that receives a grant, contract, or cooperative agreement under subsection (a) shall use funds received under such grant—

(1) to provide fully integrated services rather than serial or parallel services;

(2) to employ staff that are cross-trained in the diagnosis and treatment of both serious mental illness and substance abuse;

(3) to provide integrated mental health and substance abuse services at the same location;

(4) to provide services that are linguistically appropriate and culturally competent;

(5) to provide at least 10 programs for integrated treatment of both mental illness and substance abuse at sites that previously provided only mental health services or only substance abuse services; and

(6) to provide services in coordination with other existing public and private community programs.

(d) CONDITION.—The Secretary shall ensure that a State, political subdivision of a State, Indian tribe, tribal organization, or private nonprofit organization that receives a grant, contract, or cooperative agreement under subsection (a) maintains the level of effort necessary to sustain existing mental health and substance abuse programs for other populations served by mental health systems in the community.

(e) DISTRIBUTION OF AWARDS.—The Secretary shall ensure that grants, contracts, or cooperative agreements awarded under subsection (a) are equitably distributed among the geographical regions of the United States and between urban and rural populations.

(f) DURATION.—The Secretary shall award grants, contract, or cooperative agreements under this subsection for a period of not more than 5 years.

(g) APPLICATION.—A State, political subdivision of a State, Indian tribe, tribal organization, or private nonprofit organization that desires a grant, contract, or cooperative agreement under this subsection shall prepare and submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require. Such application shall include a plan for the rigorous evaluation of activities funded with an award under such subsection, including a process and outcomes evaluation.

(h) EVALUATION.—A State, political subdivision of a State, Indian tribe, tribal organization, or private nonprofit organization that receives a grant, contract, or cooperative agreement under this subsection shall prepare and submit a plan for the rigorous evaluation of the program funded under such grant, contract, or agreement, including both process and outcomes evaluation, and the submission of an evaluation at the end of the project period.

(i) AUTHORIZATION OF APPROPRIATION.—There is authorized to be appropriated to carry out this subsection $40,000,000 for fiscal year 2001, and such sums as may be necessary for fiscal years 2002 through 2003.

SEC. 520J.[290bb–41] TRAINING GRANTS.

(a) IN GENERAL.—The Secretary shall award grants in accordance with the provisions of this section.

(b) MENTAL ILLNESS AWARENESS TRAINING GRANTS.—

(1) IN GENERAL.—The Secretary shall award grants to States, political subdivisions of States, Indian tribes, tribal organizations, and nonprofit private entities to train teachers and other relevant school personnel to recognize symptoms of childhood and adolescent mental disorders, to refer family members to the appropriate mental health services if necessary, to train emergency services personnel to identify and appropriately respond to persons with a mental illness, and to provide education to such teachers and personnel regarding resources that are available in the community for individuals with a mental illness.

(2) EMERGENCY SERVICES PERSONNEL[22].—In this subsection, the term "emergency services personnel" includes paramedics, firefighters, and emergency medical technicians.

(3) DISTRIBUTION OF AWARDS[23].—The Secretary shall ensure that such grants awarded under this subsection are equitably distributed among the geographical regions of the United States and between urban and rural populations.

(4) APPLICATION.—A State, political subdivision of a State, Indian tribe, tribal organization, or nonprofit private entity that desires a grant under this subsection shall submit an ap-

[22] So in law. Words in the heading (except the first) probably should be all small caps. See section 3213 of Public Law 106–310 (114 Stat. 1206).

[23] Probably should be "2001 through 2003". Section 3203(b) of Public Law 106–310 (114 Stat. 1191) amended section 535(a) of this Act, which provides the authorization of appropriations for this part, by striking "1991 through 1994" and inserting "2001 through 2003". Such Public Law did not conform the reference in section 521 above.

plication to the Secretary at such time, in such manner, and containing such information as the Secretary may require, including a plan for the rigorous evaluation of activities that are carried out with funds received under a grant under this subsection.

(5) USE OF FUNDS.—A State, political subdivision of a State, Indian tribe, tribal organization, or nonprofit private entity receiving a grant under this subsection shall use funds from such grant to—

(A) train teachers and other relevant school personnel to recognize symptoms of childhood and adolescent mental disorders and appropriately respond;

(B) train emergency services personnel to identify and appropriately respond to persons with a mental illness; and

(C) provide education to such teachers and personnel regarding resources that are available in the community for individuals with a mental illness.

(6) EVALUATION.—A State, political subdivision of a State, Indian tribe, tribal organization, or nonprofit private entity that receives a grant under this subsection shall prepare and submit an evaluation to the Secretary at such time, in such manner, and containing such information as the Secretary may reasonably require, including an evaluation of activities carried out with funds received under the grant under this subsection and a process and outcome evaluation.

(7) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this subsection, $25,000,000 for fiscal year 2001 and such sums as may be necessary for each of fiscal years 2002 through 2003.

SEC. 520K.[290bb–42] AWARDS FOR CO-LOCATING PRIMARY AND SPECIALTY CARE IN COMMUNITY-BASED MENTAL HEALTH SETTINGS.

(a) DEFINITIONS.—In this section:

(1) ELIGIBLE ENTITY.—The term "eligible entity" means a qualified community mental health program defined under section 1913(b)(1).

(2) SPECIAL POPULATIONS.—The term "special populations" means adults with mental illnesses who have co-occurring primary care conditions and chronic diseases.

(b) PROGRAM AUTHORIZED.—The Secretary, acting through the Administrator shall award grants and cooperative agreements to eligible entities to establish demonstration projects for the provision of coordinated and integrated services to special populations through the co-location of primary and specialty care services in community-based mental and behavioral health settings.

(c) APPLICATION.—To be eligible to receive a grant or cooperative agreement under this section, an eligible entity shall submit an application to the Administrator at such time, in such manner, and accompanied by such information as the Administrator may require, including a description of partnerships, or other arrangements with local primary care providers, including community health centers, to provide services to special populations.

(d) USE OF FUNDS.—

(1) IN GENERAL.—For the benefit of special populations, an eligible entity shall use funds awarded under this section for—

(A) the provision, by qualified primary care professionals, of on site primary care services;

(B) reasonable costs associated with medically necessary referrals to qualified specialty care professionals, other coordinators of care or, if permitted by the terms of the grant or cooperative agreement, by qualified specialty care professionals on a reasonable cost basis on site at the eligible entity;

(C) information technology required to accommodate the clinical needs of primary and specialty care professionals; or

(D) facility modifications needed to bring primary and specialty care professionals on site at the eligible entity.

(2) LIMITATION.—Not to exceed 15 percent of grant or cooperative agreement funds may be used for activities described in subparagraphs (C) and (D) of paragraph (1).

(e) EVALUATION.—Not later than 90 days after a grant or cooperative agreement awarded under this section expires, an eligible entity shall submit to the Secretary the results of an evaluation to be conducted by the entity concerning the effectiveness of the activities carried out under the grant or agreement.

(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, $50,000,000 for fiscal year 2010 and such sums as may be necessary for each of fiscal years 2011 through 2014.

PART C—PROJECTS FOR ASSISTANCE IN TRANSITION FROM HOMELESSNESS

SEC. 521.[290cc–21] FORMULA GRANTS TO STATES.

For the purpose of carrying out section 522, the Secretary, acting through the Director of the Center for Mental Health Services, shall for each of the fiscal years 1991 through 1994 make an allotment for each State in an amount determined in accordance with section 524. The Secretary shall make payments, as grants, each such fiscal year to each State from the allotment for the State if the Secretary approves for the fiscal year involved an application submitted by the State pursuant to section 529.

SEC. 522.[290cc–22] PURPOSE OF GRANTS.

(a) IN GENERAL.—The Secretary may not make payments under section 521 unless the State involved agrees that the payments will be expended solely for making grants to political subdivisions of the State, and to nonprofit private entities (including community-based veterans organizations and other community organizations), for the purpose of providing the services specified in subsection (b) to individuals who—

(1)(A) are suffering from serious mental illness; or

(B) are suffering from serious mental illness and from substance abuse; and

(2) are homeless or at imminent risk of becoming homeless.

(b) SPECIFICATION OF SERVICES.—The services referred to in subsection (a) are—

(1) outreach services;

(2) screening and diagnostic treatment services;

(3) habilitation and rehabilitation services;

(4) community mental health services;

(5) alcohol or drug treatment services;

(6) staff training, including the training of individuals who work in shelters, mental health clinics, substance abuse programs, and other sites where homeless individuals require services;

(7) case management services, including—

(A) preparing a plan for the provision of community mental health services to the eligible homeless individual involved, and reviewing such plan not less than once every 3 months;

(B) providing assistance in obtaining and coordinating social and maintenance services for the eligible homeless individuals, including services relating to daily living activities, personal financial planning, transportation services, and habilitation and rehabilitation services, prevocational and vocational services, and housing services;

(C) providing assistance to the eligible homeless individual in obtaining income support services, including housing assistance, supplemental nutrition assistance program benefits, and supplemental security income benefits;

(D) referring the eligible homeless individual for such other services as may be appropriate; and

(E) providing representative payee services in accordance with section 1631(a)(2) of the Social Security Act if the eligible homeless individual is receiving aid under title XVI of such act and if the applicant is designated by the Secretary to provide such services;

(8) supportive and supervisory services in residential settings;

(9) referrals for primary health services, job training, educational services, and relevant housing services;

(10) subject to subsection (h)(1)—

(A) minor renovation, expansion, and repair of housing;

(B) planning of housing;

(C) technical assistance in applying for housing assistance;

(D) improving the coordination of housing services;

(E) security deposits;

(F) the costs associated with matching eligible homeless individuals with appropriate housing situations; and

(G) 1-time rental payments to prevent eviction; and

(11) other appropriate services, as determined by the Secretary.

(c) COORDINATION.—The Secretary may not make payments under section 521 unless the State involved agrees to make grants pursuant to subsection (a) only to entities that have the capacity

to provide, directly or through arrangements, the services specified in section 522(b), including coordinating the provision of services in order to meet the needs of eligible homeless individuals who are both mentally ill and suffering from substance abuse.

(d) SPECIAL CONSIDERATION REGARDING VETERANS.—The Secretary may not make payments under section 521 unless the State involved agrees that, in making grants to entities pursuant to subsection (a), the State will give special consideration to entities with a demonstrated effectiveness in serving homeless veterans.

(e) SPECIAL RULES.—The Secretary may not make payments under section 521 unless the State involved agrees that grants pursuant to subsection (a) will not be made to any entity that—

(1) has a policy of excluding individuals from mental health services due to the existence or suspicion of substance abuse; or

(2) has a policy of excluding individuals from substance abuse services due to the existence or suspicion of mental illness.

(f) ADMINISTRATIVE EXPENSES.—The Secretary may not make payments under section 521 unless the State involved agrees that not more than 4 percent of the payments will be expended for administrative expenses regarding the payments.

(g) MAINTENANCE OF EFFORT.—The Secretary may not make payments under section 521 unless the State involved agrees that the State will maintain State expenditures for services specified in subsection (b) at a level that is not less than the average level of such expenditures maintained by the State for the 2-year period preceding the fiscal year for which the State is applying to receive such payments.

(h) RESTRICTIONS ON USE OF FUNDS.—The Secretary may not make payments under section 521 unless the State involved agrees that—

(1) not more than 20 percent of the payments will be expended for housing services under subsection (b)(10); and

(2) the payments will not be expended—

(A) to support emergency shelters or construction of housing facilities;

(B) for inpatient psychiatric treatment costs or inpatient substance abuse treatment costs; or

(C) to make cash payments to intended recipients of mental health or substance abuse services.

(i) WAIVER FOR TERRITORIES.—With respect to the United States Virgin Islands, Guam, American Samoa, Palau, the Marshall Islands, and the Commonwealth of the Northern Mariana Islands, the Secretary may waive the provisions of this part that the Secretary determines to be appropriate.

SEC. 523.[290cc–23] REQUIREMENT OF MATCHING FUNDS.

(a) IN GENERAL.—The Secretary may not make payments under section 521 unless, with respect to the costs of providing services pursuant to section 522, the State involved agrees to make available, directly or through donations from public or private entities, non-Federal contributions toward such costs in an amount

that is not less than $1 for each $3 of Federal funds provided in such payments.

(b) DETERMINATION OF AMOUNT.—Non-Federal contributions required in subsection (a) may be in cash or in kind, fairly evaluated, including plant, equipment, or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, shall not be included in determining the amount of such non-Federal contributions.

(c) LIMITATION REGARDING GRANTS BY STATES.—The Secretary may not make payments under section 521 unless the State involved agrees that the State will not require the entities to which grants are provided pursuant to section 522(a) to provide non-Federal contributions in excess of the non-Federal contributions described in subsection (a).

SEC. 524.[290cc–24] DETERMINATION OF AMOUNT OF ALLOTMENT.

(a) MINIMUM ALLOTMENT.—The allotment for a State under section 521 for a fiscal year shall be the greater of—

(1) $300,000 for each of the several States, the District of Columbia, and the Commonwealth of Puerto Rico, and $50,000 for each of Guam, the Virgin Islands, American Samoa, and the Commonwealth of the Northern Mariana Islands; and

(2) an amount determined in accordance with subsection (b).

(b) DETERMINATION UNDER FORMULA.—The amount referred to in subsection (a)(2) is the product of—

(1) an amount equal to the amount appropriated under section 535(a) for the fiscal year; and

(2) a percentage equal to the quotient of—

(A) an amount equal to the population living in urbanized areas of the State involved, as indicated by the most recent data collected by the Bureau of the Census; and

(B) an amount equal to the population living in urbanized areas of the United States, as indicated by the sum of the respective amounts determined for the States under subparagraph (A).

SEC. 525.[290cc–25] CONVERSION TO CATEGORICAL PROGRAM IN EVENT OF FAILURE OF STATE REGARDING EXPENDITURE OF GRANTS.

(a) IN GENERAL.—Subject to subsection (c), the Secretary shall, from the amounts specified in subsection (b), make grants to public and nonprofit private entities for the purpose of providing to eligible homeless individuals the services specified in section 522(b).

(b)[24] SPECIFICATION OF FUNDS.—The amounts referred to in subsection (a) are any amounts made available in appropriations Acts for allotments under section 521 that are not paid to a State as a result of—

(A) the failure of the State to submit an application under section 529;

(B) the failure of the State, in the determination of the Secretary, to prepare the application in accordance with

[24] So in law. Subparagraphs (A) through (C) probably should be redesignated as paragraphs (1) through (3), respectively. See section 511 of Public Law 104–645 (104 Stat. 4729).

such section or to submit the application within a reasonable period of time; or

(C) the State informing the Secretary that the State does not intend to expend the full amount of the allotment made to the State.

(c) REQUIREMENT OF PROVISION OF SERVICES IN STATE INVOLVED.—With respect to grants under subsection (a), amounts made available under subsection (b) as a result of the State involved shall be available only for grants to provide services in such State.

SEC. 526.[290cc–26] PROVISION OF CERTAIN INFORMATION FROM STATE.

The Secretary may not make payments under section 521 to a State unless, as part of the application required in section 529, the State submits to the Secretary a statement—

(1) identifying existing programs providing services and housing to eligible homeless individuals and identify gaps in the delivery systems of such programs;

(2) containing a plan for providing services and housing to eligible homeless individuals, which plan—

(A) describes the coordinated and comprehensive means of providing services and housing to homeless individuals; and

(B) includes documentation that suitable housing for eligible homeless individuals will accompany the provision of services to such individuals;

(3) describes the source of the non-Federal contributions described in section 523;

(4) contains assurances that the non-Federal contributions described in section 523 will be available at the beginning of the grant period;

(5) describe any voucher system that may be used to carry out this part; and

(6) contain such other information or assurances as the Secretary may reasonably require.

SEC. 527.[290cc–27] DESCRIPTION OF INTENDED EXPENDITURES OF GRANT.

(a) IN GENERAL.—The Secretary may not make payments under section 521 unless—

(1) as part of the application required in section 529, the State involved submits to the Secretary a description of the intended use for the fiscal year of the amounts for which the State is applying pursuant to such section;

(2) such description identifies the geographic areas within the State in which the greatest numbers of homeless individuals with a need for mental health, substance abuse, and housing services are located;

(3) such description provides information relating to the programs and activities to be supported and services to be provided, including information relating to coordinating such programs and activities with any similar programs and activities of public and private entities; and

(4) the State agrees that such description will be revised throughout the year as may be necessary to reflect substantial changes in the programs and activities assisted by the State pursuant to section 522.

(b) OPPORTUNITY FOR PUBLIC COMMENT.—The Secretary may not make payments under section 521 unless the State involved agrees that, in developing and carrying out the description required in subsection (a), the State will provide public notice with respect to the description (including any revisions) and such opportunities as may be necessary to provide interested persons, such as family members, consumers, and mental health, substance abuse, and housing agencies, an opportunity to present comments and recommendations with respect to the description.

(c) RELATIONSHIP TO STATE COMPREHENSIVE MENTAL HEALTH SERVICES PLAN.—

(1) IN GENERAL.—The Secretary may not make payments under section 521 unless the services to be provided pursuant to the description required in subsection (a) are consistent with the State comprehensive mental health services plan required in subpart 2 of part B of title XIX.

(2) SPECIAL RULE.—The Secretary may not make payments under section 521 unless the services to be provided pursuant to the description required in subsection (a) have been considered in the preparation of, have been included in, and are consistent with, the State comprehensive mental health services plan referred to in paragraph (1).

SEC. 528.[290cc–28] REQUIREMENT OF REPORTS BY STATES.

(a) IN GENERAL.—The Secretary may not make payments under section 521 unless the State involved agrees that, by not later than January 31 of each fiscal year, the State will prepare and submit to the Secretary a report in such form and containing such information as the Secretary determines (after consultation with the Administrator of the Substance Abuse and Mental Health Services Administration) to be necessary for—

(1) securing a record and a description of the purposes for which amounts received under section 521 were expended during the preceding fiscal year and of the recipients of such amounts; and

(2) determining whether such amounts were expended in accordance with the provisions of this part.

(b) AVAILABILITY TO PUBLIC OF REPORTS.—The Secretary may not make payments under section 521 unless the State involved agrees to make copies of the reports described in subsection (a) available for public inspection.

(c) EVALUATIONS BY COMPTROLLER GENERAL.—The Administrator of the Substance Abuse and Mental Health Services Administration shall evaluate at least once every 3 years the expenditures of grants under this part by eligible entities in order to ensure that expenditures are consistent with the provisions of this part, and shall include in such evaluation recommendations regarding changes needed in program design or operations.

SEC. 529.[290cc–29] REQUIREMENT OF APPLICATION.

The Secretary may not make payments under section 521 unless the State involved—

(1) submits to the Secretary an application for the payments containing agreements and information in accordance with this part;

(2) the agreements are made through certification from the chief executive officer of the State; and

(3) the application otherwise is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this part.

SEC. 530.[290cc–30] TECHNICAL ASSISTANCE.

The Secretary, through[25] the National Institute of Mental Health, the National Institute of Alcohol Abuse and Alcoholism, and the National Institute on Drug Abuse, shall provide technical assistance to eligible entities in developing planning and operating programs in accordance with the provisions of this part.

SEC. 531.[290cc–31] FAILURE TO COMPLY WITH AGREEMENTS.

(a) REPAYMENT OF PAYMENTS.—

(1) The Secretary may, subject to subsection (c), require a State to repay any payments received by the State under section 521 that the Secretary determines were not expended by the State in accordance with the agreements required to be contained in the application submitted by the State pursuant to section 529.

(2) If a State fails to make a repayment required in paragraph (1), the Secretary may offset the amount of the repayment against the amount of any payment due to be paid to the State under section 521.

(b) WITHHOLDING OF PAYMENTS.—

(1) The Secretary may, subject to subsection (c), withhold payments due under section 521 if the Secretary determines that the State involved is not expending amounts received under such section in accordance with the agreements required to be contained in the application submitted by the State pursuant to section 529.

(2) The Secretary shall cease withholding payments from a State under paragraph (1) if the Secretary determines that there are reasonable assurances that the State will expend amounts received under section 521 in accordance with the agreements referred to in such paragraph.

(3) The Secretary may not withhold funds under paragraph (1) from a State for a minor failure to comply with the agreements referred to in such paragraph.

[25] Section 162(2) of Public Law 102–321 (106 Stat. 375) provides that section 530 is amended by striking out "through the National" and all that follows through "Abuse" and inserting in lieu thereof "through the agencies of the Administration". The amendment cannot be executed because it does not specify to which instance of the term "Abuse" the amendment applies. Additionally, section 163(a)(3) of such law described an amendment that could not be executed, as the amendment included instructions to strike "on Alcohol Abuse" while "of Alcohol Abuse" is the term in section 530. This latter amendment attempted to insert "Administrator of the Substance Abuse and Mental Health Services Administration". Subsequently, such section 163(a)(3) was struck by section 2(b)(2) of Public Law 102–352 (106 Stat. 939).

(c) OPPORTUNITY FOR HEARING.—Before requiring repayment of payments under subsection (a)(1), or withholding payments under subsection (b)(1), the Secretary shall provide to the State an opportunity for a hearing.

(d) RULE OF CONSTRUCTION.—Notwithstanding any other provision of this part, a State receiving payments under section 521 may not, with respect to any agreements required to be contained in the application submitted under section 529, be considered to be in violation of any such agreements by reason of the fact that the State, in the regular course of providing services under section 522(b) to eligible homeless individuals, incidentally provides services to homeless individuals who are not eligible homeless individuals.

SEC. 532.[290cc–32] PROHIBITION AGAINST CERTAIN FALSE STATEMENTS.

(a) IN GENERAL.—

(1) A person may not knowingly make or cause to be made any false statement or representation of a material fact in connection with the furnishing of items or services for which amounts may be paid by a State from payments received by the State under section 521.

(2) A person with knowledge of the occurrence of any event affecting the right of the person to receive any amounts from payments made to the State under section 521 may not conceal or fail to disclose any such event with the intent of securing such an amount that the person is not authorized to receive or securing such an amount in an amount greater than the amount the person is authorized to receive.

(b) CRIMINAL PENALTY FOR VIOLATION OF PROHIBITION.—Any person who violates a prohibition established in subsection (a) may for each violation be fined in accordance with title 18, United States Code, or imprisoned for not more than 5 years, or both.

SEC. 533.[290cc–33] NONDISCRIMINATION.

(a) IN GENERAL.—

(1) RULE OF CONSTRUCTION REGARDING CERTAIN CIVIL RIGHTS LAWS.—For the purpose of applying the prohibitions against discrimination on the basis of age under the Age Discrimination Act of 1975, on the basis of handicap under section 504 of the Rehabilitation Act of 1973, on the basis of sex under title IX of the Education Amendments of 1972, or on the basis of race, color, or national origin under title VI of the Civil Rights Act of 1964, programs and activities funded in whole or in part with funds made available under section 521 shall be considered to be programs and activities receiving Federal financial assistance.

(2) PROHIBITION.—No person shall on the ground of sex or religion be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any program or activity funded in whole or in part with funds made available under section 521.

(b) ENFORCEMENT.—

(1) REFERRALS TO ATTORNEY GENERAL AFTER NOTICE.—Whenever the Secretary finds that a State, or an entity that

has received a payment pursuant to section 521, has failed to comply with a provision of law referred to in subsection (a)(1), with subsection (a)(2), or with an applicable regulation (including one prescribed to carry out subsection (a)(2)), the Secretary shall notify the chief executive officer of the State and shall request the chief executive officer to secure compliance. If within a reasonable period of time, not to exceed 60 days, the chief executive officer fails or refuses to secure compliance, the Secretary may—

(A) refer the matter to the Attorney General with a recommendation that an appropriate civil action be instituted;

(B) exercise the powers and functions provided by the Age Discrimination Act of 1975, section 504 of the Rehabilitation Act of 1973, title IX of the Education Amendments of 1972, or title VI of the Civil Rights Act of 1964, as may be applicable; or

(C) take such other actions as may be authorized by law.

(2) AUTHORITY OF ATTORNEY GENERAL.—When a matter is referred to the Attorney General pursuant to paragraph (1)(A), or whenever the Attorney General has reason to believe that a State or an entity is engaged in a pattern or practice in violation of a provision of law referred to in subsection (a)(1) or in violation of subsection (a)(2), the Attorney General may bring a civil action in any appropriate district court of the United States for such relief as may be appropriate, including injunctive relief.

SEC. 534.[290cc–34] DEFINITIONS.

For purposes of this part:

(1) ELIGIBLE HOMELESS INDIVIDUAL.—The term "eligible homeless individual" means an individual described in section 522(a).

(2) HOMELESS INDIVIDUAL.—The term "homeless individual" has the meaning given such term in section 330(h)(5).

(3) STATE.—The term "State" means each of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

(4) SUBSTANCE ABUSE.—The term "substance abuse" means the abuse of alcohol or other drugs.

SEC. 535.[290cc–35] FUNDING.

(a) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this part, there is authorized to be appropriated $75,000,000 for each of the fiscal years 2001 through 2003.

(b) EFFECT OF INSUFFICIENT APPROPRIATIONS FOR MINIMUM ALLOTMENTS.—

(1) IN GENERAL.—If the amounts made available under subsection (a) for a fiscal year are insufficient for providing each State with an allotment under section 521 of not less than the applicable amount under section 524(a)(1), the Secretary shall, from such amounts as are made available under such

subsection, make grants to the States for providing to eligible homeless individuals the services specified in section 522(b).

(2) RULE OF CONSTRUCTION.—Paragraph (1) may not be construed to require the Secretary to make a grant under such paragraph to each State.

PART D—MISCELLANEOUS PROVISIONS RELATING TO SUBSTANCE ABUSE AND MENTAL HEALTH

SEC. 541.[290dd] SUBSTANCE ABUSE AMONG GOVERNMENT AND OTHER EMPLOYEES.

(a) PROGRAMS AND SERVICES.—

(1) DEVELOPMENT.—The Secretary, acting through the Administrator of the Substance Abuse and Mental Health Services Administration, shall be responsible for fostering substance abuse prevention and treatment programs and services in State and local governments and in private industry.

(2) MODEL PROGRAMS.—

(A) IN GENERAL.—Consistent with the responsibilities described in paragraph (1), the Secretary, acting through the Administrator of the Substance Abuse and Mental Health Services Administration, shall develop a variety of model programs suitable for replication on a cost-effective basis in different types of business concerns and State and local governmental entities.

(B) DISSEMINATION OF INFORMATION.—The Secretary, acting through the Administrator of the Substance Abuse and Mental Health Services Administration, shall disseminate information and materials relative to such model programs to the State agencies responsible for the administration of substance abuse prevention, treatment, and rehabilitation activities and shall, to the extent feasible provide technical assistance to such agencies as requested.

(b) DEPRIVATION OF EMPLOYMENT.—

(1) PROHIBITION.—No person may be denied or deprived of Federal civilian employment or a Federal professional or other license or right solely on the grounds of prior substance abuse.

(2) APPLICATION.—This subsection shall not apply to employment in—

(A) the Central Intelligence Agency;

(B) the Federal Bureau of Investigation;

(C) the National Security Agency;

(D) any other department or agency of the Federal Government designated for purposes of national security by the President; or

(E) in any position in any department or agency of the Federal Government, not referred to in subparagraphs (A) through (D), which position is determined pursuant to regulations prescribed by the head of such agency or department to be a sensitive position.

(3) REHABILITATION ACT.—The inapplicability of the prohibition described in paragraph (1) to the employment described in paragraph (2) shall not be construed to reflect on the applicability of the Rehabilitation Act of 1973 or other anti-discrimination laws to such employment.

(c) CONSTRUCTION.—This section shall not be construed to prohibit the dismissal from employment of a Federal civilian employee who cannot properly function in his employment.

SEC. 542.[290dd–1] ADMISSION OF SUBSTANCE ABUSERS TO PRIVATE AND PUBLIC HOSPITALS AND OUTPATIENT FACILITIES.

(a) NONDISCRIMINATION.—Substance abusers who are suffering from medical conditions shall not be discriminated against in admission or treatment, solely because of their substance abuse, by any private or public general hospital, or outpatient facility (as defined in section 1624(4)) which receives support in any form from any program supported in whole or in part by funds appropriated to any Federal department or agency.

(b) REGULATIONS.—

(1) IN GENERAL.—The Secretary shall issue regulations for the enforcement of the policy of subsection (a) with respect to the admission and treatment of substance abusers in hospitals and outpatient facilities which receive support of any kind from any program administered by the Secretary. Such regulations shall include procedures for determining (after opportunity for a hearing if requested) if a violation of subsection (a) has occurred, notification of failure to comply with such subsection, and opportunity for a violator to comply with such subsection. If the Secretary determines that a hospital or outpatient facility subject to such regulations has violated subsection (a) and such violation continues after an opportunity has been afforded for compliance, the Secretary may suspend or revoke, after opportunity for a hearing, all or part of any support of any kind received by such hospital from any program administered by the Secretary. The Secretary may consult with the officials responsible for the administration of any other Federal program from which such hospital or outpatient facility receives support of any kind, with respect to the suspension or revocation of such other Federal support for such hospital or outpatient facility.

(2) DEPARTMENT OF VETERANS AFFAIRS.—The Secretary of Veterans Affairs, acting through the Under Secretary for Health, shall, to the maximum feasible extent consistent with their responsibilities under title 38, United States Code, prescribe regulations making applicable the regulations prescribed by the Secretary under paragraph (1) to the provision of hospital care, nursing home care, domiciliary care, and medical services under such title 38 to veterans suffering from substance abuse. In prescribing and implementing regulations pursuant to this paragraph, the Secretary shall, from time to time, consult with the Secretary of Health and Human Services in order to achieve the maximum possible coordination of the regulations, and the implementation thereof, which they each prescribe.

SEC. 543.[290dd–2] CONFIDENTIALITY OF RECORDS.

(a) REQUIREMENT.—Records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any program or activity relating to substance abuse education, prevention, training, treatment, reha-

bilitation, or research, which is conducted, regulated, or directly or indirectly assisted by any department or agency of the United States shall, except as provided in subsection (e), be confidential and be disclosed only for the purposes and under the circumstances expressly authorized under subsection (b).

(b) PERMITTED DISCLOSURE.—

(1) CONSENT.—The content of any record referred to in subsection (a) may be disclosed in accordance with the prior written consent of the patient with respect to whom such record is maintained, but only to such extent, under such circumstances, and for such purposes as may be allowed under regulations prescribed pursuant to subsection (g).

(2) METHOD FOR DISCLOSURE.—Whether or not the patient, with respect to whom any given record referred to in subsection (a) is maintained, gives written consent, the content of such record may be disclosed as follows:

(A) To medical personnel to the extent necessary to meet a bona fide medical emergency.

(B) To qualified personnel for the purpose of conducting scientific research, management audits, financial audits, or program evaluation, but such personnel may not identify, directly or indirectly, any individual patient in any report of such research, audit, or evaluation, or otherwise disclose patient identities in any manner.

(C) If authorized by an appropriate order of a court of competent jurisdiction granted after application showing good cause therefor, including the need to avert a substantial risk of death or serious bodily harm. In assessing good cause the court shall weigh the public interest and the need for disclosure against the injury to the patient, to the physician-patient relationship, and to the treatment services. Upon the granting of such order, the court, in determining the extent to which any disclosure of all or any part of any record is necessary, shall impose appropriate safeguards against unauthorized disclosure.

(c) USE OF RECORDS IN CRIMINAL PROCEEDINGS.—Except as authorized by a court order granted under subsection (b)(2)(C), no record referred to in subsection (a) may be used to initiate or substantiate any criminal charges against a patient or to conduct any investigation of a patient.

(d) APPLICATION.—The prohibitions of this section continue to apply to records concerning any individual who has been a patient, irrespective of whether or when such individual ceases to be a patient.

(e) NONAPPLICABILITY.—The prohibitions of this section do not apply to any interchange of records—

(1) within the Uniformed Services or within those components of the Department of Veterans Affairs furnishing health care to veterans; or

(2) between such components and the Uniformed Services.

The prohibitions of this section do not apply to the reporting under State law of incidents of suspected child abuse and neglect to the appropriate State or local authorities.

(f) PENALTIES.—Any person who violates any provision of this section or any regulation issued pursuant to this section shall be fined in accordance with title 18, United States Code.

(g) REGULATIONS.—Except as provided in subsection (h), the Secretary shall prescribe regulations to carry out the purposes of this section. Such regulations may contain such definitions, and may provide for such safeguards and procedures, including procedures and criteria for the issuance and scope of orders under subsection (b)(2)(C), as in the judgment of the Secretary are necessary or proper to effectuate the purposes of this section, to prevent circumvention or evasion thereof, or to facilitate compliance therewith.

(h) APPLICATION TO DEPARTMENT OF VETERANS AFFAIRS.—The Secretary of Veterans Affairs, acting through the Chief Medical Director, shall, to the maximum feasible extent consistent with their responsibilities under title 38, United States Code, prescribe regulations making applicable the regulations prescribed by the Secretary of Health and Human Services under subsection (g) of this section to records maintained in connection with the provision of hospital care, nursing home care, domiciliary care, and medical services under such title 38 to veterans suffering from substance abuse. In prescribing and implementing regulations pursuant to this subsection, the Secretary of Veterans Affairs shall, from time to time, consult with the Secretary of Health and Human Services in order to achieve the maximum possible coordination of the regulations, and the implementation thereof, which they each prescribe.

PART E—CHILDREN WITH SERIOUS EMOTIONAL DISTURBANCES

SEC. 561.[290ff] COMPREHENSIVE COMMUNITY MENTAL HEALTH SERVICES FOR CHILDREN WITH SERIOUS EMOTIONAL DISTURBANCES.

(a) GRANTS TO CERTAIN PUBLIC ENTITIES.—

(1) IN GENERAL.—The Secretary, acting through the Director of the Center for Mental Health Services, shall make grants to public entities for the purpose of providing comprehensive community mental health services to children with a serious emotional disturbance.

(2) DEFINITION OF PUBLIC ENTITY.—For purposes of this part, the term "public entity" means any State, any political subdivision of a State, and any Indian tribe or tribal organization (as defined in section 4(b) and section 4(c) of the Indian Self-Determination and Education Assistance Act).

(b) CONSIDERATIONS IN MAKING GRANTS.—

(1) REQUIREMENT OF STATUS AS GRANTEE UNDER PART B OF TITLE XIX.—The Secretary may make a grant under subsection (a) to a public entity only if—

(A) in the case of a public entity that is a State, the State is such a grantee under section 1911;

(B) in the case of a public entity that is a political subdivision of a State, the State in which the political subdivision is located is such a grantee; and

(C) in the case of a public entity that is an Indian tribe or tribal organization, the State in which the tribe or tribal organization is located is such a grantee.

(2) REQUIREMENT OF STATUS AS MEDICAID PROVIDER.—

(A) Subject to subparagraph (B), the Secretary may make a grant under subsection (a) only if, in the case of any service under such subsection that is covered in the State plan approved under title XIX of the Social Security Act for the State involved—

(i) the public entity involved will provide the service directly, and the entity has entered into a participation agreement under the State plan and is qualified to receive payments under such plan; or

(ii) the public entity will enter into an agreement with an organization under which the organization will provide the service, and the organization has entered into such a participation agreement and is qualified to receive such payments.

(B)(i) In the case of an organization making an agreement under subparagraph (A)(ii) regarding the provision of services under subsection (a), the requirement established in such subparagraph regarding a participation agreement shall be waived by the Secretary if the organization does not, in providing health or mental health services, impose a charge or accept reimbursement available from any third-party payor, including reimbursement under any insurance policy or under any Federal or State health benefits program.

(ii) A determination by the Secretary of whether an organization referred to in clause (i) meets the criteria for a waiver under such clause shall be made without regard to whether the organization accepts voluntary donations regarding the provision of services to the public.

(3) CERTAIN CONSIDERATIONS.—In making grants under subsection (a), the Secretary shall—

(A) equitably allocate such assistance among the principal geographic regions of the United States;

(B) consider the extent to which the public entity involved has a need for the grant; and

(C) in the case of any public entity that is a political subdivision of a State or that is an Indian tribe or tribal organization—

(i) shall consider any comments regarding the application of the entity for such a grant that are received by the Secretary from the State in which the entity is located; and

(ii) shall give special consideration to the entity if the State agrees to provide a portion of the non-Federal contributions required in subsection (c) regarding such a grant.

(c) MATCHING FUNDS.—

(1) IN GENERAL.—A funding agreement for a grant under subsection (a) is that the public entity involved will, with respect to the costs to be incurred by the entity in carrying out the purpose described in such subsection, make available (directly or through donations from public or private entities)

non-Federal contributions toward such costs in an amount that—

(A) for the first fiscal year for which the entity receives payments from a grant under such subsection, is not less than $1 for each $3 of Federal funds provided in the grant;

(B) for any second or third such fiscal year, is not less than $1 for each $3 of Federal funds provided in the grant;

(C) for any fourth such fiscal year, is not less than $1 for each $1 of Federal funds provided in the grant; and

(D) for any fifth and sixth such fiscal year, is not less than $2 for each $1 of Federal funds provided in the grant.

(2) DETERMINATION OF AMOUNT CONTRIBUTED.—

(A) Non-Federal contributions required in paragraph (1) may be in cash or in kind, fairly evaluated, including plant, equipment, or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

(B) In making a determination of the amount of non-Federal contributions for purposes of subparagraph (A), the Secretary may include only non-Federal contributions in excess of the average amount of non-Federal contributions made by the public entity involved toward the purpose described in subsection (a) for the 2-year period preceding the first fiscal year for which the entity receives a grant under such section.

SEC. 562.[290ff–1] REQUIREMENTS WITH RESPECT TO CARRYING OUT PURPOSE OF GRANTS.

(a) SYSTEMS OF COMPREHENSIVE CARE.—

(1) IN GENERAL.—A funding agreement for a grant under section 561(a) is that, with respect to children with a serious emotional disturbance, the public entity involved will carry out the purpose described in such section only through establishing and operating 1 or more systems of care for making each of the mental health services specified in subsection (c) available to each child provided access to the system. In providing for such a system, the public entity may make grants to, and enter into contracts with, public and nonprofit private entities.

(2) STRUCTURE OF SYSTEM.—A funding agreement for a grant under section 561(a) is that a system of care under paragraph (1) will—

(A) be established in a community selected by the public entity involved;

(B) consist of such public agencies and nonprofit private entities in the community as are necessary to ensure that each of the services specified in subsection (c) is available to each child provided access to the system;

(C) be established pursuant to agreements that the public entity enters into with the agencies and entities described in subparagraph (B);

(D) coordinate the provision of the services of the system; and

(E) establish an office whose functions are to serve as the location through which children are provided access to the system, to coordinate the provision of services of the system, and to provide information to the public regarding the system.

(3) COLLABORATION OF LOCAL PUBLIC ENTITIES.—A funding agreement for a grant under section 561(a) is that, for purposes of the establishment and operation of a system of care under paragraph (1), the public entity involved will seek collaboration among all public agencies that provide human services in the community in which the system is established, including but not limited to those providing mental health services, educational services, child welfare services, or juvenile justice services.

(b) LIMITATION ON AGE OF CHILDREN PROVIDED ACCESS TO SYSTEM.—A funding agreement for a grant under section 561(a) is that a system of care under subsection (a) will not provide an individual with access to the system if the individual is more than 21 years of age.

(c) REQUIRED MENTAL HEALTH SERVICES OF SYSTEM.—A funding agreement for a grant under section 561(a) is that mental health services provided by a system of care under subsection (a) will include, with respect to a serious emotional disturbance in a child—

(1) diagnostic and evaluation services;

(2) outpatient services provided in a clinic, office, school or other appropriate location, including individual, group and family counseling services, professional consultation, and review and management of medications;

(3) emergency services, available 24-hours a day, 7 days a week;

(4) intensive home-based services for children and their families when the child is at imminent risk of out-of-home placement;

(5) intensive day-treatment services;

(6) respite care;

(7) therapeutic foster care services, and services in therapeutic foster family homes or individual therapeutic residential homes, and groups homes caring for not more than 10 children; and

(8) assisting the child in making the transition from the services received as a child to the services to be received as an adult.

(d) REQUIRED ARRANGEMENTS REGARDING OTHER APPROPRIATE SERVICES.—

(1) IN GENERAL.—A funding agreement for a grant under section 561(a) is that—

(A) a system of care under subsection (a) will enter into a memorandum of understanding with each of the providers specified in paragraph (2) in order to facilitate the availability of the services of the provider involved to each child provided access to the system; and

(B) the grant under such section 561(a), and the non-Federal contributions made with respect to the grant, will

not be expended to pay the costs of providing such non-mental health services to any individual.

(2) SPECIFICATION OF NON-MENTAL HEALTH SERVICES.—The providers referred to in paragraph (1) are providers of medical services other than mental health services, providers of educational services, providers of vocational counseling and vocational rehabilitation services, and providers of protection and advocacy services with respect to mental health.

(3) FACILITATION OF SERVICES OF CERTAIN PROGRAMS.—A funding agreement for a grant under section 561(a) is that a system of care under subsection (a) will, for purposes of paragraph (1), enter into a memorandum of understanding regarding facilitation of—

(A) services available pursuant to title XIX of the Social Security Act, including services regarding early periodic screening, diagnosis, and treatment;

(B) services available under parts B and C of the Individuals with Disabilities Education Act; and

(C) services available under other appropriate programs, as identified by the Secretary.

(e) GENERAL PROVISIONS REGARDING SERVICES OF SYSTEM.—

(1) CASE MANAGEMENT SERVICES.—A funding agreement for a grant under section 561(a) is that a system of care under subsection (a) will provide for the case management of each child provided access to the system in order to ensure that—

(A) the services provided through the system to the child are coordinated and that the need of each such child for the services is periodically reassessed;

(B) information is provided to the family of the child on the extent of progress being made toward the objectives established for the child under the plan of services implemented for the child pursuant to section 563; and

(C) the system provides assistance with respect to—

(i) establishing the eligibility of the child, and the family of the child, for financial assistance and services under Federal, State, or local programs providing for health services, mental health services, educational services, social services, or other services; and

(ii) seeking to ensure that the child receives appropriate services available under such programs.

(2) OTHER PROVISIONS.—A funding agreement for a grant under section 561(a) is that a system of care under subsection (a), in providing the services of the system, will—

(A) provide the services of the system in the cultural context that is most appropriate for the child and family involved;

(B) ensure that individuals providing such services to the child can effectively communicate with the child and family in the most direct manner;

(C) provide the services without discriminating against the child or the family of the child on the basis of race, religion, national origin, sex, disability, or age;

(D) seek to ensure that each child provided access to the system of care remains in the least restrictive, most normative environment that is clinically appropriate; and

(E) provide outreach services to inform individuals, as appropriate, of the services available from the system, including identifying children with a serious emotional disturbance who are in the early stages of such disturbance.

(3) RULE OF CONSTRUCTION.—An agreement made under paragraph (2) may not be construed—

(A) with respect to subparagraph (C) of such paragraph—

(i) to prohibit a system of care under subsection (a) from requiring that, in housing provided by the grantee for purposes of residential treatment services authorized under subsection (c), males and females be segregated to the extent appropriate in the treatment of the children involved; or

(ii) to prohibit the system of care from complying with the agreement made under subsection (b); or

(B) with respect to subparagraph (D) of such paragraph, to authorize the system of care to expend the grant under section 561(a) (or the non-Federal contributions made with respect to the grant) to provide legal services or any service with respect to which expenditures regarding the grant are prohibited under subsection (d)(1)(B).

(f) RESTRICTIONS ON USE OF GRANT.—A funding agreement for a grant under section 561(a) is that the grant, and the non-Federal contributions made with respect to the grant, will not be expended—

(1) to purchase or improve real property (including the construction or renovation of facilities);

(2) to provide for room and board in residential programs serving 10 or fewer children;

(3) to provide for room and board or other services or expenditures associated with care of children in residential treatment centers serving more than 10 children or in inpatient hospital settings, except intensive home-based services and other services provided on an ambulatory or outpatient basis; or

(4) to provide for the training of any individual, except training authorized in section 564(a)(2) and training provided through any appropriate course in continuing education whose duration does not exceed 2 days.

(g) WAIVERS.—The Secretary may waive one or more of the requirements of subsection (c) for a public entity that is an Indian Tribe or tribal organization, or American Samoa, Guam, the Marshall Islands, the Federated States of Micronesia, the Commonwealth of the Northern Mariana Islands, the Republic of Palau, or the United States Virgin Islands if the Secretary determines, after peer review, that the system of care is family-centered and uses the least restrictive environment that is clinically appropriate.

SEC. 563.[290ff–2] INDIVIDUALIZED PLAN FOR SERVICES.

(a) IN GENERAL.—A funding agreement for a grant under section 561(a) is that a system of care under section 562(a) will develop and carry out an individualized plan of services for each child provided access to the system, and that the plan will be developed and carried out with the participation of the family of the child and, unless clinically inappropriate, with the participation of the child.

(b) MULTIDISCIPLINARY TEAM.—A funding agreement for a grant under section 561(a) is that the plan required in subsection (a) will be developed, and reviewed and as appropriate revised not less than once each year, by a multidisciplinary team of appropriately qualified individuals who provide services through the system, including as appropriate mental health services, other health services, educational services, social services, and vocational counseling and rehabilitation;[26]

(c) COORDINATION WITH SERVICES UNDER INDIVIDUALS WITH DISABILITIES EDUCATION ACT.—A funding agreement for a grant under section 561(a) is that, with respect to a plan under subsection (a) for a child, the multidisciplinary team required in subsection (b) will—

(1) in developing, carrying out, reviewing, and revising the plan consider any individualized education program in effect for the child pursuant to part B of the Individuals with Disabilities Education Act;

(2) ensure that the plan is consistent with such individualized education program and provides for coordinating services under the plan with services under such program; and

(3) ensure that the memorandum of understanding entered into under section 562(d)(3)(B) regarding such Act includes provisions regarding compliance with this subsection.

(d) CONTENTS OF PLAN.—A funding agreement for a grant under section 561(a) is that the plan required in subsection (a) for a child will—

(1) identify and state the needs of the child for the services available pursuant to section 562 through the system;

(2) provide for each of such services that is appropriate to the circumstances of the child, including, except in the case of children who are less than 14 years of age, the provision of appropriate vocational counseling and rehabilitation, and transition services (as defined in section 602 of the Individuals with Disabilities Education Act);

(3) establish objectives to be achieved regarding the needs of the child and the methodology for achieving the objectives; and

(4) designate an individual to be responsible for providing the case management required in section 562(e)(1) or certify that case management services will be provided to the child as part of the individualized education program of the child under the Individuals with Disabilities Education Act.

[26] So in law. See section 119 of Public Law 102–321 (106 Stat. 349). Probably should be a period.

SEC. 564.[290ff–3] ADDITIONAL PROVISIONS.

(a) OPTIONAL SERVICES.—In addition to services described in subsection (c) of section 562, a system of care under subsection (a) of such section may, in expending a grant under section 561(a), provide for—

(1) preliminary assessments to determine whether a child should be provided access to the system;

(2) training in—

(A) the administration of the system;

(B) the provision of intensive home-based services under paragraph (4) of section 562(c), intensive day treatment under paragraph (5) of such section, and foster care or group homes under paragraph (7) of such section; and

(C) the development of individualized plans for purposes of section 563;

(3) recreational activities for children provided access to the system; and

(4) such other services as may be appropriate in providing for the comprehensive needs with respect to mental health of children with a serious emotional disturbance.

(b) COMPREHENSIVE PLAN.—The Secretary may make a grant under section 561(a) only if, with respect to the jurisdiction of the public entity involved, the entity has submitted to the Secretary, and has had approved by the Secretary, a plan for the development of a jurisdiction-wide system of care for community-based services for children with a serious emotional disturbance that specifies the progress the public entity has made in developing the jurisdiction-wide system, the extent of cooperation across agencies serving children in the establishment of the system, the Federal and non-Federal resources currently committed to the establishment of the system, and the current gaps in community services and the manner in which the grant under section 561(a) will be expended to address such gaps and establish local systems of care.

(c) LIMITATION ON IMPOSITION OF FEES FOR SERVICES.—A funding agreement for a grant under section 561(a) is that, if a charge is imposed for the provision of services under the grant, such charge—

(1) will be made according to a schedule of charges that is made available to the public;

(2) will be adjusted to reflect the income of the family of the child involved; and

(3) will not be imposed on any child whose family has income and resources of equal to or less than 100 percent of the official poverty line, as established by the Director of the Office of Management and Budget and revised by the Secretary in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1981.

(d) RELATIONSHIP TO ITEMS AND SERVICES UNDER OTHER PROGRAMS.—A funding agreement for a grant under section 561(a) is that the grant, and the non-Federal contributions made with respect to the grant, will not be expended to make payment for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to such item or service—

(1) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program; or

(2) by an entity that provides health services on a prepaid basis.

(e) LIMITATION ON ADMINISTRATIVE EXPENSES.—A funding agreement for a grant under section 561(a) is that not more than 2 percent of the grant will be expended for administrative expenses incurred with respect to the grant by the public entity involved.

(f) REPORTS TO SECRETARY.—A funding agreement for a grant under section 561(a) is that the public entity involved will annually submit to the Secretary a report on the activities of the entity under the grant that includes a description of the number of children provided access to systems of care operated pursuant to the grant, the demographic characteristics of the children, the types and costs of services provided pursuant to the grant, the availability and use of third-party reimbursements, estimates of the unmet need for such services in the jurisdiction of the entity, and the manner in which the grant has been expended toward the establishment of a jurisdiction-wide system of care for children with a serious emotional disturbance, and such other information as the Secretary may require with respect to the grant.

(g) DESCRIPTION OF INTENDED USES OF GRANT.—The Secretary may make a grant under section 561(a) only if—

(1) the public entity involved submits to the Secretary a description of the purposes for which the entity intends to expend the grant;

(2) the description identifies the populations, areas, and localities in the jurisdiction of the entity with a need for services under this section; and

(3) the description provides information relating to the services and activities to be provided, including a description of the manner in which the services and activities will be coordinated with any similar services or activities of public or nonprofit entities.

(h) REQUIREMENT OF APPLICATION.—The Secretary may make a grant under section 561(a) only if an application for the grant is submitted to the Secretary, the application contains the description of intended uses required in subsection (g), and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

SEC. 565.[290ff–4] GENERAL PROVISIONS.

(a) DURATION OF SUPPORT.—The period during which payments are made to a public entity from a grant under section 561(a) may not exceed 6 fiscal years.

(b) TECHNICAL ASSISTANCE.—

(1) IN GENERAL.—The Secretary shall, upon the request of a public entity receiving a grant under section 561(a)—

(A) provide technical assistance to the entity regarding the process of submitting to the Secretary applications for grants under section 561(a); and

(B) provide to the entity training and technical assistance with respect to the planning, development, and operation of systems of care pursuant to section 562.

(2) AUTHORITY FOR GRANTS AND CONTRACTS.—The Secretary may provide technical assistance under subsection (a) directly or through grants to, or contracts with, public and nonprofit private entities.

(c) EVALUATIONS AND REPORTS BY SECRETARY.—

(1) IN GENERAL.—The Secretary shall, directly or through contracts with public or private entities, provide for annual evaluations of programs carried out pursuant to section 561(a). The evaluations shall assess the effectiveness of the systems of care operated pursuant to such section, including longitudinal studies of outcomes of services provided by such systems, other studies regarding such outcomes, the effect of activities under this part on the utilization of hospital and other institutional settings, the barriers to and achievements resulting from interagency collaboration in providing community-based services to children with a serious emotional disturbance, and assessments by parents of the effectiveness of the systems of care.

(2) REPORT TO CONGRESS.—The Secretary shall, not later than 1 year after the date on which amounts are first appropriated under subsection (c), and annually thereafter, submit to the Congress a report summarizing evaluations carried out pursuant to paragraph (1) during the preceding fiscal year and making such recommendations for administrative and legislative initiatives with respect to this section as the Secretary determines to be appropriate.

(d) DEFINITIONS.—For purposes of this part:

(1) The term "child" means an individual not more than 21 years of age.

(2) The term "family", with respect to a child provided access to a system of care under section 562(a), means—

(A) the legal guardian of the child; and

(B) as appropriate regarding mental health services for the child, the parents of the child (biological or adoptive, as the case may be) and any foster parents of the child.

(3) The term "funding agreement", with respect to a grant under section 561(a) to a public entity, means that the Secretary may make such a grant only if the public entity makes the agreement involved.

(4) The term "serious emotional disturbance" includes, with respect to a child, any child who has a serious emotional disorder, a serious behavioral disorder, or a serious mental disorder.

(e) RULE OF CONSTRUCTION.—Nothing in this part shall be construed as limiting the rights of a child with a serious emotional disturbance under the Individuals with Disabilities Education Act.

(f) FUNDING.—

(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this part, there are authorized to be appropriated $100,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 and 2003.

(2)[27] LIMITATION REGARDING TECHNICAL ASSISTANCE.—Not more than 10 percent of the amounts appropriated under paragraph (1) for a fiscal year may be expended for carrying out subsection (b).

PART F—MODEL COMPREHENSIVE PROGRAM FOR TREATMENT OF SUBSTANCE ABUSE[28]

PART G[29]—PROJECTS FOR CHILDREN AND VIOLENCE

SEC. 581.[290hh] CHILDREN AND VIOLENCE.

(a) IN GENERAL.—The Secretary, in consultation with the Secretary of Education and the Attorney General, shall carry out directly or through grants, contracts or cooperative agreements with public entities a program to assist local communities in developing ways to assist children in dealing with violence.

(b) ACTIVITIES.—Under the program under subsection (a), the Secretary may—

(1) provide financial support to enable local communities to implement programs to foster the health and development of children;

(2) provide technical assistance to local communities with respect to the development of programs described in paragraph (1);

(3) provide assistance to local communities in the development of policies to address violence when and if it occurs;

(4) assist in the creation of community partnerships among law enforcement, education systems and mental health and substance abuse service systems; and

(5) establish mechanisms for children and adolescents to report incidents of violence or plans by other children or adolescents to commit violence.

(c) REQUIREMENTS.—An application for a grant, contract or cooperative agreement under subsection (a) shall demonstrate that—

(1) the applicant will use amounts received to create a partnership described in subsection (b)(4) to address issues of violence in schools;

(2) the activities carried out by the applicant will provide a comprehensive method for addressing violence, that will include—

(A) security;

(B) educational reform;

(C) the review and updating of school policies;

(D) alcohol and drug abuse prevention and early intervention services;

(E) mental health prevention and treatment services; and

[27] Indentation is so in law. See section 2017(2)(C)(ii) of Public Law 103–43 (107 Stat. 218).

[28] The part designation and heading for part F are so in law. Part F formerly consisted of section 571. That section was repealed by section 3301(c)(4) of Public Law 106–310 (114 Stat. 1209), but there was no conforming amendment to strike the designation and heading for part F.

[29] There is another part G in this title, which also begins with a section 581. See page 677. That part G relates to services provided through religious organizations.

(F) early childhood development and psychosocial services; and

(3) the applicant will use amounts received only for the services described in subparagraphs (D), (E), and (F) of paragraph (2).

(d) GEOGRAPHICAL DISTRIBUTION.—The Secretary shall ensure that grants, contracts or cooperative agreements under subsection (a) will be distributed equitably among the regions of the country and among urban and rural areas.

(e) DURATION OF AWARDS.—With respect to a grant, contract or cooperative agreement under subsection (a), the period during which payments under such an award will be made to the recipient may not exceed 5 years.

(f) EVALUATION.—The Secretary shall conduct an evaluation of each project carried out under this section and shall disseminate the results of such evaluations to appropriate public and private entities.

(g) INFORMATION AND EDUCATION.—The Secretary shall establish comprehensive information and education programs to disseminate the findings of the knowledge development and application under this section to the general public and to health care professionals.

(h) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $100,000,000 for fiscal year 2001, and such sums as may be necessary for each of fiscal years 2002 and 2003.

SEC. 582.[290hh–1] GRANTS TO ADDRESS THE PROBLEMS OF PERSONS WHO EXPERIENCE VIOLENCE RELATED STRESS.

(a) IN GENERAL.—The Secretary shall award grants, contracts or cooperative agreements to public and nonprofit private entities, as well as to Indian tribes and tribal organizations, for the purpose of developing programs focusing on the behavioral and biological aspects of psychological trauma response and for developing knowledge with regard to evidence-based practices for treating psychiatric disorders of children and youth resulting from witnessing or experiencing a traumatic event.

(b) PRIORITIES.—In awarding grants, contracts or cooperative agreements under subsection (a) related to the development of knowledge on evidence-based practices for treating disorders associated with psychological trauma, the Secretary shall give priority to mental health agencies and programs that have established clinical and basic research experience in the field of trauma-related mental disorders.

(c) GEOGRAPHICAL DISTRIBUTION.—The Secretary shall ensure that grants, contracts or cooperative agreements under subsection (a) with respect to centers of excellence are distributed equitably among the regions of the country and among urban and rural areas.

(d) EVALUATION.—The Secretary, as part of the application process, shall require that each applicant for a grant, contract or cooperative agreement under subsection (a) submit a plan for the rigorous evaluation of the activities funded under the grant, contract or agreement, including both process and outcomes evalua-

tion, and the submission of an evaluation at the end of the project period.

(e) DURATION OF AWARDS.—With respect to a grant, contract or cooperative agreement under subsection (a), the period during which payments under such an award will be made to the recipient may not exceed 5 years. Such grants, contracts or agreements may be renewed.

(f) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $50,000,000 for fiscal year 2001, and such sums as may be necessary for each of fiscal years 2003 through 2006.

(g) SHORT TITLE.—This section may be cited as the "Donald J. Cohen National Child Traumatic Stress Initiative".

PART H—REQUIREMENT RELATING TO THE RIGHTS OF RESIDENTS OF CERTAIN FACILITIES

SEC. 591.[290ii] REQUIREMENT RELATING TO THE RIGHTS OF RESIDENTS OF CERTAIN FACILITIES.

(a) IN GENERAL.—A public or private general hospital, nursing facility, intermediate care facility, or other health care facility, that receives support in any form from any program supported in whole or in part with funds appropriated to any Federal department or agency shall protect and promote the rights of each resident of the facility, including the right to be free from physical or mental abuse, corporal punishment, and any restraints or involuntary seclusions imposed for purposes of discipline or convenience.

(b) REQUIREMENTS.—Restraints and seclusion may only be imposed on a resident of a facility described in subsection (a) if—

(1) the restraints or seclusion are imposed to ensure the physical safety of the resident, a staff member, or others; and

(2) the restraints or seclusion are imposed only upon the written order of a physician, or other licensed practitioner permitted by the State and the facility to order such restraint or seclusion, that specifies the duration and circumstances under which the restraints are to be used (except in emergency circumstances specified by the Secretary until such an order could reasonably be obtained).

(c) CURRENT LAW.—This part shall not be construed to affect or impede any Federal or State law or regulations that provide greater protections than this part regarding seclusion and restraint.

(d) DEFINITIONS.—In this section:

(1) RESTRAINTS.—The term "restraints" means—

(A) any physical restraint that is a mechanical or personal restriction that immobilizes or reduces the ability of an individual to move his or her arms, legs, or head freely, not including devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or any other methods that involves the physical holding of a resident for the purpose of conducting routine physical examinations or tests or to protect the resident from fall-

ing out of bed or to permit the resident to participate in activities without the risk of physical harm to the resident (such term does not include a physical escort); and

(B) a drug or medication that is used as a restraint to control behavior or restrict the resident's freedom of movement that is not a standard treatment for the resident's medical or psychiatric condition.

(2) SECLUSION.—The term "seclusion" means a behavior control technique involving locked isolation. Such term does not include a time out.

(3) PHYSICAL ESCORT.—The term "physical escort" means the temporary touching or holding of the hand, wrist, arm, shoulder or back for the purpose of inducing a resident who is acting out to walk to a safe location.

(4) TIME OUT.—The term "time out" means a behavior management technique that is part of an approved treatment program and may involve the separation of the resident from the group, in a non-locked setting, for the purpose of calming. Time out is not seclusion.

SEC. 592.[290ii–1] REPORTING REQUIREMENT.

(a) IN GENERAL.—Each facility to which the Protection and Advocacy for Mentally Ill Individuals Act of 1986[30] applies shall notify the appropriate agency, as determined by the Secretary, of each death that occurs at each such facility while a patient is restrained or in seclusion, of each death occurring within 24 hours after the patient has been removed from restraints and seclusion, or where it is reasonable to assume that a patient's death is a result of such seclusion or restraint. A notification under this section shall include the name of the resident and shall be provided not later than 7 days after the date of the death of the individual involved.

(b) FACILITY.—In this section, the term "facility" has the meaning given the term "facilities" in section 102(3) of the Protection and Advocacy for Mentally Ill Individuals Act of 1986[32] (42 U.S.C. 10802(3)).

SEC. 593.[31][290ii–3] REGULATIONS AND ENFORCEMENT.

(a) TRAINING.—Not later than 1 year after the date of the enactment of this part, the Secretary, after consultation with appropriate State and local protection and advocacy organizations, physicians, facilities, and other health care professionals and patients, shall promulgate regulations that require facilities to which the Protection and Advocacy for Mentally Ill Individuals Act of 1986 (42 U.S.C. 10801 et seq.) applies, to meet the requirements of subsection (b).

(b) REQUIREMENTS.—The regulations promulgated under subsection (a) shall require that—

[30] Probably should be Protection and Advocacy for Individuals with Mental Illness Act. See section 3206(a) of Public Law 106–310 (114 Stat. 1193).

[32] See footnote for subsection (a).

[31] Section 593 appears according to the probable intent of the Congress. Section 3207 of Public Law 106–310 (114 Stat. 1196) added sections 591 and 592, and closing quotations were provided at the end of section 592. Immediately following that section, however, section 593 appeared in quotations, and closing quotations were provided at the end of the section. The probable intent of the Congress is that closing quotations should not have been provided at the end of section 592.

(1) facilities described in subsection (a) ensure that there is an adequate number of qualified professional and supportive staff to evaluate patients, formulate written individualized, comprehensive treatment plans, and to provide active treatment measures;

(2) appropriate training be provided for the staff of such facilities in the use of restraints and any alternatives to the use of restraints; and

(3) such facilities provide complete and accurate notification of deaths, as required under section 592(a).

(c) ENFORCEMENT.—A facility to which this part applies that fails to comply with any requirement of this part, including a failure to provide appropriate training, shall not be eligible for participation in any program supported in whole or in part by funds appropriated to any Federal department or agency.

PART I—REQUIREMENT RELATING TO THE RIGHTS OF RESIDENTS OF CERTAIN NON-MEDICAL, COMMUNITY-BASED FACILITIES FOR CHILDREN AND YOUTH

SEC. 595.[290jj] REQUIREMENT RELATING TO THE RIGHTS OF RESIDENTS OF CERTAIN NON-MEDICAL, COMMUNITY-BASED FACILITIES FOR CHILDREN AND YOUTH.

(a) PROTECTION OF RIGHTS.—

(1) IN GENERAL.—A public or private non-medical, community-based facility for children and youth (as defined in regulations to be promulgated by the Secretary) that receives support in any form from any program supported in whole or in part with funds appropriated under this Act shall protect and promote the rights of each resident of the facility, including the right to be free from physical or mental abuse, corporal punishment, and any restraints or involuntary seclusions imposed for purposes of discipline or convenience.

(2) NONAPPLICABILITY.—Notwithstanding this part, a facility that provides inpatient psychiatric treatment services for individuals under the age of 21, as authorized and defined in subsections (a)(16) and (h) of section 1905 of the Social Security Act, shall comply with the requirements of part H.

(3) APPLICABILITY OF MEDICAID PROVISIONS.—A non-medical, community-based facility for children and youth funded under the Medicaid program under title XIX of the Social Security Act shall continue to meet all existing requirements for participation in such program that are not affected by this part.

(b) REQUIREMENTS.—

(1) IN GENERAL.—Physical restraints and seclusion may only be imposed on a resident of a facility described in subsection (a) if—

(A) the restraints or seclusion are imposed only in emergency circumstances and only to ensure the immediate physical safety of the resident, a staff member, or

others and less restrictive interventions have been determined to be ineffective; and

(B) the restraints or seclusion are imposed only by an individual trained and certified, by a State-recognized body (as defined in regulation promulgated by the Secretary) and pursuant to a process determined appropriate by the State and approved by the Secretary, in the prevention and use of physical restraint and seclusion, including the needs and behaviors of the population served, relationship building, alternatives to restraint and seclusion, de-escalation methods, avoiding power struggles, thresholds for restraints and seclusion, the physiological and psychological impact of restraint and seclusion, monitoring physical signs of distress and obtaining medical assistance, legal issues, position asphyxia, escape and evasion techniques, time limits, the process for obtaining approval for continued restraints, procedures to address problematic restraints, documentation, processing with children, and follow-up with staff, and investigation of injuries and complaints.

(2) INTERIM PROCEDURES RELATING TO TRAINING AND CERTIFICATION.—

(A) IN GENERAL.—Until such time as the State develops a process to assure the proper training and certification of facility personnel in the skills and competencies referred in paragraph (1)(B), the facility involved shall develop and implement an interim procedure that meets the requirements of subparagraph (B).

(B) REQUIREMENTS.—A procedure developed under subparagraph (A) shall—

(i) ensure that a supervisory or senior staff person with training in restraint and seclusion who is competent to conduct a face-to-face assessment (as defined in regulations promulgated by the Secretary), will assess the mental and physical well-being of the child or youth being restrained or secluded and assure that the restraint or seclusion is being done in a safe manner;

(ii) ensure that the assessment required under clause (i) take place as soon as practicable, but in no case later than 1 hour after the initiation of the restraint or seclusion; and

(iii) ensure that the supervisory or senior staff person continues to monitor the situation for the duration of the restraint and seclusion.

(3) LIMITATIONS.—

(A) IN GENERAL.—The use of a drug or medication that is used as a restraint to control behavior or restrict the resident's freedom of movement that is not a standard treatment for the resident's medical or psychiatric condition in nonmedical community-based facilities for children and youth described in subsection (a)(1) is prohibited.

(B) PROHIBITION.—The use of mechanical restraints in non-medical, community-based facilities for children and youth described in subsection (a)(1) is prohibited.

(C) LIMITATION.—A non-medical, community-based facility for children and youth described in subsection (a)(1) may only use seclusion when a staff member is continuously face-to-face monitoring the resident and when strong licensing or accreditation and internal controls are in place.

(c) RULE OF CONSTRUCTION.—

(1) IN GENERAL.—Nothing in this section shall be construed as prohibiting the use of restraints for medical immobilization, adaptive support, or medical protection.

(2) CURRENT LAW.—This part shall not be construed to affect or impede any Federal or State law or regulations that provide greater protections than this part regarding seclusion and restraint.

(d) DEFINITIONS.—In this section:

(1) MECHANICAL RESTRAINT.—The term "mechanical restraint" means the use of devices as a means of restricting a resident's freedom of movement.

(2) PHYSICAL ESCORT.—The term "physical escort" means the temporary touching or holding of the hand, wrist, arm, shoulder or back for the purpose of inducing a resident who is acting out to walk to a safe location.

(3) PHYSICAL RESTRAINT.—The term "physical restraint" means a personal restriction that immobilizes or reduces the ability of an individual to move his or her arms, legs, or head freely. Such term does not include a physical escort.

(4) SECLUSION.—The term "seclusion" means a behavior control technique involving locked isolation. Such term does not include a time out.

(5) TIME OUT.—The term "time out" means a behavior management technique that is part of an approved treatment program and may involve the separation of the resident from the group, in a non-locked setting, for the purpose of calming. Time out is not seclusion.

SEC. 595A.[290jj–1] REPORTING REQUIREMENT.

Each facility to which this part applies shall notify the appropriate State licensing or regulatory agency, as determined by the Secretary—

(1) of each death that occurs at each such facility. A notification under this section shall include the name of the resident and shall be provided not later than 24 hours after the time of the individuals death; and

(2) of the use of seclusion or restraints in accordance with regulations promulgated by the Secretary, in consultation with the States.

SEC. 595B.[290jj–2] REGULATIONS AND ENFORCEMENT.

(a) TRAINING.—Not later than 6 months after the date of the enactment of this part, the Secretary, after consultation with appropriate State, local, public and private protection and advocacy organizations, health care professionals, social workers, facilities, and patients, shall promulgate regulations that—

(1) require States that license non-medical, community-based residential facilities for children and youth to develop li-

censing rules and monitoring requirements concerning behavior management practice that will ensure compliance with Federal regulations and to meet the requirements of subsection (b);

(2) require States to develop and implement such licensing rules and monitoring requirements within 1 year after the promulgation of the regulations referred to in the matter preceding paragraph (1); and

(3) support the development of national guidelines and standards on the quality, quantity, orientation and training, required under this part, as well as the certification or licensure of those staff responsible for the implementation of behavioral intervention concepts and techniques.

(b) REQUIREMENTS.—The regulations promulgated under subsection (a) shall require—

(1) that facilities described in subsection (a) ensure that there is an adequate number of qualified professional and supportive staff to evaluate residents, formulate written individualized, comprehensive treatment plans, and to provide active treatment measures;

(2) the provision of appropriate training and certification of the staff of such facilities in the prevention and use of physical restraint and seclusion, including the needs and behaviors of the population served, relationship building, alternatives to restraint, de-escalation methods, avoiding power struggles, thresholds for restraints, the physiological impact of restraint and seclusion, monitoring physical signs of distress and obtaining medical assistance, legal issues, position asphyxia, escape and evasion techniques, time limits for the use of restraint and seclusion, the process for obtaining approval for continued restraints and seclusion, procedures to address problematic restraints, documentation, processing with children, and follow-up with staff, and investigation of injuries and complaints; and

(3) that such facilities provide complete and accurate notification of deaths, as required under section 595A(1).

(c) ENFORCEMENT.—A State to which this part applies that fails to comply with any requirement of this part, including a failure to provide appropriate training and certification, shall not be eligible for participation in any program supported in whole or in part by funds appropriated under this Act.

PART G[33]—SERVICES PROVIDED THROUGH RELIGIOUS ORGANIZATIONS[34]

SEC. 581.[1][290kk] APPLICABILITY TO DESIGNATED PROGRAMS.

(a) DESIGNATED PROGRAMS.—Subject to subsection (b), this part applies to discretionary and formula grant programs administered by the Substance Abuse and Mental Health Services Administration that make awards of financial assistance to public or private entities for the purpose of carrying out activities to prevent or treat substance abuse (in this part referred to as a "designated program"). Designated programs include the program under subpart II of part B of title XIX (relating to formula grants to the States).

(b) LIMITATION.—This part does not apply to any award of financial assistance under a designated program for a purpose other than the purpose specified in subsection (a).

(c) DEFINITIONS.—For purposes of this part (and subject to subsection (b)):

(1) The term "designated program" has the meaning given such term in subsection (a).

(2) The term "financial assistance" means a grant, cooperative agreement, or contract.

(3) The term "program beneficiary" means an individual who receives program services.

(4) The term "program participant" means a public or private entity that has received financial assistance under a designated program.

(5) The term "program services" means treatment for substance abuse, or preventive services regarding such abuse, provided pursuant to an award of financial assistance under a designated program.

(6) The term "religious organization" means a nonprofit religious organization.

SEC. 582.[290kk–1] RELIGIOUS ORGANIZATIONS AS PROGRAM PARTICIPANTS.

(a) IN GENERAL.—Notwithstanding any other provision of law, a religious organization, on the same basis as any other nonprofit private provider—

(1) may receive financial assistance under a designated program; and

(2) may be a provider of services under a designated program.

(b) RELIGIOUS ORGANIZATIONS.—The purpose of this section is to allow religious organizations to be program participants on the same basis as any other nonprofit private provider without impair-

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[33] There are two parts G in this title. The first was added by section 3101 of Public Law 106–310 (114 Stat. 1168) and relates to projects for children and violence; that part also begins with section 581. See page 669. Sections 3207 and 3208 of such Public Law (114 Stat. 1195, 1197) added parts H and I, respectively.

Subsequently, part G above was added by section 144 of the Community Renewal Tax Relief Act of 2000 (as enacted into law by section 1(a)(7) of Public Law 106–554; 114 Stat. 2763A–619), which provides that title V of this Act "is amended by adding at the end the following part:", thereby placing that part G after the part I added by Public Law 106–310.

[34] Section 1955 of this Act also relates to religious organizations as providers of substance abuse services. That section was added by section 3305 of Public Law 106–310 (114 Stat. 1212).

[30] Probably should be Protection and Advocacy for Individuals with Mental Illness Act. See section 3206(a) of Public Law 106–310 (114 Stat. 1193).

ing the religious character of such organizations, and without diminishing the religious freedom of program beneficiaries.

(c) NONDISCRIMINATION AGAINST RELIGIOUS ORGANIZATIONS.—

(1) ELIGIBILITY AS PROGRAM PARTICIPANTS.—Religious organizations are eligible to be program participants on the same basis as any other nonprofit private organization as long as the programs are implemented consistent with the Establishment Clause and Free Exercise Clause of the First Amendment to the United States Constitution. Nothing in this Act shall be construed to restrict the ability of the Federal Government, or a State or local government receiving funds under such programs, to apply to religious organizations the same eligibility conditions in designated programs as are applied to any other nonprofit private organization.

(2) NONDISCRIMINATION.—Neither the Federal Government nor a State or local government receiving funds under designated programs shall discriminate against an organization that is or applies to be a program participant on the basis that the organization has a religious character.

(d) RELIGIOUS CHARACTER AND FREEDOM.—

(1) RELIGIOUS ORGANIZATIONS.—Except as provided in this section, any religious organization that is a program participant shall retain its independence from Federal, State, and local government, including such organization's control over the definition, development, practice, and expression of its religious beliefs.

(2) ADDITIONAL SAFEGUARDS.—Neither the Federal Government nor a State shall require a religious organization to—

(A) alter its form of internal governance; or

(B) remove religious art, icons, scripture, or other symbols,

in order to be a program participant.

(e) EMPLOYMENT PRACTICES.—Nothing in this section shall be construed to modify or affect the provisions of any other Federal or State law or regulation that relates to discrimination in employment. A religious organization's exemption provided under section 702 of the Civil Rights Act of 1964 regarding employment practices shall not be affected by its participation in, or receipt of funds from, a designated program.

(f) RIGHTS OF PROGRAM BENEFICIARIES.—

(1) IN GENERAL.—If an individual who is a program beneficiary or a prospective program beneficiary objects to the religious character of a program participant, within a reasonable period of time after the date of such objection such program participant shall refer such individual to, and the appropriate Federal, State, or local government that administers a designated program or is a program participant shall provide to such individual (if otherwise eligible for such services), program services that—

(A) are from an alternative provider that is accessible to, and has the capacity to provide such services to, such individual; and

(B) have a value that is not less than the value of the services that the individual would have received from the

program participant to which the individual had such objection.

Upon referring a program beneficiary to an alternative provider, the program participant shall notify the appropriate Federal, State, or local government agency that administers the program of such referral.

(2) NOTICES.—Program participants, public agencies that refer individuals to designated programs, and the appropriate Federal, State, or local governments that administer designated programs or are program participants shall ensure that notice is provided to program beneficiaries or prospective program beneficiaries of their rights under this section.

(3) ADDITIONAL REQUIREMENTS.—A program participant making a referral pursuant to paragraph (1) shall—

(A) prior to making such referral, consider any list that the State or local government makes available of entities in the geographic area that provide program services; and

(B) ensure that the individual makes contact with the alternative provider to which the individual is referred.

(4) NONDISCRIMINATION.—A religious organization that is a program participant shall not in providing program services or engaging in outreach activities under designated programs discriminate against a program beneficiary or prospective program beneficiary on the basis of religion or religious belief.

(g) FISCAL ACCOUNTABILITY.—

(1) IN GENERAL.—Except as provided in paragraph (2), any religious organization that is a program participant shall be subject to the same regulations as other recipients of awards of Federal financial assistance to account, in accordance with generally accepted auditing principles, for the use of the funds provided under such awards.

(2) LIMITED AUDIT.—With respect to the award involved, a religious organization that is a program participant shall segregate Federal amounts provided under award into a separate account from non-Federal funds. Only the award funds shall be subject to audit by the government.

(h) COMPLIANCE.—With respect to compliance with this section by an agency, a religious organization may obtain judicial review of agency action in accordance with chapter 7 of title 5, United States Code.

SEC. 583.[290kk–2] LIMITATIONS ON USE OF FUNDS FOR CERTAIN PURPOSES.

No funds provided under a designated program shall be expended for sectarian worship, instruction, or proselytization.

SEC. 584.[290kk–3] EDUCATIONAL REQUIREMENTS FOR PERSONNEL IN DRUG TREATMENT PROGRAMS.

(a) FINDINGS.—The Congress finds that—

(1) establishing unduly rigid or uniform educational qualification for counselors and other personnel in drug treatment programs may undermine the effectiveness of such programs; and

(2) such educational requirements for counselors and other personnel may hinder or prevent the provision of needed drug treatment services.

(b) NONDISCRIMINATION.—In determining whether personnel of a program participant that has a record of successful drug treatment for the preceding three years have satisfied State or local requirements for education and training, a State or local government shall not discriminate against education and training provided to such personnel by a religious organization, so long as such education and training includes basic content substantially equivalent to the content provided by nonreligious organizations that the State or local government would credit for purposes of determining whether the relevant requirements have been satisfied.

December 13, 2013

PUBLIC HEALTH SERVICE ACT

As Amended Through P.L. 112–240, Enacted January 2, 2013

TITLE VI—ASSISTANCE FOR CONSTRUCTION AND MODERNIZATION OF HOSPITALS AND OTHER MEDICAL FACILITIES

DECLARATION OF PURPOSE.

SEC. 600.[291] The purpose of this title is—

(a) to assist the several States in the carrying out of their programs for the construction and modernization of such public or other nonprofit community hospitals and other medical facilities as may be necessary, in conjunction with existing facilities, to furnish adequate hospital, clinic, or similar services to all their people;

(b) to stimulate the development of new or improved types of physical facilities for medical, diagnostic, preventive, treatment, or rehabilitative services; and

(c) to promote research, experiments, and demonstrations relating to the effective development and utilization of hospital, clinic, or similar services, facilities, and resources, and to promote the coordination of such research, experiments, and demonstrations and the useful application of their results.

PART A—GRANTS AND LOANS FOR CONSTRUCTION AND MODERNIZATION OF HOSPITALS AND OTHER MEDICAL FACILITIES

AUTHORIZATION OF APPROPRIATIONS FOR CONSTRUCTION AND MODERNIZATION GRANTS.

SEC. 601.[291a] In order to assist the States in carrying out the purposes of section 600, there are authorized to be appropriated—

(a) for the fiscal year ending June 30, 1974—

(1) $20,800,000 for grants for the construction of public or other nonprofit facilities for long-term care;

(2) $70,000,000 for grants for the construction of public or other nonprofit outpatient facilities;

(3) $15,000,000 for grants for the construction of public or other nonprofit rehabilitation facilities;

(b) for grants for the construction of public or other nonprofit hospitals and public health centers, $150,000,000 for the fiscal year ending June 30, 1965, $160,000,000 for the fiscal year ending June 30, 1966, $170,000,000 for the fiscal year ending June 30, 1967, $180,000,000 each for the next two fiscal years, $195,000,000 for the fiscal year ending June 30, 1970, $147,500,000 for the fiscal year ending June 30, 1971, $152,500,000 for the fiscal year ending

June 30, 1972, $157,500,000 for the fiscal year ending June 30, 1973, and $41,400,000 for the fiscal year ending June 30, 1974; and

(c) for grants for modernization of the facilities referred to in paragraphs (a) and (b), $65,000,000 for the fiscal year ending June 30, 1971, $80,000,000 for the fiscal year ending June 30, 1972, $90,000,000 for the fiscal year ending June 30, 1973, and $50,000,000 for the fiscal year ending June 30, 1974.

STATE ALLOTMENTS.

SEC. 602.[291b] (a)(1) Each State shall be entitled for each fiscal year to an allotment bearing the same ratio to the sums appropriated for such year pursuant to subparagraphs (1), (2), and (3), respectively, of section 601(a), and to an allotment bearing the same ratio to the sums appropriated for such year pursuant to section 601(b), as the product of—

(A) the population of such State, and

(B) the square of its allotment percentage,

bears to the sum of the corresponding products for all of the States.

(2) For each fiscal year, the Secretary shall, in accordance with regulations, make allotments among the States, from the sums appropriated for such year under section 601(c), on the basis of the population, the financial need, and the extent of the need for modernization of the facilities referred to in paragraphs (a) and (b) of section 601, of the respective States.

(b)(1) The allotment to any State under subsection (a) for any fiscal year which is less than—

(A) $50,000 for the Virgin Islands, American Samoa, the Trust Territory of the Pacific Islands, or Guam and $100,000 for any other State, in the case of an allotment for grants for the construction of public or other nonprofit rehabilitation facilities.

(B) $100,000 for the Virgin Islands, American Samoa, the Trust Territory of the Pacific Islands, or Guam and $200,000 for any other State in the case of an allotment for grants for the construction of public or other nonprofit outpatient facilities.

(C) $200,000 for the Virgin Islands, American Samoa, the Trust Territory of the Pacific Islands, or Guam and $300,000 for any other State in the case of an allotment for grants for the construction of public or other nonprofit facilities for long-term care or for the construction of public or other nonprofit hospitals and public health centers, or for the modernization of facilities referred to in paragraph (a) or (b) of section 601, or

(D) $200,000 for the Virgin Islands, American Samoa, the Trust Territory of the Pacific Islands, or Guam and $300,000 for any other State in the case of an allotment for grants for the modernization of facilities referred to in paragraphs (a) and (b) of section 601,

shall be increased to that amount, the total of the increases thereby required being derived by proportionately reducing the allotment from appropriations under such subparagraph or paragraph to each of the remaining States under subsection (a) of this section, but with such adjustments as may be necessary to prevent the al-

lotment of any of such remaining States from appropriations under such subparagraph or paragraph from being thereby reduced to less than that amount.

(2) An allotment of the Virgin Islands, American Samoa, the Trust Territory of the Pacific Islands, or Guam for any fiscal year may be increased as provided in paragraph (1) only to the extent it satisfies the Surgeon General, at such time prior to the beginning of such year as the Surgeon General may designate, that such increase will be used for payments under and in accordance with the provisions of this part.

(c) For the purposes of this part—

(1) The "allotment percentage" for any State shall be 100 per centum less that percentage which bears the same ratio to 50 per centum as the per capita income of such State bears to the per capita income of the United States, except that (A) the allotment percentage shall in no case be more than 75 per centum or less than 33⅓ per centum, and (B) the allotment percentage for the Commonwealth of Puerto Rico, Guam, American Samoa, the Trust Territory of the Pacific Islands, and the Virgin Islands shall be 75 per centum.

(2) The allotment percentages shall be determined by the Surgeon General between July 1 and September 30 of each even-numbered year, on the basis of the average of the per capita incomes of each of the States and of the United States for the three most recent consecutive years for which satisfactory data are available from the Department of Commerce, and the States shall be notified promptly thereof. Such determination shall be conclusive for each of the two fiscal years in the period beginning July 1 next succeeding such determination.

(3) The population of the several States shall be determined on the basis of the latest figures certified by the Department of Commerce.

(4) The term "United States" means (but only for purposes of paragraphs (1) and (2)) the fifty States and the District of Columbia.

(d)(1) Any sum allotted to a State, other than the Virgin Islands, American Samoa, the Trust Territory of the Pacific Islands, and Guam for a fiscal year under this section and remaining unobligated at the end of such year shall remain available to such State, for the purpose for which made, for the next two fiscal years (and for such years only), in addition to the sums allotted to such State for such purposes for such next two fiscal years.

(2) Any sum allotted to the Virgin Islands, American Samoa, the Trust Territory of the Pacific Islands, or Guam for a fiscal year under this section and remaining unobligated at the end of such year shall remain available to it, for the purpose for which made, for the next two fiscal years (and for such years only), in addition to the sums allotted to it for such purpose for each of such next two fiscal years.

(e)(1) Upon the request of any State that a specified portion of any allotment of such State under subsection (a) for any fiscal year be added to any other allotment or allotments of such State under such subsection for such year, the Secretary shall promptly (but after application of subsection (b)) adjust the allotments of such

State in accordance with such request and shall notify the State agency; except that the aggregate of the portions so transferred from an allotment for a fiscal year pursuant to this paragraph may not exceed the amount specified with respect to such allotment in clause (A), (B), (C), or (D), as the case may be, of subsection (b)(1) which is applicable to such State.

(2) In addition to the transfer of portions of allotments under paragraph (1), upon the request of any State that a specified portion of any allotment of such State under subsection (a), other than an allotment for grants for the construction of public or other nonprofit rehabilitation facilities, be added to another allotment of such State under such subsection, other than an allotment for grants for the construction of public or other nonprofit hospitals and public health centers, and upon simultaneous certification to the Secretary by the State agency in such State to the effect that—

(A) it has afforded a reasonable opportunity to make applications for the portion so specified and there have been no approvable applications for such portions, or

(B) in the case of a request to transfer a portion of an allotment for grants for the construction of public or other nonprofit hospitals and public health centers, use of such portion as requested by such State agency will better carry out the purposes of this title,

the Secretary shall promptly (but after application of subsection (b)) adjust the allotments of such State in accordance with such request and shall notify the State agency.

(3) In addition to the transfer of portions of allotments under paragraph (1) or (2), upon the request of any State that a specified portion of an allotment of such State under paragraph (2) of subsection (a) be added to an allotment of such State under paragraph (1) of such subsection for grants for the construction of public or other nonprofit hospitals and public health centers, and upon simultaneous certification by the State agency in such State to the effect that the need for new public or other nonprofit hospitals and public health centers is substantially greater than the need for modernization of facilities referred to in paragraph (a) or (b) of section 601, the Secretary shall promptly (but after application of subsection (b) of this section) adjust the allotments of such State in accordance with such request and shall notify the State agency.

(4) After adjustment of allotments of any State, as provided in paragraph (1), (2), or (3) of this subsection, the allotments as so adjusted shall be deemed to be the State's allotments under this section.

(f) In accordance with regulations, any State may file with the Surgeon General a request that a specified portion of an allotment to it under this part for grants for construction of any type of facility, or for modernization of facilities, be added to the corresponding allotment of another State for the purpose of meeting a portion of the Federal share of the cost of a project for the construction of a facility of that type in such other State, or for modernization of a facility in such other State, as the case may be. If it is found by the Surgeon General (or, in the case of a rehabilitation facility, by the Surgeon General and the Secretary) that construction or modernization of the facility with respect to which the request is made

would meet needs of the State making the request and that use of the specified portion of such State's allotment, as requested by it, would assist in carrying out the purposes of this title, such portion of such State's allotment shall be added to the corresponding allotment of the other State, to be used for the purpose referred to above.

GENERAL REGULATIONS.

SEC. 603.[291c] The Surgeon General, with the approval of the Federal Hospital Council and the Secretary of Health, Education, and Welfare, shall by general regulations prescribe—

(a) the general manner in which the State agency shall determine the priority of projects based on the relative need of different areas lacking adequate facilities of various types for which assistance is available under this part, giving special consideration—

(1) in the case of projects for the construction of hospitals, to facilities serving areas with relatively small financial resources and, at the option of the State, rural communities;

(2) in the case of projects for the construction of rehabilitation facilities, to facilities operated in connection with a university teaching hospital which will provide an integrated program of medical, psychological, social, and vocational evaluation and services under competent supervision;

(3) in the case of projects for modernization of facilities, to facilities serving densely populated areas;

(4) in the case of projects for construction or modernization of outpatient facilities, to any outpatient facility that will be located in, and provide services for residents of, an area determined by the Secretary to be a rural or urban poverty area;

(5) to projects for facilities which, alone or in conjunction with other facilities, will provide comprehensive health care, including outpatient and preventive care as well as hospitalization;

(6) to facilities which will provide training in health or allied health professions; and

(7) to facilities which will provide to a significant extent, for the treatment of alcoholism;

(b) general standards of construction and equipment for facilities of different classes and in different types of location, for which assistance is available under this part;

(c) criteria for determining needs for general hospital and long-term care beds, and needs for hospitals and other facilities for which aid under this part is available, and for developing plans for the distribution of such beds and facilities;

(d) criteria for determining the extent to which existing facilities, for which aid under this part is available, are in need of modernization; and

(e) that the State plan shall provide for adequate hospitals, and other facilities for which aid under this part is available, for all persons residing in the State, and adequate hospitals (and such other facilities) to furnish needed services for persons unable to pay therefor. Such regulations may also require that before approval of an application for a project is recommended by a State agency to

the Surgeon General for approval under this part, assurance shall be received by the State from the applicant that (1) the facility or portion thereof to be constructed or modernized will be made available to all persons residing in the territorial area of the applicant; and (2) there will be made available in the facility or portion thereof to be constructed or modernized a reasonable volume of services to persons unable to pay therefor, but an exception shall be made if such a requirement is not feasible from a financial viewpoint.

STATE PLANS.

SEC. 604.[291d] (a) Any State desiring to participate in this part may submit a State plan. Such plan must—

(1) designate a single State agency as the sole agency for the administration of the plan, or designate such agency as the sole agency for supervising the administration of the plan;

(2) contain satisfactory evidence that the State agency designated in accordance with paragraph (1) will have authority to carry out such plan in conformity with this part;

(3) provide for the designation of a State advisory council which shall include (A) representatives of nongovernmental organizations or groups, and of public agencies, concerned with the operation, construction, or utilization of hospital or other facilities for diagnosis, prevention, or treatment of illness or disease, or for provision of rehabilitation services, and representatives particularly concerned with education or training of health professions personnel, and (B) an equal number of representatives of consumers familiar with the need for the services provided by such facilities, to consult with the State agency in carrying out the plan, and provide, if such council does not include any representatives of nongovernmental organizations or groups, or State agencies, concerned with rehabilitation, for consultation with organizations, groups, and State agencies so concerned;

(4) set forth, in accordance with criteria established in regulations prescribed under section 603 and on the basis of a statewide inventory of existing facilities, a survey of need, and (except to the extent provided by or pursuant to such regulations) community, area, or regional plans—

(A) the number of general hospital beds and long-term care beds, and the number and types of hospital facilities and facilities for long-term care, needed to provide adequate facilities for inpatient care of people residing in the State, and a plan for the distribution of such beds and facilities in service areas throughout the State;

(B) the public health centers needed to provide adequate public health services for people residing in the State, and a plan for the distribution of such centers throughout the State;

(C) the outpatient facilities needed to provide adequate diagnostic or treatment services to ambulatory patients residing in the State, and a plan for distribution of such facilities throughout the State;

(D) the rehabilitation facilities needed to assure adequate rehabilitation services for disabled persons residing in the State, and a plan for distribution of such facilities throughout the State; and

(E) effective January 1, 1966, the extent to which existing facilities referred to in section 601 (a) or (b) in the State are in need of modernization;

(5) set forth a construction and modernization program conforming to the provisions set forth pursuant to paragraph (4) and regulations prescribed under section 603 and providing for construction or modernization of the hospital or long-term care facilities, public health centers, outpatient facilities and rehabilitation facilities which are needed, as determined under the provisions so set forth pursuant to paragraph (4);

(6) set forth, with respect to each of such types of medical facilities, the relative need, determined in accordance with regulations prescribed under section 603, for projects for facilities of that type, and provide for the construction or modernization, insofar as financial resources available therefor and for maintenance and operation make possible, in the order of such relative need;

(7) provide minimum standards (to be fixed in the discretion of the State) for the maintenance and operation of facilities providing inpatient care which receive aid under this part and, effective July 1, 1966, provide for enforcement of such standards with respect to projects approved by the Surgeon General under this part after June 30, 1964;

(8) provide such methods of administration of the State plan, including methods relating to the establishment and maintenance of personnel standards on a merit basis (except that the Surgeon General shall exercise no authority with respect to the selection, tenure of office, or compensation of any individual employed in accordance with such methods), as are found by the Surgeon General to be necessary for the proper and efficient operation of the plan;

(9) provide for affording to every applicant for a construction or modernization project an opportunity for a hearing before the State agency;

(10) provide that the State agency will make such reports, in such form and containing such information, as the Surgeon General may from time to time reasonably require, and will keep such records and afford such access thereto as the Surgeon General may find necessary to assure the correctness and verification of such reports;

(11) provide that the Comptroller General of the United States or his duly authorized representatives shall have access for the purpose of audit and examination to the records specified in paragraph (10);

(12) provide that the State agency will from time to time, but not less often than annually, review its State plan and submit to the Surgeon General any modifications thereof which it considers necessary; and

(13) effective July 1, 1971, provide that before any project for construction or modernization of any general hospital is ap-

proved by the State agency there will be reasonable assurance of adequate provision for extended care services (as determined in accordance with regulations) to patients of such hospital when such services are medically appropriate for them, with such services being provided in facilities which (A) are structurally part of, physically connected with, or in immediate proximity to, such hospital, and (B) either (i) are under the supervision of the professional staff of such hospital or (ii) have organized medical staffs and have in effect transfer agreements with such hospital; except that the Secretary may, at the request of the State agency, waive compliance with clause (A) or (B), or both such clauses, as the case may be, in the case of any project if the State agency has determined that compliance with such clause or clauses in such case would be inadvisable.

(b) The Surgeon General shall approve any State plan and any modification thereof which complies with the provisions of subsection (a). If any such plan or modification thereof shall have been disapproved by the Surgeon General for failure to comply with subsection (a), the Federal Hospital Council shall, upon request of the State agency, afford it an opportunity for hearing. If such Council determines that the plan or modification complies with the provisions of such subsection, the Surgeon General shall thereupon approve such plan or modification.

APPROVAL OF PROJECTS FOR CONSTRUCTION OR MODERNIZATION.

SEC. 605.[291e] (a) For each project pursuant to a State plan approved under this part, there shall be submitted to the Surgeon General, through the State agency, an application by the State or a political subdivision thereof or by a public or other nonprofit agency. If two or more such agencies join in the project, the application may be filed by one or more of such agencies. Such application shall set forth—

(1) a description of the site for such project;

(2) plans and specifications therefor, in accordance with regulations prescribed under section 603;

(3) reasonable assurance that title to such site is or will be vested on one or more of the agencies filing the application or in a public or other nonprofit agency which is to operate the facility on completion of the project;

(4) reasonable assurance that adequate financial support will be available for the completion of the project and for its maintenance and operation when completed;

(5) reasonable assurance that all laborers and mechanics employed by contractors or subcontractors in the performance of construction or modernization on the project will be paid wages at rates not less than those prevailing on similar work in the locality as determined by the Secretary of Labor in accordance with the Davis-Bacon Act, as amended (40 U.S.C. 276a—276a–5); and the Secretary of Labor shall have with respect to the labor standards specified in this paragraph the authority and functions set forth in Reorganization Plan Numbered 14 of 1950 (15 F.R. 3176; 5 U.S.C. 133z–15) and section

2 of the Act of June 13, 1934, as amended (40 U.S.C. 276c); and

(6) a certification by the State agency of the Federal share for the project.

(b) The Surgeon General shall approve such application if sufficient funds to pay the Federal share of the cost of such project are available from the appropriate allotment to the State, and if the Surgeon General finds (1) that the application contains such reasonable assurance as to title, financial support, and payment of prevailing rates of wages; (2) that the plans and specifications are in accord with the regulations prescribed pursuant to section 603; (3) that the application is in conformity with the State plan approved under section 604 and contains an assurance that in the operation of the project there will be compliance with the applicable requirements of the regulations prescribed under section 603(e), and with State standards for operation and maintenance; and (4) that the application has been approved and recommended by the State agency, opportunity has been provided, prior to such approval and recommendation, for consideration of the project by the public or nonprofit private agency or organization which has developed the comprehensive regional, metropolitan area, or other local area plan or plans referred to in section 314(b) covering the area in which such project is to be located or, if there is no such agency or organization, by the State agency administering or supervising the administration of the State plan approved under section 314(a), and the application is for a project which is entitled to priority over other projects within the State in accordance with the regulations prescribed pursuant to section 603(a). Notwithstanding the preceding sentence, the Surgeon General may approve such an application for a project for construction or modernization of a rehabilitation facility only if it is also approved by the Secretary of Health, Education, and Welfare.

(c) No application shall be disapproved until the Surgeon General has afforded the State agency an opportunity for a hearing.

(d) Amendment of any approved application shall be subject to approval in the same manner as an original application.

(e) Notwithstanding any other provision of this title, no application for an outpatient facility shall be approved under this section unless the applicant is (1) a State, political subdivision, or public agency, or (2) a corporation or association which owns and operates a nonprofit hospital (as defined in section 645) or which provides reasonable assurance that the services of a general hospital will be available to patients of such facility who are in need of hospital care.

PAYMENTS FOR CONSTRUCTION OR MODERNIZATION.

SEC. 606.[291f] (a) Upon certification to the Surgeon General by the State agency, based upon inspection by it, that work has been performed upon a project, or purchases have been made, in accordance with the approved plans and specifications, and that payment of an installment is due to the applicant, such installment shall be paid to the State, from the applicable allotment of such State, except that (1) if the State is not authorized by law to make

payments to the applicant, or if the State so requests, the payment shall be made directly to the applicant, (2) if the Surgeon General, after investigation or otherwise, has reason to believe that any act (or failure to act) has occurred requiring action pursuant to section 607, payment may, after he has given the State agency notice of opportunity for hearing pursuant to such section, be withheld, in whole or in part, pending corrective action or action based on such hearing, and (3) the total of payments under this subsection with respect to such project may not exceed an amount equal to the Federal share of the cost of construction of such project.

(b) In case an amendment to an approved application is approved as provided in section 605 or the estimated cost of a project is revised upward, any additional payment with respect thereto may be made from the applicable allotment of the State for the fiscal year in which such amendment or revision is approved.

(c)(1) At the request of any State, a portion of any allotment or allotments of such State under this part shall be available to pay one-half (or such smaller share as the State may request) of the expenditures found necessary by the Surgeon General for the proper and efficient administration during such year of the State plan approved under this part; except that not more than 4 per centum of the total of the allotments of such State for a year, or $100,000, whichever is less, shall be available for such purpose for such year. Payments of amounts due under this paragraph may be made in advance or by way of reimbursement, and in such installments, as the Surgeon General may determine.

(2) Any amount paid under paragraph (1) to any State for any fiscal year shall be paid on condition that there shall be expended from State sources for such year for administration of the State plan approved under this part not less than the total amount expended for such purposes from such sources during the fiscal year ending June 30, 1970.

WITHHOLDING OF PAYMENTS.

SEC. 607.[291g] Whenever the Surgeon General, after reasonable notice and opportunity for hearing to the State agency designated as provided in section 604(a)(1), finds—

(a) that the State agency is not complying substantially with the provisions required by section 604 to be included in its State plan; or

(b) that any assurance required to be given in an application filed under section 605 is not being or cannot be carried out; or

(c) that there is a substantial failure to carry out plans and specifications approved by the Surgeon General under section 605; or

(d) that adequate State funds are not being provided annually for the direct administration of the State plan,

the Surgeon General may forthwith notify the State agency that—

(e) no further payments will be made to the State under this part, or

(f) no further payments will be made from the allotments of such State from appropriations under any one or more sub-

paragraphs or paragraphs of section 601, or for any project or projects, designated by the Surgeon General as being affected by the action or inaction referred to in paragraph (a), (b), (c), or (d) of this section, as the Surgeon General may determine to be appropriate under the circumstances; and, except with regard to any project for which the application has already been approved and which is not directly affected, further payments may be withheld, in whole or in part, until there is no longer any failure to comply (or carry out the assurance or plans and specifications or provide adequate State funds, as the case may be) or, if such compliance (or other action) is impossible, until the State repays or arranges for the repayment of Federal moneys to which the recipient was not entitled.

JUDICIAL REVIEW.

SEC. 608.[291h] (a) If the Surgeon General refuses to approve any application for a project submitted under section 605 or section 610, the State agency through which such application was submitted, or if any State is dissatisfied with his action under section 607 such State may appeal to the United States court of appeals for the circuit in which such State is located, by filing a petition with such court within sixty days after such action. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Surgeon General, or any officer designated by him for that purpose. The Surgeon General shall thereupon file in the court the record of the proceedings on which he based his action, as provided in section 2112 of title 28, United States Code. Upon the filing of such petition, the court shall have jurisdiction to affirm the action of the Surgeon General or to set it aside, in whole or in part, temporarily or permanently, but until the filing of the record, the Surgeon General may modify or set aside his order.

(b) The findings of the Surgeon General as to the facts, if supported by substantial evidence, shall be conclusive, but the court, for good cause shown, may remand the case to the Surgeon General to take further evidence, and the Surgeon General may thereupon make new or modified findings of fact and may modify his previous action, and shall file in the court the record of the further proceedings. Such new or modified findings of fact shall likewise be conclusive if supported by substantial evidence.

(c) The judgment of the court affirming or setting aside, in whole or in part, any action of the Surgeon General shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28, United States Code. The commencement of proceedings under this section shall not, unless so specifically ordered by the court, operate as a stay of the Surgeon General's action.

RECOVERY.

SEC. 609.[1][291i] (a) If any facility with respect to which funds have been paid under section 606 shall, at any time within 20 years after the completion of construction or modernization—

(1) be sold or transferred to any entity (A) which is not qualified to file an application under section 605, or (B) which

is not approved as a transferee by the State agency designated pursuant to section 604, or its successor, or

(2) cease to be a public health center or a public or other nonprofit hospital, outpatient facility, facility for long-term care, or rehabilitation facility,

the United States shall be entitled to recover, whether from the transferor or the transferee (or, in the case of a facility which has ceased to be public or nonprofit, from the owners thereof) an amount determined under subsection (c).

(b) The transferor of a facility which is sold or transferred as described in subsection (a)(1), or the owner of a facility the use of which is changed as described in subsection (a)(2), shall provide the Secretary written notice of such sale, transfer, or change not later than the expiration of 10 days from the date on which such sale, transfer, or change occurs.

(c)(1) except as provided in paragraph (2), the amount the United States shall be entitled to recover under subsection (a) is an amount bearing the same ratio to the then value (as determined by the agreement of the parties or in an action brought in the district court of the United States for the district for which the facility involved is situated) of so much of the facility as constituted an approved project or projects as the amount of the Federal participation bore to the cost of the construction or modernization of such project or projects.

(2)(A) After the expiration of—

(i) 180 days after the date of the sale, transfer, or change of use for which a notice is required by subsection (b), in the case of a facility which is sold or transferred or the use of which changes after the date of the enactment of this subsection, or

(ii) thirty days after the date of the enactment of this subsection or if later 180 days after the date of the sale, transfer, or change of use for which a notice is required by subsection (b), in the case of a facility which was sold or transferred or the use of which changed before the date of the enactment of this subsection.[2]

the amount which the United States is entitled to recover under paragraph (1) with respect to a facility shall be the amount prescribed by paragraph (1) plus interest, during the period described in subparagraph (B), at a rate (determined by the Secretary) based on the average of the bond equivalent of the weekly ninety-day Treasury bill auction rate.

(B) The period referred to in subparagraph (A) is the period beginning—

(i) in the case of a facility which was sold or transferred or the use of which changed before the date of the enactment of this subsection, thirty days after such date or if later 180 days after the date of the sale, transfer, or change of use for which a notice is required by subsection (b),

(ii) in the case of a facility with respect to which notice is provided in accordance with subsection (b), upon the expiration of 180 days after the receipt of such notice, or

[2] So in law. The period probably should be a comma.

(iii) in the case of a facility with respect to which such notice is not provided as prescribed by subsection (b), on the date of the sale, transfer, or change of use for which such notice was to be provided,

and ending on the date the amount the United States is entitled to under paragraph (1) is collected.

(d)(1) The Secretary may waive the recovery rights of the United States under subsection (a)(1) with respect to a facility in any State if the Secretary determines, in accordance with regulations, that the entity to which the facility was sold or transferred—

(A) has established an irrevocable trust—

(i) in an amount equal to the greater of twice the cost of the remaining obligation of the facility under clause (2) of section 603(e) or the amount, determined under subsection (c), that the United States is entitled to recover, and

(ii) which will only be used by the entity to provide the care required by clause (2) of section 603(e); and

(B) will meet the obligation of the facility under clause (1) of section 603(e).

(2) The Secretary may waive the recovery rights of the United States under subsection (a)(2) with respect to a facility in any State if the Secretary determines, in accordance with regulations, that there is good cause for waiving such rights with respect to such facility.

(e) The right of recovery of the United States under subsection (a) shall not constitute a lien on any facility with respect to which funds have been paid under section 606.

LOANS FOR CONSTRUCTION OR MODERNIZATION OF HOSPITALS AND OTHER MEDICAL FACILITIES.

SEC. 610.[291j] (a) In order further to assist the States in carrying out the purposes of this title, the Surgeon General is authorized to make a loan of funds to the applicant for any project for construction or modernization which meets all of the conditions specified for a grant under this part.

(b) Except as provided in this section, an application for a loan with respect to any project under this part shall be submitted, and shall be approved by the Surgeon General, in accordance with the same procedures and subject to the same limitations and conditions as would be applicable to the making of a grant under this part for such project. Any such application may be approved in any fiscal year only if sufficient funds are available from the allotment for the type of project involved. All loans under this section shall be paid directly to the applicant.

(c)(1) The amount of a loan under this part shall not exceed an amount equal to the Federal share of the estimated cost of construction or modernization under the project. Where a loan and a grant are made under this part with respect to the same project, the aggregate amount of such loan and such grant shall not exceed an amount equal to the Federal share of the estimated cost of construction or modernization under the project. Each loan shall bear interest at the rate arrived at by adding one-quarter of 1 per cen-

tum per annum to the rate which the Secretary of the Treasury determines to be equal to the current average yield on all outstanding marketable obligations of the United States as of the last day of the month preceding the date the application for the loan is approved and by adjusting the result so obtained to the nearest one-eighth of 1 per centum. Each loan made under this part shall mature not more than forty years after the date on which such loan is made, except that nothing in this part shall prohibit the payment of all or part of the loan at any time prior to the maturity date. In addition to the terms and conditions provided for, each loan under this part shall be made subject to such terms, conditions, and covenants relating to repayment of principal, payment of interest, and other matters as may be agreed upon by the applicant and the Surgeon General.

(2) The Surgeon General may enter into agreements modifying any of the terms and conditions of a loan made under this part whenever he determines such action is necessary to protect the financial interest of the United States.

(3) If, at any time before a loan for a project has been repaid in full, any of the events specified in clause (a) or clause (b) of section 609 occurs with respect to such project, the unpaid balance of the loan shall become immediately due and payable by the applicant, and any transferee of the facility shall be liable to the United States for such repayment.

(d) Any loan under this part shall be made out of the allotment from which a grant for the project concerned would be made. Payments of interest and repayments of principal on loans under this part shall be deposited in the Treasury as miscellaneous receipts.

PART B—LOAN GUARANTEES AND LOANS FOR MODERNIZATION AND CONSTRUCTION OF HOSPITALS AND OTHER MEDICAL FACILITIES

AUTHORIZATION OF LOAN GUARANTEES AND LOANS.

SEC. 621.[291j–1] (a)(1) In order to assist nonprofit private agencies to carry out needed projects for the modernization or construction of nonprofit private hospitals, facilities for long-term care, outpatient facilities, and rehabilitation facilities, the Secretary, during the period July 1, 1970, through June 30, 1974, may, in accordance with the provisions of this part, guarantee to non-Federal lenders making loans to such agencies for such projects, payment of principal of and interest on loans, made by such lenders, which are approved under this part.

(2) In order to assist public agencies to carry out needed projects for the modernization or construction of public health centers, and public hospitals, facilities for long-term care, outpatient facilities, and rehabilitation facilities, the Secretary, during the period July 1, 1970, through June 30, 1974, may, in accordance with the provisions of this part, make loans to such agencies which shall be sold and guaranteed in accordance with section 627.

(b)(1) No loan guarantee under this part with respect to any modernization or construction project may apply to so much of the principal amount thereof as, when added to the amount of any grant or loan under part A with respect to such project, exceeds 90 per centum of the cost of such project.

(2) No loan to a public agency under this part shall be made in an amount which, when added to the amount of any grant or loan under part A with respect to such project, exceeds 90 per centum of the cost of such project.

(c) The Secretary, with the consent of the Secretary of Housing and Urban Development, shall obtain from the Department of Housing and Urban Development such assistance with respect to the administration of this part as will promote efficiency and economy thereof.

ALLOCATION AMONG THE STATES.

SEC. 622.[291j–2] (a) For each fiscal year, the total amount of principal of loans to nonprofit private agencies which may be guaranteed or loans to public agencies which may be directly made under this part shall be allotted by the Secretary among the States, in accordance with regulations, on the basis of each State's relative population, financial need, need for construction of the facilities referred to in section 621(a), and need for modernization of such facilities.

(b) Any amount allotted under subsection (a) to a State for a fiscal year ending before July 1, 1973, and remaining unobligated at the end of such year shall remain available to such State, for the purpose for which made, for the next two fiscal years (and for such years only), and any such amount shall be in addition to the amounts allotted to such State for such purpose for each of such next two fiscal years; except that, with the consent of any such State, any such amount remaining unobligated at the end of the first of such next fiscal year may be reallotted (on such basis as the Secretary deems equitable and consistent with the purposes of this title) to other States which have need therefor. Any amounts so reallotted to a State shall be available for the purposes for which made until the close of the second such next two fiscal years and shall be in addition to the amount allotted and available to such State for the same period.

(c) Any amount allotted or reallotted to a State under this section for a fiscal year shall not, until the expiration of the period during which it is available for obligation, be considered as available for allotment for a subsequent fiscal year.

(d) The allotments of any State under subsection (a) for the fiscal year ending June 30, 1971, and the succeeding fiscal year shall also be available to guarantee loans with respect to any project, for modernization or construction of a nonprofit private hospital or other health facility referred to in section 621(a)(1), if the modernization or construction of such facility was not commenced earlier than January 1, 1968, and if the State certifies and the Secretary finds that without such guaranteed loan such facility could not be completed and begin to operate or could not continue to operate, but with such guaranteed loan would be able to do so: *Provided*, That this subsection shall not apply to more than two projects in any one State.

APPLICATIONS AND CONDITIONS.

SEC. 623.[291j–3] (a) For each project for which a guarantee of a loan to a nonprofit private agency or a direct loan to a public agency is sought under this part, there shall be submitted to the Secretary, through the State agency designated in accordance with section 604, an application by such private nonprofit agency or by such public agency. If two or more private nonprofit agencies, or two or more public agencies, join in the project, the application may be filed by one or more such agencies. Such application shall (1) set forth all of the descriptions, plans, specifications, assurances, and information which are required by the third sentence of section 605(a) (other than clause (6) thereof) with respect to applications submitted under that section, (2) contain such other information as the Secretary may require to carry out the purposes of this part, and (3) include a certification by the State agency of the total cost of the project and the amount of the loan for which a guarantee is sought under this part, or the amount of the direct loan sought under this part, as the case may be.

(b) The Secretary may approve such application only if—

(1) there remains sufficient balance in the allotment determined for such State pursuant to section 622 to cover the amount of the loan for which a guarantee is sought, or the amount of the direct loan sought (as the case may be), in such application,

(2) he makes each of the findings which are required by clauses (1) through (4) of section 605(b) for the approval of applications for projects thereunder (except that, in the case of the finding required under such clause (4) of entitlement of a project to a priority established under section 603(a), such finding shall be made without regard to the provisions of clauses (1) and (3) of such section),

(3) he finds that there is compliance with section 605(e),

(4) he obtains assurances that the applicant will keep such records, and afford such access thereto, and make such reports, in such form and containing such information, as the Secretary may reasonably require, and

(5) he also determines, in the case of a loan for which a guarantee is sought, that the terms, conditions, maturity, security (if any), and schedule and amounts of repayments with respect to the loan are sufficient to protect the financial interests of the United States and are otherwise reasonable and in accord with regulations, including a determination that the rate of interest does not exceed such per centum per annum on the principal obligation outstanding as the Secretary determines to be reasonable, taking into account the range of interest rates prevailing in the private market for similar loans and the risks assumed by the United States.

(c) No application under this section shall be disapproved until the Secretary has afforded the State agency an opportunity for a hearing.

(d) Amendment of an approved application shall be subject to approval in the same manner as an original application.

(e)(1) In the case of any loan to a nonprofit private agency, the United States shall be entitled to recover from the applicant the amount of any payments made pursuant to any guarantee of such loan under this part, unless the Secretary for good cause waives its right of recovery, and, upon making any such payment, the United States shall be subrogated to all of the rights of the recipient of the payments with respect to which the guarantee was made.

(2) Guarantees of loans to nonprofit private agencies under this part shall be subject to such further terms and conditions as the Secretary determines to be necessary to assure that the purposes of this part will be achieved, and, to the extent permitted by subsection (f), any of such terms and conditions may be modified by the Secretary to the extent he determines it to be consistent with the financial interest of the United States.

(f) Any guarantee of a loan to a nonprofit private agency made by the Secretary pursuant to this part shall be incontestable in the hands of an applicant on whose behalf such guarantee is made, and as to any person who makes or contracts to make a loan to such applicant in reliance thereon, except for fraud or misrepresentation on the part of such applicant or such other person.

PAYMENT OF INTEREST ON GUARANTEED LOAN.

SEC. 624.**[**291j–4**]** (a) Subject to the provisions of subsection (b), in the case of a guarantee of any loan to a nonprofit private agency under this part with respect to a hospital or other medical facility, the Secretary shall pay, to the holder of such loan and for and on behalf of such hospital or other medical facility amounts sufficient to reduce by 3 per centum per annum the net effective interest rate otherwise payable on such loan. Each holder of a loan, to a nonprofit private agency, which is guaranteed under this part shall have a contractual right to receive from the United States interest payments required by the preceding sentence.

(b) Contracts to make the payments provided for in this section shall not carry an aggregate amount greater than such amount as may be provided in appropriations Acts.

LIMITATION ON AMOUNT OF LOANS GUARANTEED OR DIRECTLY MADE.

SEC. 625.**[**291j–5**]** The cumulative total of the principal of the loans outstanding at any time with respect to which guarantees have been issued, or which have been directly made, under this part may not exceed the lesser of—

(1) such limitations as may be specified in appropriations Acts, or

(2) in the case of loans covered by allotments for the fiscal year ending June 30, 1971, $500,000,000; for the fiscal year ending June 30, 1972, $1,000,000,000; and for each of the fiscal years ending June 30, 1973, and June 30, 1974.

LOAN GUARANTEE AND LOAN FUND.

SEC. 626.**[**291j–6**]** (a)(1) There is hereby established in the Treasury a loan guarantee and loan fund (hereinafter in this section referred to as the "fund") which shall be available to the Secretary without fiscal year limitation, in such amounts as may be

specified from time to time in appropriations Acts, (i) to enable him to discharge his responsibilities under guarantees issued by him under this part, (ii) for payment of interest on the loans to nonprofit agencies which are guaranteed, (iii) for direct loans to public agencies which are sold and guaranteed, (iv) for payment of interest with respect to such loans, and (v) for repurchase by him of direct loans to public agencies which have been sold and guaranteed. There are authorized to be appropriated to the fund from time to time such amounts as may be necessary to provide capital required for the fund. To the extent authorized from time to time in appropriation Acts, there shall be deposited in the fund amounts received by the Secretary as interest payments or repayments of principal on loans and any other moneys, property, or assets derived by him from his operations under this part, including any moneys derived from the sale of assets.

(2) Of the moneys in the fund, there shall be available to the Secretary for the purpose of making of direct loans to public agencies only such sums as shall have been appropriated for such purpose pursuant to section 627 or sums received by the Secretary from the sale of such loans (in accordance with such section) and authorized in appropriations Acts to be used for such purpose.

(b) If at any time the moneys in the fund are insufficient to enable the Secretary to discharge his responsibilities under this part—

(i)[3] to make payments of interest on loans to nonprofit private agencies which he has guaranteed under this part;

(ii) to otherwise comply with guarantees under this part of loans to nonprofit private agencies;

(iii) to make payments of interest subsidies with respect to loans to public agencies which he has made, sold, and guaranteed under this part;

(iv) in the event of default by public agencies to make payments of principal and interest on loans which the Secretary has made, sold, and guaranteed, under this part, to make such payments to the purchaser of such loan;

(v) to repurchase loans to public agencies which have been sold and guaranteed under this part,

he is authorized to issue to the Secretary of the Treasury notes or other obligations in such forms and denominations, bearing such maturities, and subject to such terms and conditions, as may be prescribed by the Secretary with the approval of the Secretary of the Treasury, but only in such amounts as may be specified from time to time in appropriations Acts. Such notes or other obligations shall bear interest at a rate determined by the Secretary of the Treasury, taking into consideration the current average market yield on outstanding marketable obligations of the United States of comparable maturities during the month preceding the issuance of the notes or other obligations. The Secretary of the Treasury is authorized and directed to purchase any notes and other obligations issued hereunder and for that purpose he is authorized to use as a public debt transaction the proceeds from the sale of any securi-

[3] Clauses (i) through (v) probably should be redesignated as paragraphs (1) through (5), respectively. See section 201 of Public Law 91–296 (84 Stat. 347).

ties issued under the Second Liberty Bond Act, as amended, and the purposes for which securities may be issued under that Act, as amended, are extended to include any purchase of such notes and obligations. The Secretary of the Treasury may at any time sell any of the notes or other obligations acquired by him under this subsection. All redemptions, purchases, and sales by the Secretary of the Treasury of such notes or other obligations shall be treated as public debt transactions of the United States. Sums borrowed under this subsection shall be deposited in the fund and redemption of such notes and obligations shall be made by the Secretary from such fund.

PROVISIONS APPLICABLE TO LOANS TO PUBLIC FACILITIES.

SEC. 627.[291j–7] (a)(1) Any loan made by the Secretary to a public agency under this part for the modernization or construction of a public hospital or other health facility shall require such public agency to pay interest thereon at a rate comparable to the current rate of interest prevailing with respect to loans, to nonprofit private agencies, which are guaranteed under this part, for the modernization or construction of similar facilities in the same or similar areas, minus 3 per centum per annum.

(2)(A) No loan to a public agency shall be made under this part unless—

(i) the Secretary is reasonably satisfied that such agency will be able to make payments of principal and interest thereon when due, and

(ii) such agency provides the Secretary with reasonable assurances that there will be available to such agency such additional funds as may be necessary to complete the project with respect to which such loan is requested.

(B) Any loan to a public agency shall have such security, have such maturity date, be repayable in such installments, and be subject to such other terms and conditions (including provision for recovery in case of default) as the Secretary determines to be necessary to carry out the purposes of this part while adequately protecting the financial interests of the United States.

(3) In making loans to public agencies under this part, the Secretary shall give due regard to achieving an equitable geographical distribution of such loans.

(b)(1) The Secretary shall from time to time, but with due regard to the financial interests of the United States, sell loans referred to in subsection (a)(1) either on the private market or to the Federal National Mortgage Association in accordance with section 302 of the Federal National Mortgage Association Charter Act.

(2) Any loan so sold shall be sold for an amount which is equal (or approximately equal) to the amount of the unpaid principal of such loan as of the time of sale.

(c)(1) The Secretary is authorized to enter into an agreement with the purchaser of any loan sold under this part under which the Secretary agrees—

(A) to guarantee to such purchaser (and any successor in interest to such purchaser) payments of the principal and interest payable under such loan, and

(B) to pay as an interest subsidy to such purchaser (and any successor in interest of such purchaser) amounts which when added to the amount of interest payable on such loan, are equivalent to a reasonable rate of interest on such loan as determined by the Secretary, after taking into account the range of prevailing interest rates in the private market on similar loans and the risks assumed by the United States.

(2) Any such agreement—

(A) may provide that the Secretary shall act as agent of any such purchaser, for the purpose of collecting from the public agency to which such loan was made and paying over to such purchaser, any payments of principal and interest payable by such agency under such loan;

(B) may provide for the repurchase by the Secretary of any such loan on such terms and conditions as may be specified in the agreement;

(C) shall provide that, in the event of any default by the public agency to which such loan was made in payment of principal and interest due on such loan, the Secretary shall, upon notification to the purchaser (or to the successor in interest of such purchaser), have the option to close out such loan (and any obligations of the Secretary with respect thereto) by paying to the purchaser (or his successor in interest) the total amount of outstanding principal and interest due thereon at the time of such notification; and

(D) shall provide that, in the event such loan is closed out as provided in subparagraph (C), or in the event of any other loss incurred by the Secretary by reason of the failure of such public agency to make payments of principal and interest on such loan, the Secretary shall be subrogated to all rights of such purchaser for recovery of such loss from such public agency.

(d) The Secretary may, for good cause, waive any right of recovery which he has against a public agency by reason of the failure of such agency to make payments of principal and interest on a loan made to such agency under this part.

(e) After any loan to a public agency under this part has been sold and guaranteed, interest paid on such loan and any interest subsidy paid by the Secretary with respect to such loan which is received by the purchaser thereof (or his successor in interest) shall be included in gross income for the purposes of chapter 1 of the Internal Revenue Code of 1954.

(f) Amounts received by the Secretary as proceeds from the sale of loans under this section shall be deposited in the loan fund established by section 626, and shall be available to the Secretary for the making of further loans under this part in accordance with the provisions of subsection (a)(2) of such section.

(g) There is authorized to be appropriated to the Secretary, for deposit in the loan fund established by section 626, $30,000,000 to provide initial capital for the making of direct loans by the Secretary to public agencies for the modernization or construction of facilities referred to in subsection (a)(1).

PART C—CONSTRUCTION OR MODERNIZATION OF EMERGENCY ROOMS

AUTHORIZATION.

SEC. 631.[291j–8] In order to assist in the provision of adequate emergency room service in various communities of the Nation for treatment of accident victims and handling of other medical emergencies through special project grants for the construction or modernization of emergency rooms of general hospitals, there are authorized to be appropriated $20,000,000 each for the fiscal year ending June 30, 1971, and the next two fiscal years.

ELIGIBILITY FOR GRANTS.

SEC. 632.[291j–9] Funds appropriated pursuant to section 631 shall be available for grants by the Secretary for not to exceed 50 per centum of the cost of construction or modernization of emergency rooms of public or nonprofit general hospitals, including provision or replacement of medical transportation facilities. Such grants shall be made by the Secretary only after consultation with the State agency designated in accordance with section 604(a)(1) of the Public Health Service Act. In order to be eligible for a grant under this part, the project, and the applicant therefor, must meet such criteria as may be prescribed by regulations. Such regulations shall be so designed as to provide aid only with respect to projects for which adequate assistance is not readily available from other Federal, State, local, or other sources, and to assist in providing modern, efficient, and effective emergency room service needed to care for victims of highway, industrial, agricultural, or other accidents and to handle other medical emergencies, and to assist in providing such service in geographical areas which have special need therefor.

PAYMENTS.

SEC. 633.[291j–10] Grants under this part shall be paid in advance or by way of reimbursement, in such installments and on such conditions, as in the judgment of the Secretary will best carry out the purposes of this part.

PART D—GENERAL

FEDERAL HOSPITAL COUNCIL AND ADVISORY COMMITTEES.

SEC. 641.[291k] (a) In administering this title, the Surgeon General shall consult with a Federal Hospital Council consisting of the Surgeon General, who shall serve as Chairman ex officio, and twelve members appointed by the Secretary of Health, Education, and Welfare. Six of the twelve appointed members shall be persons who are outstanding in fields pertaining to medical facility and health activities, and three of these six shall be authorities in matters relating to the operation of hospitals or other medical facilities, one of them shall be an authority in matters relating to individuals with intellectual disabilities, and one of them shall be an authority in matters relating to mental health, and the other six members shall be appointed to represent the consumers of services provided

by such facilities and shall be persons familiar with the need for such services in urban or rural areas.

(b) Each appointed member shall hold office for a term of four years, except that any member appointed to fill a vacancy occurring prior to the expiration of the term for which his predecessor was appointed shall be appointed for the remainder of such term. An appointed member shall not be eligible to serve continuously for more than two terms (whether beginning before or after enactment of this section) but shall be eligible for reappointment if he has not served immediately preceding his reappointment.

(c) The Council shall meet as frequently as the Surgeon General deems necessary, but not less than once each year. Upon request by three or more members, it shall be the duty of the Surgeon General to call a meeting of the Council.

(d) The Council is authorized to appoint such special advisory or technical committees as may be useful in carrying out its functions.

CONFERENCE OF STATE AGENCIES.

SEC. 642.[291l] Whenever in his opinion the purposes of this title would be promoted by a conference, the Surgeon General may invite representatives of as many State agencies, designated in accordance with section 604, to confer as he deems necessary or proper. A conference of the representatives of all such State agencies shall be called annually by the Surgeon General. Upon the application of five or more of such State agencies, it shall be the duty of the Surgeon General to call a conference of representatives of all State agencies joining in the request.

STATE CONTROL OF OPERATIONS.

SEC. 643.[291m] Except as otherwise specifically provided, nothing in this title shall be construed as conferring on any Federal office or employee the right to exercise any supervision or control over the administration, personnel, maintenance, or operation of any facility with respect to which any funds have been or may be expended under this title.

LOANS FOR CERTAIN HOSPITAL EXPERIMENTATION PROJECTS.

SEC. 643A.[291m–1] (a) In order to alleviate hardship on any recipient of a grant under section 636 of this title (as in effect immediately before the enactment of the Hospital and Medical Facilities Amendments of 1964) for a project for the construction of an experimental or demonstration facility having as its specific purpose the application of novel means for the reduction of hospital costs with respect to which there has been a substantial increase in the cost of such construction (over the estimated cost of such project on the basis of which such grant was made) through no fault of such recipient, the Secretary is authorized to make a loan to such recipient not exceeding 66⅔ per centum of such increased costs, as determined by the Secretary, if the Secretary determines that such recipient is unable to obtain such an amount for such purpose from other public or private sources.

(b) Any such loan shall be made only on the basis of an application submitted to the Secretary in such form and containing such information and assurances as he may prescribe.

(c) Each such loan shall bear interest at the rate of 2½ per centum per annum on the unpaid balance thereof and shall be repayable over a period determined by the Secretary to be appropriate, but not exceeding fifty years.

(d) There are hereby authorized to be appropriated $3,500,000 to carry out the provisions of this section.

DEFINITIONS.

SEC. 645.[4] [291o] For the purposes of this title—

(a) The term "State" includes the Commonwealth of Puerto Rico, Guam, American Samoa, the Trust Territory of the Pacific Islands, the Virgin Islands, and the District of Columbia.

(b)(1) The term "Federal share" with respect to any project means the proportion of the cost of such project to be paid by the Federal Government under this title.

(2) With respect to any project in any State for which a grant is made from an allotment from an appropriation under section 601, the Federal share shall be the amount determined by the State agency designated in accordance with section 604, but not more than 66⅔ per centum or the State's allotment percentage, whichever is the lower, except that, if the State's allotment percentage is lower than 50 per centum, such allotment percentage shall be deemed to be 50 per centum for purposes of this paragraph.

(3) Prior to the approval of the first project in a State during any fiscal year the State agency designated in accordance with section 604 shall give the Secretary written notification of the maximum Federal share established pursuant to paragraph (2) for projects in such State to be approved by the Secretary during such fiscal year and the method for determining the actual Federal share to be paid with respect to such projects; and such maximum Federal share and such method of determination for projects in such State approved during such fiscal year shall not be changed after such approval.

(4) Notwithstanding the provisions of paragraphs (2) and (3) of this subsection, the Federal share shall, at the option of the State agency, be equal to the per centum provided under such paragraphs plus an incentive per centum (which when combined with the per centum provided under such paragraphs shall not exceed 90 per centum) specified by the State agency in the case of (A) projects that will provide services primarily for persons in an area determined by the Secretary to be a rural or urban poverty area, and (B) projects that offer potential for reducing health care costs through shared services among health care facilities, through interfacility cooperation, or through the construction or modernization of free-standing outpatient facilities.

(c) The term "hospital" includes general, tuberculosis, and other types of hospitals, and related facilities, such as laboratories, outpatient departments, nurses' home facilities, extended care fa-

[4] Section 644 was repealed by section 3(b) of Public Law 90–174.

cilities, facilities related to programs for home health services, self-care units, and central service facilities, operated in connection with hospitals, and also includes education or training facilities for health professions personnel operated as an integral part of a hospital, but does not include any hospital furnishing primarily domiciliary care.

(d) The term "public health center" means a publicly owned facility for the provision of public health services, including related publicly owned facilities such as laboratories, clinics, and administrative offices operated in connection with such a facility.

(e) The term "nonprofit" as applied to any facility means a facility which is owned and operated by one or more nonprofit corporations or associations no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual.

(f) The term "outpatient facility" means a facility (located in or apart from a hospital) for the diagnosis or diagnosis and treatment of ambulatory patients (including ambulatory inpatients)—

(1) which is operated in connection with a hospital, or

(2) in which patient care is under the professional supervision of persons licensed to practice medicine or surgery in the State, or in the case of dental diagnosis or treatment, under the professional supervision of persons licensed to practice dentistry in the State; or

(3) which offers to patients not requiring hospitalization the services of licensed physicians in various medical specialties, and which provides to its patients a reasonably full-range of diagnostic and treatment services.

(g) The term "rehabilitation facility" means a facility which is operated for the primary purpose of assisting in the rehabilitation of disabled persons through an integrated program of—

(1) medical evaluation and services, and

(2) psychological, social, or vocational evaluation and services,

under competent professional supervision, and in the case of which—

(3) the major portion of the required evaluation and services is furnished within the facility; and

(4) either (A) the facility is operated in connection with a hospital, or (B) all medical and related health services are prescribed by, or are under the general direction of, persons licensed to practice medicine or surgery in the State.

(h) The term "facility for long-term care" means a facility (including an extended care facility) providing in-patient care for convalescent or chronic disease patients who require skilled nursing care and related medical services—

(1) which is a hospital (other than a hospital primarily for the care and treatment of mentally ill or tuberculous patients) or is operated in connection with a hospital, or

(2) in which such nursing care and medical services are prescribed by, or are performed under the general direction of, persons licensed to practice medicine or surgery in the State.

(i) The term "construction" includes construction of new buildings, expansion, remodeling, and alteration of existing buildings,

and initial equipment of any such buildings (including medical transportation facilities) and, in any case in which it will help to provide a service not previously provided in the community, equipment of any buildings; including architects' fees, but excluding the cost of off-site improvements and, except with respect to public health centers, the cost of the acquisition of land.

(j) The term "cost" as applied to construction or modernization means the amount found by the Surgeon General to be necessary for construction and modernization respectively, under a project, except that such term, as applied to a project for modernization of a facility for which a grant or loan is to be made from an allotment under section 602(a)(2), does not include any amount found by the Surgeon General to be attributable to expansion of the bed capacity of such facility.

(k) The term "modernization" includes alteration, major repair (to the extent permitted by regulations), remodeling, replacement, and renovation of existing buildings (including initial equipment thereof), and replacement of obsolete, built-in (as determined in accordance with regulations) equipment of existing buildings.

(l) The term "title," when used with reference to a site for a project, means a fee simple, or such other estate or interest (including a leasehold on which the rental does not exceed 4 per centum of the value of the land) as the Surgeon General finds sufficient to assure for a period of not less than fifty years' undisturbed use and possession for the purposes of construction and operation of the project.

FINANCIAL STATEMENTS.

SEC. 646.[291o–1] In the case of any facility for which a grant, loan, or loan guarantee has been made under this title, the applicant for such grant, loan, or loan guarantee (or, if appropriate, such other person as the Secretary may prescribe) shall file at least annually with the State agency for the State in which the facility is located a statement which shall be in such form, and contain such information, as the Secretary may require to accurately show—

(1) the financial operations of the facility, and

(2) the costs to the facility of providing health services in the facility and the charges made by the facility for providing such services,

during the period with respect to which the statement is filed.

December 13, 2013

PUBLIC HEALTH SERVICE ACT-TITLE VII(HEALTH PROFESSIONS EDUCATION)

As Amended Through P.L. 113–4, Enacted March 7, 2013

TITLE VII—HEALTH PROFESSIONS EDUCATION

PART A—STUDENT LOANS

Subpart I—Insured Health Education Assistance Loans to Graduate Students

SEC. 701.[292] STATEMENT OF PURPOSE.

The purpose of this subpart is to enable the Secretary to provide a Federal program of student loan insurance for students in (and certain former students of) eligible institutions (as defined in section 719).

SEC. 702.[292a] SCOPE AND DURATION OF LOAN INSURANCE PROGRAM.

(a) IN GENERAL.—The total principal amount of new loans made and installments paid pursuant to lines of credit (as defined in section 719) to borrowers covered by Federal loan insurance under this subpart shall not exceed $350,000,000 for fiscal year 1993, $375,000,000 for fiscal year 1994, and $425,000,000 for fiscal year 1995. If the total amount of new loans made and installments paid pursuant to lines of credit in any fiscal year is less than the ceiling established for such year, the difference between the loans made and installments paid and the ceiling shall be carried over to the next fiscal year and added to the ceiling applicable to that fiscal year, and if in any fiscal year no ceiling has been established, any difference carried over shall constitute the ceiling for making new loans (including loans to new borrowers) and paying installments for such fiscal year. Thereafter, Federal loan insurance pursuant to this subpart may be granted only for loans made (or for loan installments paid pursuant to lines of credit) to enable students, who have obtained prior loans insured under this subpart, to continue or complete their educational program or to obtain a loan under section 705(a)(1)(B) to pay interest on such prior loans; but no insurance may be granted for any loan made or installment paid after September 30, 1998. The total principal amount of Federal loan insurance available under this subsection shall be granted by the Secretary without regard to any apportionment for the purpose of chapter 15 of title 31, United States Code, and without regard to any similar limitation.

(b) CERTAIN LIMITATIONS AND PRIORITIES.—

(1) LIMITATIONS REGARDING LENDERS, STATES, OR AREAS.—The Secretary may, if necessary to assure an equitable distribution of the benefits of this subpart, assign, within the maximum amounts specified in subsection (a), Federal loan insurance quotas applicable to eligible lenders, or to States or areas, and may from time to time reassign unused portions of these quotas.

(2) PRIORITY FOR CERTAIN LENDERS.—In providing certificates of insurance under section 706 through comprehensive contracts, the Secretary shall give priority to eligible lenders that agree—

(A) to make loans to students at interest rates below the rates prevailing, during the period involved, for loans covered by Federal loan insurance pursuant to this subpart; or

(B) to make such loans under terms that are otherwise favorable to the student relative to the terms under which eligible lenders are generally making such loans during such period.

(c) AUTHORITY OF STUDENT LOAN MARKETING ASSOCIATION.—

(1) IN GENERAL.—Subject to paragraph (2), the Student Loan Marketing Association, established under part B of title IV of the Higher Education Act of 1965, is authorized to make advances on the security of, purchase, service, sell, consolidate, or otherwise deal in loans which are insured by the Secretary under this subpart, except that if any loan made under this subpart is included in a consolidated loan pursuant to the authority of the Association under part B of title IV of the Higher Education Act of 1965, the interest rate on such consolidated loan shall be set at the weighted average interest rate of all such loans offered for consolidation and the resultant per centum shall be rounded downward to the nearest one-eighth of 1 per centum, except that the interest rate shall be no less than the applicable interest rate of the guaranteed student loan program established under part B of title IV of the Higher Education Act of 1965. In the case of such a consolidated loan, the borrower shall be responsible for any interest which accrues prior to the beginning of the repayment period of the loan, or which accrues during a period in which principal need not be paid (whether or not such principal is in fact paid) by reason of any provision of the Higher Education Act of 1965.

(2) APPLICABILITY OF CERTAIN FEDERAL REGULATIONS.—With respect to Federal regulations for lenders, this subpart may not be construed to preclude the applicability of such regulations to the Student Loan Marketing Association or to any other entity in the business of purchasing student loans, including such regulations with respect to applications, contracts, and due diligence.

SEC. 703.[292b] LIMITATIONS ON INDIVIDUAL INSURED LOANS AND ON LOAN INSURANCE.

(a) IN GENERAL.—The total of the loans made to a student in any academic year or its equivalent (as determined by the Secretary) which may be covered by Federal loan insurance under this subpart may not exceed $20,000 in the case of a student enrolled

in a school of medicine, osteopathic medicine, dentistry, veterinary medicine, optometry, or podiatric medicine, and $12,500 in the case of a student enrolled in a school of pharmacy, public health, allied health, or chiropractic, or a graduate program in health administration or behavioral and mental health practice, including clinical psychology. The aggregate insured unpaid principal amount for all such insured loans made to any borrower shall not at any time exceed $80,000 in the case of a borrower who is or was a student enrolled in a school of medicine, osteopathic medicine, dentistry, veterinary medicine, optometry, or podiatric medicine, and $50,000 in the case of a borrower who is or was a student enrolled in a school of pharmacy, public health, allied health, or chiropractic, or a graduate program in health administration or clinical psychology. The annual insurable limit per student shall not be exceeded by a line of credit under which actual payments by the lender to the borrower will not be made in any year in excess of the annual limit.

(b) EXTENT OF INSURANCE LIABILITY.—The insurance liability on any loan insured by the Secretary under this subpart shall be 100 percent of the unpaid balance of the principal amount of the loan plus interest. The full faith and credit of the United States is pledged to the payment of all amounts which may be required to be paid under the provisions of section 707 or 714.

SEC. 704.[292c] SOURCES OF FUNDS.

Loans made by eligible lenders in accordance with this subpart shall be insurable by the Secretary whether made from funds fully owned by the lender or from funds held by the lender in a trust or similar capacity and available for such loans.

SEC. 705.[292d] ELIGIBILITY OF BORROWERS AND TERMS OF INSURED LOANS.

(a) IN GENERAL.—A loan by an eligible lender shall be insurable by the Secretary under the provisions of this subpart only if—

(1) made to—

(A) a student who—

(i)(I) has been accepted for enrollment at an eligible institution, or (II) in the case of a student attending an eligible institution, is in good standing at that institution, as determined by the institution;

(ii) is or will be a full-time student at the eligible institution;

(iii) has agreed that all funds received under such loan shall be used solely for tuition, other reasonable educational expenses, including fees, books, and laboratory expenses, and reasonable living expenses, incurred by such students;

(iv) if required under section 3 of the Military Selective Service Act to present himself for and submit to registration under such section, has presented himself and submitted to registration under such section; and

(v) in the case of a pharmacy student, has satisfactorily completed three years of training; or

(B) an individual who—

(i) has previously had a loan insured under this subpart when the individual was a full-time student at an eligible institution;

(ii) is in a period during which, pursuant to paragraph (2), the principal amount of such previous loan need not be paid;

(iii) has agreed that all funds received under the proposed loan shall be used solely for repayment of interest due on previous loans made under this subpart; and

(iv) if required under section 3 of the Military Selective Service Act to present himself for and submit to registration under such section, has presented himself and submitted to registration under such section;

(2) evidenced by a note or other written agreement which—

(A) is made without security and without endorsement, except that if the borrower is a minor and such note or other written agreement executed by him would not, under the applicable law, create a binding obligation, an endorsement may be required;

(B) provides for repayment of the principal amount of the loan in installments over a period of not less than 10 years (unless sooner repaid) nor more than 25 years beginning not earlier than 9 months nor later than 12 months after the date of—

(i) the date on which—

(I) the borrower ceases to be a participant in an accredited internship or residency program of not more than four years in duration;

(II) the borrower completes the fourth year of an accredited internship or residency program of more than four years in duration; or

(III) the borrower, if not a participant in a program described in subclause (I) or (II), ceases to carry, at an eligible institution, the normal full-time academic workload as determined by the institution; or

(ii) the date on which a borrower who is a graduate of an eligible institution ceases to be a participant in a fellowship training program not in excess of two years or a participant in a full-time educational activity not in excess of two years, which—

(I) is directly related to the health profession for which the borrower prepared at an eligible institution, as determined by the Secretary; and

(II) may be engaged in by the borrower during such a two-year period which begins within twelve months after the completion of the borrower's participation in a program described in subclause (I) or (II) of clause (i) or prior to the completion of the borrower's participation in such program,

except as provided in subparagraph (C), except that the period of the loan may not exceed 33 years from the date

of execution of the note or written agreement evidencing it, and except that the note or other written instrument may contain such provisions relating to repayment in the event of default in the payment of interest or in the payment of the costs of insurance premiums, or other default by the borrower, as may be authorized by regulations of the Secretary in effect at the time the loan is made;

(C) provides that periodic installments of principal and interest need not be paid, but interest shall accrue, during any period (i) during which the borrower is pursuing a full-time course of study at an eligible institution (or at an institution defined by section 102(a) of the Higher Education Act of 1965); (ii) not in excess of four years during which the borrower is a participant in an accredited internship or residency program (including any period in such a program described in subclause (I) or subclause (II) of subparagraph (B)(i)); (iii) not in excess of three years, during which the borrower is a member of the Armed Forces of the United States; (iv) not in excess of three years during which the borrower is in service as a volunteer under the Peace Corps Act; (v) not in excess of three years during which the borrower is a member of the National Health Service Corps; (vi) not in excess of three years during which the borrower is in service as a full-time volunteer under title I of the Domestic Volunteer Service Act of 1973; (vii) not in excess of 3 years, for a borrower who has completed an accredited internship or residency training program in osteopathic general practice, family medicine, general internal medicine, preventive medicine, or general pediatrics and who is practicing primary care; (viii) not in excess of 1 year, for borrowers who are graduates of schools of chiropractic; (ix) any period not in excess of two years which is described in subparagraph (B)(ii); (x) not in excess of three years, during which the borrower is providing health care services to Indians through an Indian health program (as defined in section 108(a)(2)(A) of the Indian Health Care Improvement Act (25 U.S.C. 1616a(a)(2)(A)) [1]; and (xi) in addition to all other deferments for which the borrower is eligible under clauses (i) through (x), any period during which the borrower is a member of the Armed Forces on active duty during the Persian Gulf conflict, and any period described in clauses (i) through (xi) shall not be included in determining the 25-year period described in subparagraph (B);

(D) provides for interest on the unpaid principal balance of the loan at a yearly rate, not exceeding the applicable maximum rate prescribed and defined by the Secretary (within the limits set forth in subsection (b)) on a national, regional, or other appropriate basis, which interest shall be compounded not more frequently than annually and payable in installments over the period of the loan except as provided in subparagraph (C), except that the note or

[1] So in law. Probably should include another closing parenthesis.

other written agreement may provide that payment of any interest may be deferred until not later than the date upon which repayment of the first installment of principal falls due or the date repayment of principal is required to resume (whichever is applicable) and may further provide that, on such date, the amount of the interest which has so accrued may be added to the principal for the purposes of calculating a repayment schedule;

(E) offers, in accordance with criteria prescribed by regulation by the Secretary, a schedule for repayment of principal and interest under which payment of a portion of the principal and interest otherwise payable at the beginning of the repayment period (as defined in such regulations) is deferred until a later time in the period;

(F) entitles the borrower to accelerate without penalty repayment of the whole or any part of the loan;

(G) provides that the check for the proceeds of the loan shall be made payable jointly to the borrower and the eligible institution in which the borrower is enrolled; and

(H) contains such other terms and conditions consistent with the provisions of this subpart and with the regulations issued by the Secretary pursuant to this subpart, as may be agreed upon by the parties to such loan, including, if agreed upon, a provision requiring the borrower to pay to the lender, in addition to principal and interest, amounts equal to the insurance premiums payable by the lender to the Secretary with respect to such loan; and

(3) subject to the consent of the student and subject to applicable law, the eligible lender has obtained from the student appropriate demographic information regarding the student, including racial or ethnic background.

(b) LIMITATION ON RATE OF INTEREST.—The rate of interest prescribed and defined by the Secretary for the purpose of subsection (a)(2)(D) may not exceed the average of the bond equivalent rates of the 91-day Treasury bills auctioned for the previous quarter plus 3 percentage points, rounded to the next higher one-eighth of 1 percent.

(c) MINIMUM ANNUAL PAYMENT BY BORROWER.—The total of the payments by a borrower during any year or any repayment period with respect to the aggregate amount of all loans to that borrower which are insured under this subpart shall not be less than the annual interest on the outstanding principal, except as provided in subsection (a)(2)(C), unless the borrower, in the written agreement described in subsection (a)(2), agrees to make payments during any year or any repayment period in a lesser amount.

(d) APPLICABILITY OF CERTAIN LAWS ON RATE OR AMOUNT OF INTEREST.—No provision of any law of the United States (other than subsections (a)(2)(D) and (b)) or of any State that limits the rate or amount of interest payable on loans shall apply to a loan insured under this subpart.

(e) DETERMINATION REGARDING FORBEARANCE.—Any period of time granted to a borrower under this subpart in the form of for-

bearance on the loan shall not be included in the 25-year total loan repayment period under subsection (a)(2)(C).

(f) LOAN REPAYMENT SCHEDULE.—Lenders and holders under this subpart shall offer borrowers graduated loan repayment schedules that, during the first 5 years of loan repayment, are based on the borrower's debt-to-income ratio.

(g) RULE OF CONSTRUCTION REGARDING DETERMINATION OF NEED OF STUDENTS.—With respect to any determination of the financial need of a student for a loan covered by Federal loan insurance under this subpart, this subpart may not be construed to limit the authority of any school to make such allowances for students with special circumstances as the school determines appropriate.

(h) DEFINITIONS.—For purposes of this section:

(1) The term "active duty" has the meaning given such term in section 101(18) of title 37, United States Code, except that such term does not include active duty for training.

(2) The term "Persian Gulf conflict" means the period beginning on August 2, 1990, and ending on the date thereafter prescribed by Presidential proclamation or by law.

SEC. 706.[292e] CERTIFICATE OF LOAN INSURANCE; EFFECTIVE DATE OF INSURANCE.

(a) IN GENERAL.—

(1) AUTHORITY FOR ISSUANCE OF CERTIFICATE.—If, upon application by an eligible lender, made upon such form, containing such information, and supported by such evidence as the Secretary may require, and otherwise in conformity with this section, the Secretary finds that the applicant has made a loan to an eligible borrower which is insurable under the provisions of this subpart, he may issue to the applicant a certificate of insurance covering the loan and setting forth the amount and terms of the insurance.

(2) EFFECTIVE DATE OF INSURANCE.—Insurance evidenced by a certificate of insurance pursuant to subsection (a)(1) shall become effective upon the date of issuance of the certificate, except that the Secretary is authorized, in accordance with regulations, to issue commitments with respect to proposed loans, or with respect to lines (or proposed lines) of credit, submitted by eligible lenders, and in that event, upon compliance with subsection (a)(1) by the lender, the certificate of insurance may be issued effective as of the date when any loan, or any payment by the lender pursuant to a line of credit, to be covered by such insurance is made to a student described in section 705(a)(1). Such insurance shall cease to be effective upon 60 days' default by the lender in the payment of any installment of the premiums payable pursuant to section 708.

(3) CERTAIN AGREEMENTS FOR LENDERS.—An application submitted pursuant to subsection (a)(1) shall contain—

(A) an agreement by the applicant to pay, in accordance with regulations, the premiums fixed by the Secretary pursuant to section 708; and

(B) an agreement by the applicant that if the loan is covered by insurance the applicant will submit such supplementary reports and statements during the effective period of the loan agreement, upon such forms, at such

times, and containing such information as the Secretary may prescribe by or pursuant to regulation.

(b) AUTHORITY REGARDING COMPREHENSIVE INSURANCE COVERAGE.—

(1) IN GENERAL.—In lieu of requiring a separate insurance application and issuing a separate certificate of insurance for each loan made by an eligible lender as provided in subsection (a), the Secretary may, in accordance with regulations consistent with section 702, issue to any eligible lender applying therefor a certificate of comprehensive insurance coverage which shall, without further action by the Secretary, insure all insurable loans made by that lender, on or after the date of the certificate and before a specified cutoff date, within the limits of an aggregate maximum amount stated in the certificate. Such regulations may provide for conditioning such insurance, with respect to any loan, upon compliance by the lender with such requirements (to be stated or incorporated by reference in the certificate) as in the Secretary's judgment will best achieve the purpose of this subsection while protecting the financial interest of the United States and promoting the objectives of this subpart, including (but not limited to) provisions as to the reporting of such loans and information relevant thereto to the Secretary and as to the payment of initial and other premiums and the effect of default therein, and including provision for confirmation by the Secretary from time to time (through endorsement of the certificate) of the coverage of specific new loans by such certificate, which confirmation shall be incontestable by the Secretary in the absence of fraud or misrepresentation of fact or patent error.

(2) LINES OF CREDIT BEYOND CUTOFF DATE.—If the holder of a certificate of comprehensive insurance coverage issued under this subsection grants to a borrower a line of credit extending beyond the cutoff date specified in that certificate, loans or payments thereon made by the holder after that date pursuant to the line of credit shall not be deemed to be included in the coverage of that certificate except as may be specifically provided therein; but, subject to the limitations of section 702, the Secretary may, in accordance with regulations, make commitments to insure such future loans or payments, and such commitments may be honored either as provided in subsection (a) or by inclusion of such insurance in comprehensive coverage under this subsection for the period or periods in which such future loans or payments are made.

(c) ASSIGNMENT OF INSURANCE RIGHTS.—The rights of an eligible lender arising under insurance evidenced by a certificate of insurance issued to it under this section may be assigned by such lender, subject to regulation by the Secretary, only to—

(1) another eligible lender (including a public entity in the business of purchasing student loans); or

(2) the Student Loan Marketing Association.

(d) EFFECT OF REFINANCING OR CONSOLIDATION OF OBLIGATIONS.—The consolidation of the obligations of two or more federally insured loans obtained by a borrower in any fiscal year into a single obligation evidenced by a single instrument of indebted-

ness or the refinancing of a single loan shall not affect the insurance by the United States. If the loans thus consolidated are covered by separate certificates of insurance issued under subsection (a), the Secretary may upon surrender of the original certificates issue a new certificate of insurance in accordance with that subsection upon the consolidated obligation. If the loans thus consolidated are covered by a single comprehensive certificate issued under subsection (b), the Secretary may amend that certificate accordingly.

(e) RULE OF CONSTRUCTION REGARDING CONSOLIDATION OF DEBTS AND REFINANCING.—Nothing in this section shall be construed to preclude the lender and the borrower, by mutual agreement, from consolidating all of the borrower's loans insured under this subpart into a single instrument (or, if the borrower obtained only 1 loan insured under this subpart, refinancing the loan 1 time) under the terms applicable to an insured loan made at the same time as the consolidation. The lender or loan holder should provide full information to the borrower concerning the advantages and disadvantages of loan consolidation or refinancing. Nothing in this section shall be construed to preclude the consolidation of the borrower's loans insured under this subpart under section 428C of the Higher Education Act of 1965. Any loans insured pursuant to this subpart that are consolidated under section 428C of such Act shall not be eligible for special allowance payments under section 438 of such Act.

SEC. 707.[292f] DEFAULT OF BORROWER.

(a) CONDITIONS FOR PAYMENT TO BENEFICIARY.—

(1) IN GENERAL.—Upon default by the borrower on any loan covered by Federal loan insurance pursuant to this subpart, and after a substantial collection effort (including, subject to subsection (h), commencement and prosecution of an action) as determined under regulations of the Secretary, the insurance beneficiary shall promptly notify the Secretary and the Secretary shall, if requested (at that time or after further collection efforts) by the beneficiary, or may on his own motion, if the insurance is still in effect, pay to the beneficiary the amount of the loss sustained by the insured upon that loan as soon as that amount has been determined, except that, if the insurance beneficiary including any servicer of the loan is not designated for "exceptional performance", as set forth in paragraph (2), the Secretary shall pay to the beneficiary a sum equal to 98 percent of the amount of the loss sustained by the insured upon that loan.

(2) EXCEPTIONAL PERFORMANCE.—

(A) AUTHORITY.—Where the Secretary determines that an eligible lender, holder, or servicer has a compliance performance rating that equals or exceeds 97 percent, the Secretary shall designate that eligible lender, holder, or servicer, as the case may be, for exceptional performance.

(B) COMPLIANCE PERFORMANCE RATING.—For purposes of subparagraph (A), a compliance performance rating is determined with respect to compliance with due diligence in the disbursement, servicing, and collection of loans

under this subpart for each year for which the determination is made. Such rating shall be equal to the percentage of all due diligence requirements applicable to each loan, on average, as established by the Secretary, with respect to loans serviced during the period by the eligible lender, holder, or servicer.

(C) ANNUAL AUDITS FOR LENDERS, HOLDERS, AND SERVICERS.—Each eligible lender, holder, or servicer desiring a designation under subparagraph (A) shall have an annual financial and compliance audit conducted with respect to the loan portfolio of such eligible lender, holder, or servicer, by a qualified independent organization from a list of qualified organizations identified by the Secretary and in accordance with standards established by the Secretary. The standards shall measure the lender's, holder's, or servicer's compliance with due diligence standards and shall include a defined statistical sampling technique designed to measure the performance rating of the eligible lender, holder, or servicer for the purpose of this section. Each eligible lender, holder, or servicer shall submit the audit required by this section to the Secretary.

(D) SECRETARY'S DETERMINATIONS.—The Secretary shall make the determination under subparagraph (A) based upon the audits submitted under this paragraph and any information in the possession of the Secretary or submitted by any other agency or office of the Federal Government.

(E) QUARTERLY COMPLIANCE AUDIT.—To maintain its status as an exceptional performer, the lender, holder, or servicer shall undergo a quarterly compliance audit at the end of each quarter (other than the quarter in which status as an exceptional performer is established through a financial and compliance audit, as described in subparagraph (C)), and submit the results of such audit to the Secretary. The compliance audit shall review compliance with due diligence requirements for the period beginning on the day after the ending date of the previous audit, in accordance with standards determined by the Secretary.

(F) REVOCATION AUTHORITY.—The Secretary shall revoke the designation of a lender, holder, or servicer under subparagraph (A) if any quarterly audit required under subparagraph (E) is not received by the Secretary by the date established by the Secretary or if the audit indicates the lender, holder, or servicer has failed to meet the standards for designation as an exceptional performer under subparagraph (A). A lender, holder, or servicer receiving a compliance audit not meeting the standard for designation as an exceptional performer may reapply for designation under subparagraph (A) at any time.

(G) DOCUMENTATION.—Nothing in this section shall restrict or limit the authority of the Secretary to require the submission of claims documentation evidencing servicing performed on loans, except that the Secretary may not require exceptional performers to submit greater docu-

mentation than that required for lenders, holders, and servicers not designated under subparagraph (A).

(H) COST OF AUDITS.—Each eligible lender, holder, or servicer shall pay for all the costs associated with the audits required under this section.

(I) ADDITIONAL REVOCATION AUTHORITY.—Notwithstanding any other provision of this section, a designation under subparagraph (A) may be revoked at any time by the Secretary if the Secretary determines that the eligible lender, holder, or servicer has failed to maintain an overall level of compliance consistent with the audit submitted by the eligible lender, holder, or servicer under this paragraph or if the Secretary asserts that the lender, holder, or servicer may have engaged in fraud in securing designation under subparagraph (A) or is failing to service loans in accordance with program requirements.

(J) NONCOMPLIANCE.—A lender, holder, or servicer designated under subparagraph (A) that fails to service loans or otherwise comply with applicable program regulations shall be considered in violation of the Federal False Claims Act.

(b) SUBROGATION.—Upon payment by the Secretary of the amount of the loss pursuant to subsection (a), the United States shall be subrogated for all of the rights of the holder of the obligation upon the insured loan and shall be entitled to an assignment of the note or other evidence of the insured loan by the insurance beneficiary. If the net recovery made by the Secretary on a loan after deduction of the cost of that recovery (including reasonable administrative costs) exceeds the amount of the loss, the excess shall be paid over to the insured. The Secretary may sell without recourse to eligible lenders (or other entities that the Secretary determines are capable of dealing in such loans) notes or other evidence of loans received through assignment under the first sentence.

(c) FORBEARANCE.—Nothing in this section or in this subpart shall be construed to preclude any forbearance for the benefit of the borrower which may be agreed upon by the parties to the insured loan and approved by the Secretary or to preclude forbearance by the Secretary in the enforcement of the insured obligation after payment on that insurance.

(d) REASONABLE CARE AND DILIGENCE REGARDING LOANS.—Nothing in this section or in this subpart shall be construed to excuse the eligible lender or holder of a federally insured loan from exercising reasonable care and diligence in the making of loans under the provisions of this subpart and from exercising a substantial effort in the collection of loans under the provisions of this subpart. If the Secretary, after reasonable notice and opportunity for hearing to an eligible lender, finds that the lender has failed to exercise such care and diligence, to exercise such substantial efforts, to make the reports and statements required under section 706(a)(3), or to pay the required Federal loan insurance premiums, he shall disqualify that lender from obtaining further Federal insurance on loans granted pursuant to this subpart until he is satisfied that its failure has ceased and finds that there is reasonable

assurance that the lender will in the future exercise necessary care and diligence, exercise substantial effort, or comply with such requirements, as the case may be.

(e) DEFINITIONS.—For purposes of this section:

(1) The term "insurance beneficiary" means the insured or its authorized assignee in accordance with section 706(c).

(2) The term "amount of the loss" means, with respect to a loan, unpaid balance of the principal amount and interest on such loan, less the amount of any judgment collected pursuant to default proceedings commenced by the eligible lender or holder involved.

(3) The term "default" includes only such defaults as have existed for 120 days.

(4) The term "servicer" means any agency acting on behalf of the insurance beneficiary.

(f) REDUCTIONS IN FEDERAL REIMBURSEMENTS OR PAYMENTS FOR DEFAULTING BORROWERS.—The Secretary shall, after notice and opportunity for a hearing, cause to be reduced Federal reimbursements or payments for health services under any Federal law to borrowers who are practicing their professions and have defaulted on their loans insured under this subpart in amounts up to the remaining balance of such loans. Procedures for reduction of payments under the medicare program are provided under section 1892 of the Social Security Act. Notwithstanding such section 1892, any funds recovered under this subsection shall be deposited in the insurance fund established under section 710.

(g) CONDITIONS FOR DISCHARGE OF DEBT IN BANKRUPTCY.—Notwithstanding any other provision of Federal or State law, a debt that is a loan insured under the authority of this subpart may be released by a discharge in bankruptcy under any chapter of title 11, United States Code, only if such discharge is granted—

(1) after the expiration of the seven-year period beginning on the first date when repayment of such loan is required, exclusive of any period after such date in which the obligation to pay installments on the loan is suspended;

(2) upon a finding by the Bankruptcy Court that the nondischarge of such debt would be unconscionable; and

(3) upon the condition that the Secretary shall not have waived the Secretary's rights to apply subsection (f) to the borrower and the discharged debt.

(h) REQUIREMENT REGARDING ACTIONS FOR DEFAULT.—

(1) IN GENERAL.—With respect to the default by a borrower on any loan covered by Federal loan insurance under this subpart, the Secretary shall, under subsection (a), require an eligible lender or holder to commence and prosecute an action for such default unless—

(A) in the determination of the Secretary—

(i) the eligible lender or holder has made reasonable efforts to serve process on the borrower involved and has been unsuccessful with respect to such efforts, or

(ii) prosecution of such an action would be fruitless because of the financial or other circumstances of the borrower;

(B) for such loans made before the date of the enactment of the Health Professions Reauthorization Act of 1988, the loan involved was made in an amount of less than $5,000; or

(C) for such loans made after such date, the loan involved was made in an amount of less than $2,500.

(2) RELATIONSHIP TO CLAIM FOR PAYMENT.—With respect to an eligible lender or holder that has commenced an action pursuant to subsection (a), the Secretary shall make the payment required in such subsection, or deny the claim for such payment, not later than 60 days after the date on which the Secretary determines that the lender or holder has made reasonable efforts to secure a judgment and collect on the judgment entered into pursuant to this subsection.

(3) STATE COURT JUDGMENTS.—With respect to any State court judgment that is obtained by a lender or holder against a borrower for default on a loan insured under this subpart and that is subrogated to the United States under subsection (b), any United States attorney may register such judgment with the Federal courts for enforcement.

(i) INAPPLICABILITY OF FEDERAL AND STATE STATUTE OF LIMITATIONS ON ACTIONS FOR LOAN COLLECTION.—Notwithstanding any other provision of Federal or State law, there shall be no limitation on the period within which suit may be filed, a judgment may be enforced, or an offset, garnishment, or other action may be initiated or taken by the Secretary, the Attorney General, or other administrative head of another Federal agency, as the case may be, for the repayment of the amount due from a borrower on a loan made under this subpart that has been assigned to the Secretary under subsection (b).

(j) SCHOOL COLLECTION ASSISTANCE.—An institution or postgraduate training program attended by a borrower may assist in the collection of any loan of that borrower made under this subpart which becomes delinquent, including providing information concerning the borrower to the Secretary and to past and present lenders and holders of the borrower's loans, contacting the borrower in order to encourage repayment, and withholding services in accordance with regulations issued by the Secretary under section 715(a)(7). The institution or postgraduate training program shall not be subject to section 809 of the Fair Debt Collection Practices Act for purposes of carrying out activities authorized by this section.

SEC. 708.[292g] RISK-BASED PREMIUMS.

(a) AUTHORITY.—With respect to a loan made under this subpart on or after January 1, 1993, the Secretary, in accordance with subsection (b), shall assess a risk-based premium on an eligible borrower and, if required under this section, an eligible institution that is based on the default rate of the eligible institution involved (as defined in section 719).

(b) ASSESSMENT OF PREMIUM.—Except as provided in subsection (d)(2), the risk-based premium to be assessed under subsection (a) shall be as follows:

(1) LOW-RISK RATE.—With respect to an eligible borrower seeking to obtain a loan for attendance at an eligible institution that has a default rate of not to exceed five percent, such borrower shall be assessed a risk-based premium in an amount equal to 6 percent of the principal amount of the loan.

(2) MEDIUM-RISK RATE.—

(A) IN GENERAL.—With respect to an eligible borrower seeking to obtain a loan for attendance at an eligible institution that has a default rate of in excess of five percent but not to exceed 10 percent—

(i) such borrower shall be assessed a risk-based premium in an amount equal to 8 percent of the principal amount of the loan; and

(ii) such institution shall be assessed a risk-based premium in an amount equal to 5 percent of the principal amount of the loan.

(B) DEFAULT MANAGEMENT PLAN.—An institution of the type described in subparagraph (A) shall prepare and submit to the Secretary for approval, an annual default management plan, that shall specify the detailed short-term and long-term procedures that such institution will have in place to minimize defaults on loans to borrowers under this subpart. Under such plan the institution shall, among other measures, provide an exit interview to all borrowers that includes information concerning repayment schedules, loan deferments, forbearance, and the consequences of default.

(3) HIGH-RISK RATE.—

(A) IN GENERAL.—With respect to an eligible borrower seeking to obtain a loan for attendance at an eligible institution that has a default rate of in excess of 10 percent but not to exceed 20 percent—

(i) such borrower shall be assessed a risk-based premium in an amount equal to 8 percent of the principal amount of the loan; and

(ii) such institution shall be assessed a risk-based premium in an amount equal to 10 percent of the principal amount of the loan.

(B) DEFAULT MANAGEMENT PLAN.—An institution of the type described in subparagraph (A) shall prepare and submit to the Secretary for approval a plan that meets the requirements of paragraph (2)(B).

(4) INELIGIBILITY.—An individual shall not be eligible to obtain a loan under this subpart for attendance at an institution that has a default rate in excess of 20 percent.

(c) REDUCTION OF RISK-BASED PREMIUM.—Lenders shall reduce by 50 percent the risk-based premium to eligible borrowers if a credit worthy parent or other responsible party co-signs the loan note.

(d) ADMINISTRATIVE WAIVERS.—

(1) HEARING.—The Secretary shall afford an institution not less than one hearing, and may consider mitigating circumstances, prior to making such institution ineligible for participation in the program under this subpart.

(2) EXCEPTIONS.—In carrying out this section with respect to an institution, the Secretary may grant an institution a waiver of requirements of paragraphs (2) through (4) of subsection (b) if the Secretary determines that the default rate for such institution is not an accurate indicator because the volume of the loans under this subpart made by such institution has been insufficient.

(3) TRANSITION FOR CERTAIN INSTITUTIONS.—During the 3-year period beginning on the effective date of the Health Professions Education Extension Amendments of 1992—

(A) subsection (b)(4) shall not apply with respect to any eligible institution that is a Historically Black College or University; and

(B) any such institution that has a default rate in excess of 20 percent, and any eligible borrower seeking a loan for attendance at the institution, shall be subject to subsection (b)(3) to the same extent and in the same manner as eligible institutions and borrowers described in such subsection.

(e) PAYOFF TO REDUCE RISK CATEGORY.—An institution may pay off the outstanding principal and interest owed by the borrowers of such institution who have defaulted on loans made under this subpart in order to reduce the risk category of the institution.

SEC. 709.[292h] OFFICE FOR HEALTH EDUCATION ASSISTANCE LOAN DEFAULT REDUCTION.

(a) ESTABLISHMENT.—The Secretary shall establish, within the Division of Student Assistance of the Bureau of Health Professions, an office to be known as the Office for Health Education Assistance Loan Default Reduction (in this section referred to as the "Office").

(b) PURPOSE AND FUNCTIONS.—It shall be the purpose of the Office to achieve a reduction in the number and amounts of defaults on loans guaranteed under this subpart. In carrying out such purpose the Office shall—

(1) conduct analytical and evaluative studies concerning loans and loan defaults;

(2) carry out activities designed to reduce loan defaults;

(3) respond to special circumstances that may exist in the financial lending environment that may lead to loan defaults;

(4) coordinate with other Federal entities that are involved with student loan programs, including—

(A) with respect to the Department of Education, in the development of a single student loan application form, a single student loan deferment form, a single disability form, and a central student loan database; and

(B) with respect to the Department of Justice, in the recovery of payments from health professionals who have defaulted on loans guaranteed under this subpart; and

(5) provide technical assistance to borrowers, lenders, holders, and institutions concerning deferments and collection activities.

(c) ADDITIONAL DUTIES.—In conjunction with the report submitted under subsection (b), the Office shall—

(1) compile, and publish in the Federal Register, a list of the borrowers who are in default under this subpart; and

(2) send the report and notices of default with respect to these borrowers to relevant Federal agencies and to schools, school associations, professional and specialty associations, State licensing boards, hospitals with which such borrowers may be associated, and any other relevant organizations.

(d) ALLOCATION OF FUNDS FOR OFFICE.—In the case of amounts reserved under section 710(a)(2)(B) for obligation under this subsection, the Secretary may obligate the amounts for the purpose of administering the Office, including 7 full-time equivalent employment positions for such Office. With respect to such purpose, amounts made available under the preceding sentence are in addition to amounts made available to the Health Resources and Services Administration for program management for the fiscal year involved. With respect to such employment positions, the positions are in addition to the number of full-time equivalent employment positions that otherwise is authorized for the Department of Health and Human Services for the fiscal year involved.

SEC. 710.[292i] INSURANCE ACCOUNT.

(a) IN GENERAL.—

(1) ESTABLISHMENT.—There is hereby established a student loan insurance account (in this section referred to as the "Account") which shall be available without fiscal year limitation to the Secretary for making payments in connection with the collection and default of loans insured under this subpart by the Secretary.

(2) FUNDING.—

(A) Except as provided in subparagraph (B), all amounts received by the Secretary as premium charges for insurance and as receipts, earnings, or proceeds derived from any claim or other assets acquired by the Secretary in connection with his operations under this subpart, and any other moneys, property, or assets derived by the Secretary from the operations of the Secretary in connection with this section, shall be deposited in the Account.

(B) With respect to amounts described in subparagraph (A) that are received by the Secretary for fiscal year 1993 and subsequent fiscal years, the Secretary may, before depositing such amounts in the Account, reserve from the amounts each such fiscal year not more than $1,000,000 for obligation under section 709(d).

(3) EXPENDITURES.—All payments in connection with the default of loans insured by the Secretary under this subpart shall be paid from the Account.

(b) CONTINGENT AUTHORITY FOR ISSUANCE OF NOTES OR OTHER OBLIGATIONS.—If at any time the moneys in the Account are insufficient to make payments in connection with the collection or default of any loan insured by the Secretary under this subpart, the Secretary of the Treasury may lend the Account such amounts as may be necessary to make the payments involved, subject to the Federal Credit Reform Act of 1990.

SEC. 711.[292j] POWERS AND RESPONSIBILITIES OF SECRETARY.

(a) IN GENERAL.—In the performance of, and with respect to, the functions, powers, and duties vested in the Secretary by this subpart, the Secretary is authorized as follows:

(1) To prescribe such regulations as may be necessary to carry out the purposes of this subpart.

(2) To sue and be sued in any district court of the United States. Such district courts shall have jurisdiction of civil actions arising under this subpart without regard to the amount in controversy, and any action instituted under this subsection by or against the Secretary shall survive notwithstanding any change in the person occupying the office of Secretary or any vacancy in that office. No attachment, injunction, garnishment, or other similar process, mesne or final, shall be issued against the Secretary or property under the control of the Secretary. Nothing herein shall be constructed to except litigation arising out of activities under this subpart from the application of sections 517 and 547 of title 28 of the United States Code.

(3) To include in any contract for Federal loan insurance such terms, conditions, and covenants relating to repayment of principal and payments of interest, relating to his obligations and rights and to those of eligible lenders, and borrowers in case of default, and relating to such other matters as the Secretary determines to be necessary to assure that the purposes of this subpart will be achieved. Any term, condition, and covenant made pursuant to this paragraph or any other provisions of this subpart may be modified by the Secretary if the Secretary determines that modification is necessary to protect the financial interest of the United States.

(4) Subject to the specific limitations in the subpart, to consent to the modification of any note or other instrument evidencing a loan which has been insured by him under this subpart (including modifications with respect to the rate of interest, time of payment of any installment of principal and interest or any portion thereof, or any other provision).

(5) To enforce, pay, compromise, waive, or release any right, title, claim, lien, or demand, however acquired, including any equity or any right or[2] redemption.

(b) ANNUAL BUDGET; ACCOUNTS.—The Secretary shall, with respect to the financial operations arising by reason of this subpart—

(1) prepare annually and submit a budget program as provided for wholly owned Government corporations by the Government Corporation Control Act; and

(2) maintain with respect to insurance under this subpart an integral set of accounts.

SEC. 712.[292k] PARTICIPATION BY FEDERAL CREDIT UNIONS IN FEDERAL, STATE, AND PRIVATE STUDENT LOAN INSURANCE PROGRAMS.

Notwithstanding any other provision of law, Federal credit unions shall, pursuant to regulations of the Administrator of the National Credit Union Administration, have power to make in-

[2] So in law. See section 102 of Public Law 102–408 (106 Stat. 1994). Probably should be "right of redemption".

sured loans to eligible students in accordance with the provisions of this subpart relating to Federal insured loans.

SEC. 713.[292l] DETERMINATION OF ELIGIBLE STUDENTS.

For purposes of determining eligible students under this part, in the case of a public school in a State that offers an accelerated, integrated program of study combining undergraduate premedical education and medical education leading to advanced entry, by contractual agreement, into an accredited four-year school of medicine which provides the remaining training leading to a degree of doctor of medicine, whenever in this part a provision refers to a student at a school of medicine, such reference shall include only a student enrolled in any of the last four years of such accelerated, integrated program of study.

SEC. 714.[292m] REPAYMENT BY SECRETARY OF LOANS OF DECEASED OR DISABLED BORROWERS.

If a borrower who has received a loan dies or becomes permanently and totally disabled (as determined in accordance with regulations of the Secretary), the Secretary shall discharge the borrower's liability on the loan by repaying the amount owed on the loan from the account established under section 710.

SEC. 715.[292n] ADDITIONAL REQUIREMENTS FOR INSTITUTIONS AND LENDERS.

(a) IN GENERAL.—Notwithstanding any other provision of this subpart, the Secretary is authorized to prescribe such regulations as may be necessary to provide for—

(1) a fiscal audit of an eligible institution with regard to any funds obtained from a borrower who has received a loan insured under this subpart;

(2) the establishment of reasonable standards of financial responsibility and appropriate institutional capability for the administration by an eligible institution of a program of student financial aid with respect to funds obtained from a student who has received a loan insured under this subpart;

(3) the limitation, suspension, or termination of the eligibility under this subpart of any otherwise eligible institution, whenever the Secretary has determined, after notice and affording an opportunity for hearing, that such institution has violated or failed to carry out any regulation prescribed under this subpart;

(4) the collection of information from the borrower, lender, or eligible institution to assure compliance with the provisions of section 705;

(5) the assessing of tuition or fees to borrowers in amounts that are the same or less than the amount of tuition and fees assessed to nonborrowers;

(6) the submission, by the institution or the lender to the Office of Health Education Assistance Loan Default Reduction, of information concerning each loan made under this subpart, including the date when each such loan was originated, the date when each such loan is sold, the identity of the loan holder and information concerning a change in the borrower's status;

(7) the withholding of services, including academic transcripts, financial aid transcripts, and alumni services, by an institution from a borrower upon the default of such borrower of a loan under this subpart, except in case of a borrower who has filed for bankruptcy; and

(8) the offering, by the lender to the borrower, of a variety of repayment options, including fixed-rate, graduated repayment with negative amortization permitted, and income dependent payments for a limited period followed by level monthly payments.

(b) RECORDING BY INSTITUTION OF INFORMATION ON STUDENTS.—The Secretary shall require an eligible institution to record, and make available to the lender and to the Secretary upon request, the name, address, postgraduate destination, and other reasonable identifying information for each student of such institution who has a loan insured under this subpart.

(c) WORKSHOP FOR STUDENT BORROWERS.—Each participating eligible institution must have, at the beginning of each academic year, a workshop concerning the provisions of this subpart that all student borrowers shall be required to attend.

SEC. 719.[292o] DEFINITIONS.

For purposes of this subpart:

(1) The term "eligible institution" means, with respect to a fiscal year, a school of medicine, osteopathic medicine, dentistry, veterinary medicine, optometry, podiatric medicine, pharmacy, public health, allied health, or chiropractic, or a graduate program in health administration or behavioral and mental health practice, including clinical psychology.

(2) The term "eligible lender" means an eligible institution that became a lender under this subpart prior to September 15, 1992, an agency or instrumentality of a State, a financial or credit institution (including an insurance company) which is subject to examination and supervision by an agency of the United States or of any State, a pension fund approved by the Secretary for this purpose, or a nonprofit private entity designated by the State, regulated by the State, and approved by the Secretary.

(3) The term "line of credit" means an arrangement or agreement between the lender and the borrower whereby a loan is paid out by the lender to the borrower in annual installments, or whereby the lender agrees to make, in addition to the initial loan, additional loans in subsequent years.

(4) The term "school of allied health" means a program in a school of allied health (as defined in section 799) which leads to a masters' degree or a doctoral degree.

(5)(A) The term "default rate", in the case of an eligible entity, means the percentage constituted by the ratio of—

(i) the principal amount of loans insured under this subpart—

(I) that are made with respect to the entity and that enter repayment status after April 7, 1987; and

(II) for which amounts have been paid under section 707(a) to insurance beneficiaries, exclusive of any

loan for which amounts have been so paid as a result of the death or total and permanent disability of the borrower; exclusive of any loan for which the borrower begins payments to the Secretary on the loan pursuant to section 707(b) and maintains payments for 12 consecutive months in accordance with the agreement involved (with the loan subsequently being included or excluded, as the case may be, as amounts paid under section 707(a) according to whether further defaults occur and whether with respect to the default involved compliance with such requirement regarding 12 consecutive months occurs); and exclusive of any loan on which payments may not be recovered by reason of the obligation under the loan being discharged in bankruptcy under title 11, United States Code; to

(ii) the total principal amount of loans insured under this subpart that are made with respect to the entity and that enter repayment status after April 7, 1987.

(B) For purposes of subparagraph (A), a loan insured under this subpart shall be considered to have entered repayment status if the applicable period described in subparagraph (B) of section 705(a)(2) regarding the loan has expired (without regard to whether any period described in subparagraph (C) of such section is applicable regarding the loan).

(C) For purposes of subparagraph (A), the term "eligible entity" means an eligible institution, an eligible lender, or a holder, as the case may be.

(D) For purposes of subparagraph (A), a loan is made with respect to an eligible entity if—

(i) in the case of an eligible institution, the loan was made to students of the institution;

(ii) in the case of an eligible lender, the loan was made by the lender; and

(iii) in the case of a holder, the loan was purchased by the holder.

SEC. 720.[292p] AUTHORIZATION OF APPROPRIATIONS.

(a) IN GENERAL.—For fiscal year 1993 and subsequent fiscal years, there are authorized to be appropriated such sums as may be necessary for the adequacy of the student loan insurance account under this subpart and for the purpose of administering this subpart.

(b) AVAILABILITY OF SUMS.—Sums appropriated under subsection (a) shall remain available until expended.

Subpart II—Federally-Supported Student Loan Funds

SEC. 721.[292q] AGREEMENTS FOR OPERATION OF SCHOOL LOAN FUNDS.

(a) FUND AGREEMENTS.—The Secretary is authorized to enter into an agreement for the establishment and operation of a student loan fund in accordance with this subpart with any public or other

nonprofit school of medicine, osteopathic medicine, dentistry, pharmacy, podiatric medicine, optometry, or veterinary medicine.

(b) REQUIREMENTS.—Each agreement entered into under this section shall—

(1) provide for establishment of a student loan fund by the school;

(2) provide for deposit in the fund of—

(A) the Federal capital contributions to the fund;

(B) an amount equal to not less than one-ninth of such Federal capital contributions, contributed by such institution;

(C) collections of principal and interest on loans made from the fund;

(D) collections pursuant to section 722(j); and

(E) any other earnings of the fund;

(3) provide that the fund shall be used only for loans to students of the school in accordance with the agreement and for costs of collection of such loans and interest thereon;

(4) provide that loans may be made from such funds only to students pursuing a full-time course of study at the school leading to a degree of doctor of medicine, doctor of dentistry or an equivalent degree, doctor of osteopathy, bachelor of science in pharmacy or an equivalent degree, doctor of pharmacy or an equivalent degree, doctor of podiatric medicine or an equivalent degree, doctor of optometry or an equivalent degree, or doctor of veterinary medicine or an equivalent degree;

(5) provide that the school shall advise, in writing, each applicant for a loan from the student loan fund of the provisions of section 722 under which outstanding loans from the student loan fund may be paid (in whole or in part) by the Secretary; and

(6) contain such other provisions as are necessary to protect the financial interests of the United States.

(c) FAILURE OF SCHOOL TO COLLECT LOANS.—

(1) IN GENERAL.—Any standard established by the Secretary by regulation for the collection by schools of medicine, osteopathic medicine, dentistry, pharmacy, podiatric medicine, optometry, or veterinary medicine of loans made pursuant to loan agreements under this subpart shall provide that the failure of any such school to collect such loans shall be measured in accordance with this subsection. This subsection may not be construed to require such schools to reimburse the student loan fund under this subpart for loans that became uncollectible prior to August 1985 or to penalize such schools with respect to such loans.

(2) EXTENT OF FAILURE.—The measurement of a school's failure to collect loans made under this subpart shall be the ratio (stated as a percentage) that the defaulted principal amount outstanding of such school bears to the matured loans of such school.

(3) DEFINITIONS.—For purposes of this subsection:

(A) The term "default" means the failure of a borrower of a loan made under this subpart to—

(i) make an installment payment when due; or

(ii) comply with any other term of the promissory note for such loan,

except that a loan made under this subpart shall not be considered to be in default if the loan is discharged in bankruptcy or if the school reasonably concludes from written contracts with the borrower that the borrower intends to repay the loan.

(B) The term "defaulted principal amount outstanding" means the total amount borrowed from the loan fund of a school that has reached the repayment stage (minus any principal amount repaid or canceled) on loans—

(i) repayable monthly and in default for at least 120 days; and

(ii) repayable less frequently than monthly and in default for at least 180 days;

(C) The term "grace period" means the period of one year beginning on the date on which the borrower ceases to pursue a full-time course of study at a school of medicine, osteopathic medicine, dentistry, pharmacy, podiatric medicine, optometry, or veterinary medicine; and

(D) The term "matured loans" means the total principal amount of all loans made by a school under this subpart minus the total principal amount of loans made by such school to students who are—

(i) enrolled in a full-time course of study at such school; or

(ii) in their grace period.

SEC. 722.[292r] LOAN PROVISIONS.

(a) AMOUNT OF LOAN.—

(1) IN GENERAL.—Loans from a student loan fund (established under an agreement with a school under section 721) may not, subject to paragraph (2), exceed for any student for a school year (or its equivalent) the cost of attendance (including tuition, other reasonable educational expenses, and reasonable living costs) for that year at the educational institution attended by the student (as determined by such educational institution).

(2) THIRD AND FOURTH YEARS OF MEDICAL SCHOOL.—For purposes of paragraph (1), the amount of the loan may, in the case of the third or fourth year of a student at a school of medicine or osteopathic medicine, be increased to the extent necessary to pay the balances of loans that, from sources other than the student loan fund under section 721, were made to the individual for attendance at the school. The authority to make such an increase is subject to the school and the student agreeing that such amount (as increased) will be expended to pay such balances.

(b) TERMS AND CONDITIONS.—Subject to section 723, any such loans shall be made on such terms and conditions as the school may determine, but may be made only to a student—

(1) who is in need of the amount thereof to pursue a full-time course of study at the school leading to a degree of doctor of medicine, doctor of dentistry or an equivalent degree, doctor

of osteopathy, bachelor of science in pharmacy or an equivalent degree, doctor of pharmacy or an equivalent degree, doctor of podiatric medicine or an equivalent degree, doctor of optometry or an equivalent degree, or doctor of veterinary medicine or an equivalent degree; and

(2) who, if required under section 3 of the Military Selective Service Act to present himself for and submit to registration under such section, has presented himself and submitted to registration under such section.

(c) REPAYMENT; EXCLUSIONS FROM REPAYMENT PERIOD.—Such loans shall be repayable in equal or graduated periodic installments (with the right of the borrower to accelerate repayment) over the period of not less than 10 years nor more than 25 years, at the discretion of the institution, which begins one year after the student ceases to pursue a full-time course of study at a school of medicine, osteopathic medicine, dentistry, pharmacy, podiatry, optometry, or veterinary medicine, excluding from such period—

(1) all periods—

(A) not in excess of three years of active duty performed by the borrower as a member of a uniformed service;

(B) not in excess of three years during which the borrower serves as a volunteer under the Peace Corps Act;

(C) during which the borrower participates in advanced professional training, including internships and residencies; and

(D) during which the borrower is pursuing a full-time course of study at such a school; and

(2) a period—

(A) not in excess of two years during which a borrower who is a full-time student in such a school leaves the school, with the intent to return to such school as a full-time student, in order to engage in a full-time educational activity which is directly related to the health profession for which the borrower is preparing, as determined by the Secretary; or

(B) not in excess of two years during which a borrower who is a graduate of such a school is a participant in a fellowship training program or a full-time educational activity which—

(i) is directly related to the health profession for which such borrower prepared at such school, as determined by the Secretary; and

(ii) may be engaged in by the borrower during such a two-year period which begins within twelve months after the completion of the borrower's participation in advanced professional training described in paragraph (1)(C) or prior to the completion of such borrower's participation in such training.

(d) CANCELLATION OF LIABILITY.—The liability to repay the unpaid balance of such a loan and accrued interest thereon shall be canceled upon the death of the borrower, or if the Secretary determines that he has become permanently, and totally disabled.

(e) RATE OF INTEREST.—Such loans shall bear interest, on the unpaid balance of the loan, computed only for periods for which the loan is repayable, at the rate of 5 percent per year.

(f) SECURITY OR ENDORSEMENT.—Loans shall be made under this subpart without security or endorsement, except that if the borrower is a minor and the note or other evidence of obligation executed by him would not, under the applicable law, create a binding obligation, either security or endorsement may be required.

(g) TRANSFERRING AND ASSIGNING LOANS.—No note or other evidence of a loan made under this subpart may be transferred or assigned by the school making the loan except that, if the borrowers transfer to another school participating in the program under this subpart, such note or other evidence of a loan may be transferred to such other school.

(h) CHARGE WITH RESPECT TO INSURANCE FOR CERTAIN CANCELLATIONS.—Subject to regulations of the Secretary, a school may assess a charge with respect to loans made this[3] subpart to cover the costs of insuring against cancellation of liability under subsection (d).

(i) CHARGE WITH RESPECT TO LATE PAYMENTS.—Subject to regulations of the Secretary, and in accordance with this section, a school shall assess a charge with respect to a loan made under this subpart for failure of the borrower to pay all or any part of an installment when it is due and, in the case of a borrower who is entitled to deferment of the loan under subsection (c), for any failure to file timely and satisfactory evidence of such entitlement. No such charge may be made if the payment of such installment or the filing of such evidence is made within 60 days after the date on which such installment or filing is due. The amount of any such charge may not exceed an amount equal to 6 percent of the amount of such installment. The school may elect to add the amount of any such charge to the principal amount of the loan as of the first day after the day on which such installment or evidence was due, or to make the amount of the charge payable to the school not later than the due date of the next installment after receipt by the borrower of notice of the assessment of the charge.

(j) AUTHORITY OF SCHOOLS REGARDING RATE OF PAYMENT.—A school may provide, in accordance with regulations of the Secretary, that during the repayment period of a loan from a loan fund established pursuant to an agreement under this subpart payments of principal and interest by the borrower with respect to all the outstanding loans made to him from loan funds so established shall be at a rate equal to not less than $40 per month.

(k) AUTHORITY REGARDING REPAYMENTS BY SECRETARY.—Upon application by a person who received, and is under an obligation to repay, any loan made to such person as a health professions student to enable him to study medicine, osteopathy, dentistry, veterinary medicine, optometry, pharmacy, or podiatry, the Secretary may undertake to repay (without liability to the applicant) all or any part of such loan, and any interest or portion thereof out-

[3] So in law. See section 102 of Public Law 102–408 (106 Stat. 1994). Probably should be "made under this subpart".

standing thereon, upon his determination, pursuant to regulations establishing criteria therefor, that the applicant—

(1) failed to complete such studies leading to his first professional degree;

(2) is in exceptionally needy circumstances;

(3) is from a low-income or disadvantaged family as those terms may be defined by such regulations; and

(4) has not resumed, or cannot reasonably be expected to resume, the study of medicine, osteopathy, dentistry, veterinary medicine, optometry, pharmacy, or podiatric medicine, within two years following the date upon which he terminated such studies.

(l) COLLECTION EFFORTS BY SECRETARY.—The Secretary is authorized to attempt to collect any loan which was made under this subpart, which is in default, and which was referred to the Secretary by a school with which the Secretary has an agreement under this subpart, on behalf of that school under such terms and conditions as the Secretary may prescribe (including reimbursement from the school's student loan fund for expenses the Secretary may reasonably incur in attempting collection), but only if the school has complied with such requirements as the Secretary may specify by regulation with respect to the collection of loans under this subpart. A loan so referred shall be treated as a debt subject to section 5514 of title 5, United States Code. Amounts collected shall be deposited in the school's student loan fund. Whenever the Secretary desires the institution of a civil action regarding any such loan, the Secretary shall refer the matter to the Attorney General for appropriate action.

(m) ELIMINATION OF STATUTE OF LIMITATION FOR LOAN COLLECTIONS.—

(1) PURPOSE.—It is the purpose of this subsection to ensure that obligations to repay loans under this section are enforced without regard to any Federal or State statutory, regulatory, or administrative limitation on the period within which debts may be enforced.

(2) PROHIBITION.—Notwithstanding any other provision of Federal or State law, no limitation shall terminate the period within which suit may be filed, a judgment may be enforced, or an offset, garnishment, or other action may be initiated or taken by a school that has an agreement with the Secretary pursuant to section 721 that is seeking the repayment of the amount due from a borrower on a loan made under this subpart after the default of the borrower on such loan.

SEC. 723.[292s] MEDICAL SCHOOLS AND PRIMARY HEALTH CARE.

(a) REQUIREMENTS FOR STUDENTS.—

(1) IN GENERAL.—Subject to the provisions of this subsection, in the case of student loan funds established under section 721 by schools of medicine or osteopathic medicine, each agreement entered into under such section with such a school shall provide (in addition to the provisions required in subsection (b) of such section) that the school will make a loan from such fund to a student only if the student agrees—

(A) to enter and complete a residency training program in primary health care not later than 4 years after the date on which the student graduates from such school; and

(B) to practice in such care for 10 years (including residency training in primary health care) or through the date on which the loan is repaid in full, whichever occurs first.

(2) INAPPLICABILITY TO CERTAIN STUDENTS.—

(A) The requirement established in paragraph (1) regarding the student loan fund of a school does not apply to a student if—

(i) the first loan to the student from such fund is made before July 1, 1993; or

(ii) the loan is made from—

(I) a Federal capital contribution under section 721 that is made from amounts appropriated under section 724(f) (in this section referred to as an "exempt Federal capital contribution"); or

(II) a school contribution made under section 721 pursuant to such a Federal capital contribution (in this section referred to as an "exempt school contribution").

(B) A Federal capital contribution under section 721 may not be construed as being an exempt Federal capital contribution if the contribution was made from amounts appropriated before October 1, 1990. A school contribution under section 721 may not be construed as being an exempt school contribution if the contribution was made pursuant to a Federal capital contribution under such section that was made from amounts appropriated before such date.

(3) NONCOMPLIANCE BY STUDENT.—Each agreement entered into with a student pursuant to paragraph (1) shall provide that, if the student fails to comply with such agreement, the loan involved will begin to accrue interest at a rate of 2 percent per year greater than the rate at which the student would pay if compliant in such year.

(4) WAIVERS.—

(A) With respect to the obligation of an individual under an agreement made under paragraph (1) as a student, the Secretary shall provide for the partial or total waiver or suspension of the obligation whenever compliance by the individual is impossible, or would involve extreme hardship to the individual, and if enforcement of the obligation with respect to the individual would be unconscionable.

(B) For purposes of subparagraph (A), the obligation of an individual shall be waived if—

(i) the status of the individual as a student of the school involved is terminated before graduation from the school, whether voluntarily or involuntarily; and

(ii) the individual does not, after such termination, resume attendance at the school or begin attendance

at any other school of medicine or osteopathic medicine.

(C) If an individual resumes or begins attendance for purposes of subparagraph (B), the obligation of the individual under the agreement under paragraph (1) shall be considered to have been suspended for the period in which the individual was not in attendance.

(D) This paragraph may not be construed as authorizing the waiver or suspension of the obligation of a student to repay, in accordance with section 722, loans from student loan funds under section 721.

(b) REQUIREMENTS FOR SCHOOLS.—

(1) IN GENERAL.—Subject to the provisions of this subsection, in the case of student loan funds established under section 721 by schools of medicine or osteopathic medicine, each agreement entered into under such section with such a school shall provide (in addition to the provisions required in subsection (b) of such section) that, for the 1-year period ending on June 30, 1997;[4] and for the 1-year period ending on June 30 of each subsequent fiscal year, the school will meet not less than 1 of the conditions described in paragraph (2) with respect to graduates of the school whose date of graduation from the school occurred approximately 4 years before the end of the 1-year period involved.

(2) DESCRIPTION OF CONDITIONS.—With respect to graduates described in paragraph (1) (in this paragraph referred to as "designated graduates"), the conditions referred to in such paragraph for a school for a 1-year period are as follows:

(A) Not less than 50 percent of designated graduates of the school meet the criterion of either being in a residency training program in primary health care, or being engaged in a practice in such care (having completed such a program).

(B) Not less than 25 percent of the designated graduates of the school meet such criterion, and such percentage is not less than 5 percentage points above the percentage of such graduates meeting such criterion for the preceding 1-year period.

(C) In the case of schools of medicine or osteopathic medicine with student loans funds under section 721, the school involved is at or above the 75th percentile of such schools whose designated graduates meet such criterion.

(3) DETERMINATIONS BY SECRETARY.—Not later than 90 days after the close of each 1-year period described in paragraph (1), the Secretary shall make a determination of whether the school involved has for such period complied with such paragraph and shall in writing inform the school of the determination. Such determination shall be made only after consideration of the report submitted to the Secretary by the school under paragraph (6).

(4) NONCOMPLIANCE BY SCHOOL.—

[4] So in law. See section 2014(c)(2)(A)(i) of Public Law 103–43 (107 Stat. 216). The semicolon probably should be a comma.

(A)(i) Subject to subparagraph (C), each agreement under section 721 with a school of medicine or osteopathic medicine shall provide that, if the school fails to comply with paragraph (1) for a 1-year period under such paragraph, the school—

(I) will pay to the Secretary the amount applicable under subparagraph (B) for the period; and

(II) will pay such amount not later than 90 days after the school is informed under paragraph (3) of the determination of the Secretary regarding such period.

(ii) Any amount that a school is required to pay under clause (i) may be paid from the student loan fund of the school under section 721.

(B) For purposes of subparagraph (A), the amount applicable for a school, subject to subparagraph (C), is—

(i) for the 1-year period ending June 30, 1997, an amount equal to 10 percent of the income received during such period by the student loan fund of the school under section 721;

(ii) for the 1-year period ending June 30, 1998, an amount equal to 20 percent of the income received during such period by the student loan fund; and

(iii) for any subsequent 1-year period under paragraph (1), an amount equal to 30 percent of the income received during such period by the student loan fund.

(C) In determining the amount of income that a student loan fund has received for purposes of subparagraph (B), the Secretary shall exclude any income derived from exempt contributions. Payments made to the Secretary under subparagraph (A) may not be made with such contributions or with income derived from such contributions.

(5) EXPENDITURE OF PAYMENTS.—

(A) Amounts paid to the Secretary under paragraph (4) shall be expended to make Federal capital contributions to student loan funds under section 721 of schools that are in compliance with paragraph (1).

(B) A Federal capital contribution under section 721 may not be construed as being an exempt Federal capital contribution if the contribution is made from payments under subparagraph (A). A school contribution under such section may not be construed as being an exempt school contribution if the contribution is made pursuant to a Federal capital contribution from such payments.

(6) REPORTS BY SCHOOLS.—Each agreement under section 721 with a school of medicine or osteopathic medicine shall provide that the school will submit to the Secretary a report for each 1-year period under paragraph (1) that provides such information as the Secretary determines to be necessary for carrying out this subsection. Each such report shall include statistics concerning the current training or practice status of all graduates of such school whose date of graduation from the

school occurred approximately 4 years before the end of the 1-year period involved.

(c) DEFINITIONS.—For purposes of this section:

(1) The term "exempt contributions" means exempt Federal capital contributions and exempt school contributions.

(2) The term "exempt Federal capital contribution" means a Federal capital contribution described in subclause (I) of subsection (a)(2)(A)(ii).

(3) The term "exempt school contribution" means a school contribution described in subclause (II) of subsection (a)(2)(A)(ii).

(4) The term "income", with respect to a student fund under section 721, means payments of principal and interest on any loan made from the fund, and any other earnings of the fund.

(5) The term "primary health care" means family medicine, general internal medicine, general pediatrics, preventive medicine, or osteopathic general practice.

(d) SENSE OF CONGRESS.—It is the sense of Congress that funds repaid under the loan program under this section should not be transferred to the Treasury of the United States or otherwise used for any other purpose other than to carry out this section.

SEC. 724.[292t] INDIVIDUALS FROM DISADVANTAGED BACKGROUNDS.

(a) FUND AGREEMENTS REGARDING CERTAIN AMOUNTS.—With respect to amounts appropriated under subsection (f), each agreement entered into under section 721 with a school shall provide (in addition to the provisions required in subsection (b) of such section) that—

(1) any Federal capital contribution made to the student loan fund of the school from such amounts, together with the school contribution appropriate under subsection (b)(2)(B) of such section to the amount of the Federal capital contribution, will be utilized only for the purpose of—

(A) making loans to individuals from disadvantaged backgrounds; and

(B) the costs of the collection of the loans and interest on the loans; and

(2) collections of principal and interest on loans made pursuant to paragraph (1), and any other earnings of the student loan fund attributable to amounts that are in the fund pursuant to such paragraph, will be utilized only for the purpose described in such paragraph.

(b) MINIMUM QUALIFICATIONS FOR SCHOOLS.—The Secretary may not make a Federal capital contribution for purposes of subsection (a) for a fiscal year unless the health professions school involved—

(1) is carrying out a program for recruiting and retaining students from disadvantaged backgrounds, including racial and ethnic minorities; and

(2) is carrying out a program for recruiting and retaining minority faculty.

(c) CERTAIN AGREEMENTS REGARDING EDUCATION OF STUDENTS; DATE CERTAIN FOR COMPLIANCE.—The Secretary may not

make a Federal capital contribution for purposes of subsection (a) for a fiscal year unless the health professions school involved agrees—

(1) to ensure that adequate instruction regarding minority health issues is provided for in the curricula of the school;

(2) with respect to health clinics providing services to a significant number of individuals who are from disadvantaged backgrounds, including members of minority groups, to enter into arrangements with 1 or more such clinics for the purpose of providing students of the school with experience in providing clinical services to such individuals;

(3) with respect to public or nonprofit private secondary educational institutions and undergraduate institutions of higher education, to enter into arrangements with 1 or more such institutions for the purpose of carrying out programs regarding the educational preparation of disadvantaged students, including minority students, to enter the health professions and regarding the recruitment of such individuals into the health professions;

(4) to establish a mentor program for assisting disadvantaged students, including minority students, regarding the completion of the educational requirements for degrees from the school;

(5) to be carrying out each of the activities specified in any of paragraphs (1) through (4) by not later than 1 year after the date on which the first Federal capital contribution is made to the school for purposes of subsection (a); and

(6) to continue carrying out such activities, and the activities specified in paragraphs (1) and (2) of subsection (b), throughout the period during which the student loan fund established pursuant to section 721(b) is in operation.

(d) AVAILABILITY OF OTHER AMOUNTS.—With respect to Federal capital contributions to student loan funds under agreements under section 721(b), any such contributions made before October 1, 1990, together with the school contributions appropriate under paragraph (2)(B) of such section to the amount of the Federal capital contributions, may be utilized for the purpose of making loans to individuals from disadvantaged backgrounds, subject to section 723(a)(2)(B).

(e) DEFINITION.—For purposes of this section, the term "disadvantaged", with respect to an individual, shall be defined by the Secretary.

(f) AUTHORIZATION OF APPROPRIATIONS.—

[(1) Repealed by section 132(b) of Public Law 105–392 (112 Stat. 3575).]

(2) SPECIAL CONSIDERATION FOR CERTAIN SCHOOLS.—In making Federal capital contributions to student loan funds for purposes of subsection (a), the Secretary shall give special consideration to health professions schools that have enrollments of underrepresented minorities above the national average for health professions schools.

SEC. 725.[292u] ADMINISTRATIVE PROVISIONS.

The Secretary may agree to modifications of agreements or loans made under this subpart, and may compromise, waive, or release any right, title, claim, or demand of the United States arising or acquired under this subpart.

SEC. 726.[292v] PROVISION BY SCHOOLS OF INFORMATION TO STUDENTS.

(a) IN GENERAL.—With respect to loans made by a school under this subpart after June 30, 1986, each school, in order to carry out the provisions of sections 721 and 722, shall, at any time such school makes such a loan to a student under this subpart, provide thorough and adequate loan information on loans made under this subpart to the student. The loan information required to be provided to the student by this subsection shall include—

(1) the yearly and cumulative maximum amounts that may be borrowed by the student;

(2) the terms under which repayment of the loan will begin;

(3) the maximum number of years in which the loan must be repaid;

(4) the interest rate that will be paid by the borrower and the minimum amount of the required monthly payment;

(5) the amount of any other fees charged to the borrower by the lender;

(6) any options the borrower may have for deferral, cancellation, prepayment, consolidation, or other refinancing of the loan;

(7) a definition of default on the loan and a specification of the consequences which will result to the borrower if the borrower defaults, including a description of any arrangements which may be made with credit bureau organizations;

(8) to the extent practicable, the effect of accepting the loan on the eligibility of the borrower for other forms of student assistance; and

(9) a description of the actions that may be taken by the Federal Government to collect the loan, including a description of the type of information concerning the borrower that the Federal Government may disclose to (A) officers, employees, or agents of the Department of Health and Human Services, (B) officers, employees, or agents of schools with which the Secretary has an agreement under this subpart, or (C) any other person involved in the collection of a loan under this subpart.

(b) STATEMENT REGARDING LOAN.—Each school shall, immediately prior to the graduation from such school of a student who receives a loan under this subpart after June 30, 1986, provide such student with a statement specifying—

(1) each amount borrowed by the student under this subpart;

(2) the total amount borrowed by the student under this subpart; and

(3) a schedule for the repayment of the amounts borrowed under this subpart, including the number, amount, and frequency of payments to be made.

SEC. 727.[292w] PROCEDURES FOR APPEAL OF TERMINATION OF AGREEMENTS.

In any case in which the Secretary intends to terminate an agreement with a school under this subpart, the Secretary shall provide the school with a written notice specifying such intention and stating that the school may request a formal hearing with respect to such termination. If the school requests such a hearing within 30 days after the receipt of such notice, the Secretary shall provide such school with a hearing conducted by an administrative law judge.

SEC. 728.[292x] DISTRIBUTION OF ASSETS FROM LOAN FUNDS.

(a) DISTRIBUTION AFTER TERMINATION OF FUND.—If a school terminates a loan fund established under an agreement pursuant to section 721(b), or if the Secretary for good cause terminates the agreement with the school, there shall be a capital distribution as follows:

(1) The Secretary shall first be paid an amount which bears the same ratio to such balance in such fund on the date of termination of the fund as the total amount of the Federal capital contributions to such fund by the Secretary pursuant to section 721(b)(2)(A) bears to the total amount in such fund derived from such Federal capital contributions and from funds deposited therein pursuant to section 721(b)(2)(B).

(2) The remainder of such balance shall be paid to the school.

(b) PAYMENT OF PROPORTIONATE SHARE TO SECRETARY.—If a capital distribution is made under subsection (a), the school involved shall, after the capital distribution, pay to the Secretary, not less often than quarterly, the same proportionate share of amounts received by the school in payment of principal or interest on loans made from the loan fund established pursuant to section 721(b) as was determined by the Secretary under subsection (a).

SEC. 735.[5][292y] GENERAL PROVISIONS.

(a) DATE CERTAIN FOR APPLICATIONS.—The Secretary shall from time to time set dates by which schools must file applications for Federal capital contributions.

(b) CONTINGENT REDUCTION IN ALLOTMENTS.—If the total of the amounts requested for any fiscal year in such applications exceeds the amounts appropriated under this section for that fiscal year, the allotment to the loan fund of each such school shall be reduced to whichever of the following is the smaller: (A) the amount requested in its application; or (B) an amount which bears the same ratio to the amounts appropriated as the number of students estimated by the Secretary to be enrolled in such school during such fiscal year bears to the estimated total number of students in all such schools during such year. Amounts remaining after allotment under the preceding sentence shall be reallotted in accordance with clause (B) of such sentence among schools whose applications requested more than the amounts so allotted to their loan funds, but with such adjustments as may be necessary to prevent

[5] Title VII does not have sections 729 through 734. See section 102 of Public Law 102–408 (106 Stat. 1994, 2021).

the total allotted to any such school's loan fund from exceeding the total so requested by it.

(c) ALLOTMENT OF EXCESS FUNDS.—Funds available in any fiscal year for payment to schools under this subpart which are in excess of the amount appropriated pursuant to this section for that year shall be allotted among schools in such manner as the Secretary determines will best carry out the purposes of this subpart.

(d) PAYMENT OF INSTALLMENTS TO SCHOOLS.—Allotments to a loan fund of a school shall be paid to it from time to time in such installments as the Secretary determines will not result in unnecessary accumulations in the loan fund at such school.

(e) DISPOSITION OF FUNDS RETURNED TO SECRETARY.—

(1) EXPENDITURE FOR FEDERAL CAPITAL CONTRIBUTIONS.—Subject to section 723(b)(5), any amounts from student loan funds under section 721 that are returned to the Secretary by health professions schools shall be expended to make Federal capital contributions to such funds.

(2) DATE CERTAIN FOR CONTRIBUTIONS.—Amounts described in paragraph (1) that are returned to the Secretary shall be obligated before the end of the succeeding fiscal year.

(3) PREFERENCE IN MAKING CONTRIBUTIONS.—In making Federal capital contributions to student loans funds under section 721 for a fiscal year from amounts described in paragraph (1), the Secretary shall give preference to health professions schools of the same disciplines as the health professions schools returning such amounts for the period during which the amounts expended for such contributions were received by the Secretary. Any such amounts that, prior to being so returned, were available only for the purpose of loans under this subpart to individuals from disadvantaged backgrounds shall be available only for such purpose.

(f) FUNDING FOR CERTAIN MEDICAL SCHOOLS.—

(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of making Federal capital contributions to student loan funds established under section 721 by schools of medicine or osteopathic medicine, there is authorized to be appropriated $10,000,000 for each of the fiscal years 1994 through 1996.

(2) MINIMUM REQUIREMENTS.—

(A) Subject to subparagraph (B), the Secretary may make a Federal capital contribution pursuant to paragraph (1) only if the school of medicine or osteopathic medicine involved meets the conditions described in subparagraph (A) of section 723(b)(2) or the conditions described in subparagraph (C) of such section.

(B) For purposes of subparagraph (A), the conditions referred to in such subparagraph shall be applied with respect to graduates of the school involved whose date of graduation occurred approximately 3 years before June 30 of the fiscal year preceding the fiscal year for which the Federal capital contribution involved is made.

PART B—HEALTH PROFESSIONS TRAINING FOR DIVERSITY

SEC. 736.[293] CENTERS OF EXCELLENCE.

(a) IN GENERAL.—The Secretary shall make grants to, and enter into contracts with, designated health professions schools described in subsection (c), and other public and nonprofit health or educational entities, for the purpose of assisting the schools in supporting programs of excellence in health professions education for under-represented minority individuals.

(b) REQUIRED USE OF FUNDS.—The Secretary may not make a grant under subsection (a) unless the designated health professions school involved agrees, subject to subsection (c)(1)(C), to expend the grant—

(1) to develop a large competitive applicant pool through linkages with institutions of higher education, local school districts, and other community-based entities and establish an education pipeline for health professions careers;

(2) to establish, strengthen, or expand programs to enhance the academic performance of under-represented minority students attending the school;

(3) to improve the capacity of such school to train, recruit, and retain under-represented minority faculty including the payment of such stipends and fellowships as the Secretary may determine appropriate;

(4) to carry out activities to improve the information resources, clinical education, curricula and cultural competence of the graduates of the school, as it relates to minority health issues;

(5) to facilitate faculty and student research on health issues particularly affecting under-represented minority groups, including research on issues relating to the delivery of health care;

(6) to carry out a program to train students of the school in providing health services to a significant number of under-represented minority individuals through training provided to such students at community-based health facilities that—

(A) provide such health services; and

(B) are located at a site remote from the main site of the teaching facilities of the school; and

(7) to provide stipends as the Secretary determines appropriate, in amounts as the Secretary determines appropriate.

(c) CENTERS OF EXCELLENCE.—

(1) DESIGNATED SCHOOLS.—

(A) IN GENERAL.—The designated health professions schools referred to in subsection (a) are such schools that meet each of the conditions specified in subparagraphs (B) and (C), and that—

(i) meet each of the conditions specified in paragraph (2)(A);

(ii) meet each of the conditions specified in paragraph (3);

(iii) meet each of the conditions specified in paragraph (4); or

(iv) meet each of the conditions specified in paragraph (5).

(B) GENERAL CONDITIONS.—The conditions specified in this subparagraph are that a designated health professions school—

(i) has a significant number of under-represented minority individuals enrolled in the school, including individuals accepted for enrollment in the school;

(ii) has been effective in assisting under-represented minority students of the school to complete the program of education and receive the degree involved;

(iii) has been effective in recruiting under-represented minority individuals to enroll in and graduate from the school, including providing scholarships and other financial assistance to such individuals and encouraging under-represented minority students from all levels of the educational pipeline to pursue health professions careers; and

(iv) has made significant recruitment efforts to increase the number of under-represented minority individuals serving in faculty or administrative positions at the school.

(C) CONSORTIUM.—The condition specified in this subparagraph is that, in accordance with subsection (e)(1), the designated health profession school involved has with other health profession schools (designated or otherwise) formed a consortium to carry out the purposes described in subsection (b) at the schools of the consortium.

(D) APPLICATION OF CRITERIA TO OTHER PROGRAMS.—In the case of any criteria established by the Secretary for purposes of determining whether schools meet the conditions described in subparagraph (B), this section may not, with respect to racial and ethnic minorities, be construed to authorize, require, or prohibit the use of such criteria in any program other than the program established in this section.

(2) CENTERS OF EXCELLENCE AT CERTAIN HISTORICALLY BLACK COLLEGES AND UNIVERSITIES.—

(A) CONDITIONS.—The conditions specified in this subparagraph are that a designated health professions school—

(i) is a school described in section 799B(1); and

(ii) received a contract under section 788B for fiscal year 1987, as such section was in effect for such fiscal year.

(B) USE OF GRANT.—In addition to the purposes described in subsection (b), a grant under subsection (a) to a designated health professions school meeting the conditions described in subparagraph (A) may be expended—

(i) to develop a plan to achieve institutional improvements, including financial independence, to en-

able the school to support programs of excellence in health professions education for under-represented minority individuals; and

(ii) to provide improved access to the library and informational resources of the school.

(C) EXCEPTION.—The requirements of paragraph (1)(C) shall not apply to a historically black college or university that receives funding under paragraphs (2) or (5)[6].

(3) HISPANIC CENTERS OF EXCELLENCE.—The conditions specified in this paragraph are that—

(A) with respect to Hispanic individuals, each of clauses (i) through (iv) of paragraph (1)(B) applies to the designated health professions school involved;

(B) the school agrees, as a condition of receiving a grant under subsection (a), that the school will, in carrying out the duties described in subsection (b), give priority to carrying out the duties with respect to Hispanic individuals; and

(C) the school agrees, as a condition of receiving a grant under subsection (a), that—

(i) the school will establish an arrangement with 1 or more public or nonprofit community based Hispanic serving organizations, or public or nonprofit private institutions of higher education, including schools of nursing, whose enrollment of students has traditionally included a significant number of Hispanic individuals, the purposes of which will be to carry out a program—

(I) to identify Hispanic students who are interested in a career in the health profession involved; and

(II) to facilitate the educational preparation of such students to enter the health professions school; and

(ii) the school will make efforts to recruit Hispanic students, including students who have participated in the undergraduate or other matriculation program carried out under arrangements established by the school pursuant to clause (i)(II) and will assist Hispanic students regarding the completion of the educational requirements for a degree from the school.

(4) NATIVE AMERICAN CENTERS OF EXCELLENCE.—Subject to subsection (e), the conditions specified in this paragraph are that—

(A) with respect to Native Americans, each of clauses (i) through (iv) of paragraph (1)(B) applies to the designated health professions school involved;

(B) the school agrees, as a condition of receiving a grant under subsection (a), that the school will, in carrying out the duties described in subsection (b), give priority to carrying out the duties with respect to Native Americans; and

[6] So in law. Probably should read "paragraph (2) or (5)".

(C) the school agrees, as a condition of receiving a grant under subsection (a), that—

(i) the school will establish an arrangement with 1 or more public or nonprofit private institutions of higher education, including schools of nursing, whose enrollment of students has traditionally included a significant number of Native Americans, the purpose of which arrangement will be to carry out a program—

(I) to identify Native American students, from the institutions of higher education referred to in clause (i), who are interested in health professions careers; and

(II) to facilitate the educational preparation of such students to enter the designated health professions school; and

(ii) the designated health professions school will make efforts to recruit Native American students, including students who have participated in the undergraduate program carried out under arrangements established by the school pursuant to clause (i) and will assist Native American students regarding the completion of the educational requirements for a degree from the designated health professions school.

(5) OTHER CENTERS OF EXCELLENCE.—The conditions specified in this paragraph are—

(A) with respect to other centers of excellence, the conditions described in clauses (i) through (iv) of paragraph (1)(B); and

(B) that the health professions school involved has an enrollment of under-represented minorities above the national average for such enrollments of health professions schools.

(d) DESIGNATION AS CENTER OF EXCELLENCE.—

(1) IN GENERAL.—Any designated health professions school receiving a grant under subsection (a) and meeting the conditions described in paragraph (2) or (5) of subsection (c) shall, for purposes of this section, be designated by the Secretary as a Center of Excellence in Under-Represented Minority Health Professions Education.

(2) HISPANIC CENTERS OF EXCELLENCE.—Any designated health professions school receiving a grant under subsection (a) and meeting the conditions described in subsection (c)(3) shall, for purposes of this section, be designated by the Secretary as a Hispanic Center of Excellence in Health Professions Education.

(3) NATIVE AMERICAN CENTERS OF EXCELLENCE.—Any designated health professions school receiving a grant under subsection (a) and meeting the conditions described in subsection (c)(4) shall, for purposes of this section, be designated by the Secretary as a Native American Center of Excellence in Health Professions Education. Any consortium receiving such a grant pursuant to subsection (e) shall, for purposes of this section, be so designated.

(e) AUTHORITY REGARDING NATIVE AMERICAN CENTERS OF EXCELLENCE.—With respect to meeting the conditions specified in subsection (c)(4), the Secretary may make a grant under subsection (a) to a designated health professions school that does not meet such conditions if—

(1) the school has formed a consortium in accordance with subsection (d)(1); and

(2) the schools of the consortium collectively meet such conditions, without regard to whether the schools individually meet such conditions.

(f) DURATION OF GRANT.—The period during which payments are made under a grant under subsection (a) may not exceed 5 years. Such payments shall be subject to annual approval by the Secretary and to the availability of appropriations for the fiscal year involved to make the payments.

(g) DEFINITIONS.—In this section:

(1) DESIGNATED HEALTH PROFESSIONS SCHOOL.—

(A) IN GENERAL.—The term "health professions school" means, except as provided in subparagraph (B), a school of medicine, a school of osteopathic medicine, a school of dentistry, a school of pharmacy, or a graduate program in behavioral or mental health.

(B) EXCEPTION.—The definition established in subparagraph (A) shall not apply to the use of the term "designated health professions school" for purposes of subsection (c)(2).

(2) PROGRAM OF EXCELLENCE.—The term "program of excellence" means any program carried out by a designated health professions school with a grant made under subsection (a), if the program is for purposes for which the school involved is authorized in subsection (b) or (c) to expend the grant.

(3) NATIVE AMERICANS.—The term "Native Americans" means American Indians, Alaskan Natives, Aleuts, and Native Hawaiians.

(h) FORMULA FOR ALLOCATIONS.—

(1) ALLOCATIONS.—Based on the amount appropriated under subsection (i) for a fiscal year, the following subparagraphs shall apply as appropriate:

(A) IN GENERAL.—If the amounts appropriated under subsection (i) for a fiscal year are $24,000,000 or less—

(i) the Secretary shall make available $12,000,000 for grants under subsection (a) to health professions schools that meet the conditions described in subsection (c)(2)(A); and

(ii) and available after grants are made with funds under clause (i), the Secretary shall make available—

(I) 60 percent of such amount for grants under subsection (a) to health professions schools that meet the conditions described in paragraph (3) or (4) of subsection (c) (including meeting the conditions under subsection (e)); and

(II) 40 percent of such amount for grants under subsection (a) to health professions schools

that meet the conditions described in subsection (c)(5).

(B) FUNDING IN EXCESS OF $24,000,000.—If amounts appropriated under subsection (i) for a fiscal year exceed $24,000,000 but are less than $30,000,000—

(i) 80 percent of such excess amounts shall be made available for grants under subsection (a) to health professions schools that meet the requirements described in paragraph (3) or (4) of subsection (c) (including meeting conditions pursuant to subsection (e)); and

(ii) 20 percent of such excess amount shall be made available for grants under subsection (a) to health professions schools that meet the conditions described in subsection (c)(5).

(C) FUNDING IN EXCESS OF $30,000,000.—If amounts appropriated under subsection (i) for a fiscal year exceed $30,000,000 but are less than $40,000,000, the Secretary shall make available—

(i) not less than $12,000,000 for grants under subsection (a) to health professions schools that meet the conditions described in subsection (c)(2)(A);

(ii) not less than $12,000,000 for grants under subsection (a) to health professions schools that meet the conditions described in paragraph (3) or (4) of subsection (c) (including meeting conditions pursuant to subsection (e));

(iii) not less than $6,000,000 for grants under subsection (a) to health professions schools that meet the conditions described in subsection (c)(5); and

(iv) after grants are made with funds under clauses (i) through (iii), any remaining excess amount for grants under subsection (a) to health professions schools that meet the conditions described in paragraph (2)(A), (3), (4), or (5) of subsection (c).

(D) FUNDING IN EXCESS OF $40,000,000.—If amounts appropriated under subsection (i) for a fiscal year are $40,000,000 or more, the Secretary shall make available—

(i) not less than $16,000,000 for grants under subsection (a) to health professions schools that meet the conditions described in subsection (c)(2)(A);

(ii) not less than $16,000,000 for grants under subsection (a) to health professions schools that meet the conditions described in paragraph (3) or (4) of subsection (c) (including meeting conditions pursuant to subsection (e));

(iii) not less than $8,000,000 for grants under subsection (a) to health professions schools that meet the conditions described in subsection (c)(5); and

(iv) after grants are made with funds under clauses (i) through (iii), any remaining funds for grants under subsection (a) to health professions schools that meet the conditions described in paragraph (2)(A), (3), (4), or (5) of subsection (c).

(2) NO LIMITATION.—Nothing in this subsection shall be construed as limiting the centers of excellence referred to in this section to the designated amount, or to preclude such entities from competing for grants under this section.

(3) MAINTENANCE OF EFFORT.—

(A) IN GENERAL.—With respect to activities for which a grant made under this part are authorized to be expended, the Secretary may not make such a grant to a center of excellence for any fiscal year unless the center agrees to maintain expenditures of non-Federal amounts for such activities at a level that is not less than the level of such expenditures maintained by the center for the fiscal year preceding the fiscal year for which the school receives such a grant.

(B) USE OF FEDERAL FUNDS.—With respect to any Federal amounts received by a center of excellence and available for carrying out activities for which a grant under this part is authorized to be expended, the center shall, before expending the grant, expend the Federal amounts obtained from sources other than the grant, unless given prior approval from the Secretary.

(i) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section—

(1) $50,000,000 for each of the fiscal years 2010 through 2015; and

(2) and such sums as are necessary for each subsequent fiscal year.

SEC. 737.[293a] SCHOLARSHIPS FOR DISADVANTAGED STUDENTS.

(a) IN GENERAL.—The Secretary may make a grant to an eligible entity (as defined in subsection (d)(1)) under this section for the awarding of scholarships by schools to any full-time student who is an eligible individual as defined in subsection (d). Such scholarships may be expended only for tuition expenses, other reasonable educational expenses, and reasonable living expenses incurred in the attendance of such school.

(b) PREFERENCE IN PROVIDING SCHOLARSHIPS.—The Secretary may not make a grant to an entity under subsection (a) unless the health professions and nursing schools involved agree that, in providing scholarships pursuant to the grant, the schools will give preference to students for whom the costs of attending the schools would constitute a severe financial hardship and, notwithstanding other provisions of this section, to former recipients of scholarships under sections 736 and 740(d)(2)(B) (as such sections existed on the day before the date of enactment of this section).

(c) AMOUNT OF AWARD.—In awarding grants to eligible entities that are health professions and nursing schools, the Secretary shall give priority to eligible entities based on the proportion of graduating students going into primary care, the proportion of underrepresented minority students, and the proportion of graduates working in medically underserved communities.

(d) DEFINITIONS.—In this section:

(1) ELIGIBLE ENTITIES.—The term "eligible entities" means an entity that—

(A) is a school of medicine, osteopathic medicine, dentistry, nursing (as defined in section 801), pharmacy, podiatric medicine, optometry, veterinary medicine, public health, chiropractic, or allied health, a school offering a graduate program in behavioral and mental health practice, or an entity providing programs for the training of physician assistants; and

(B) is carrying out a program for recruiting and retaining students from disadvantaged backgrounds, including students who are members of racial and ethnic minority groups.

(2) ELIGIBLE INDIVIDUAL.—The term "eligible individual" means an individual who—

(A) is from a disadvantaged background;

(B) has a financial need for a scholarship; and

(C) is enrolled (or accepted for enrollment) at an eligible health professions or nursing school as a full-time student in a program leading to a degree in a health profession or nursing.

SEC. 738.[293b] LOAN REPAYMENTS AND FELLOWSHIPS REGARDING FACULTY POSITIONS.

(a) LOAN REPAYMENTS.—

(1) ESTABLISHMENT OF PROGRAM.—The Secretary shall establish a program of entering into contracts with individuals described in paragraph (2) under which the individuals agree to serve as members of the faculties of schools described in paragraph (3) in consideration of the Federal Government agreeing to pay, for each year of such service, not more than $30,000 of the principal and interest of the educational loans of such individuals.

(2) ELIGIBLE INDIVIDUALS.—The individuals referred to in paragraph (1) are individuals from disadvantaged backgrounds who—

(A) have a degree in medicine, osteopathic medicine, dentistry, nursing, or another health profession;

(B) are enrolled in an approved graduate training program in medicine, osteopathic medicine, dentistry, nursing, or other health profession; or

(C) are enrolled as full-time students—

(i) in an accredited (as determined by the Secretary) school described in paragraph (3); and

(ii) in the final year of a course of a study or program, offered by such institution and approved by the Secretary, leading to a degree from such a school.

(3) ELIGIBLE HEALTH PROFESSIONS SCHOOLS.—The schools described in this paragraph are schools of medicine, nursing (as schools of nursing are defined in section 801), osteopathic medicine, dentistry, pharmacy, allied health, podiatric medicine, optometry, veterinary medicine, or public health, schools offering physician assistant education programs, or schools offering graduate programs in behavioral and mental health.

(4) REQUIREMENTS REGARDING FACULTY POSITIONS.—The Secretary may not enter into a contract under paragraph (1) unless—

(A) the individual involved has entered into a contract with a school described in paragraph (3) to serve as a member of the faculty of the school for not less than 2 years; and

(B) the contract referred to in subparagraph (A) provides that—

(i) the school will, for each year for which the individual will serve as a member of the faculty under the contract with the school, make payments of the principal and interest due on the educational loans of the individual for such year in an amount equal to the amount of such payments made by the Secretary for the year;

(ii) the payments made by the school pursuant to clause (i) on behalf of the individual will be in addition to the pay that the individual would otherwise receive for serving as a member of such faculty; and

(iii) the school, in making a determination of the amount of compensation to be provided by the school to the individual for serving as a member of the faculty, will make the determination without regard to the amount of payments made (or to be made) to the individual by the Federal Government under paragraph (1).

(5) APPLICABILITY OF CERTAIN PROVISIONS.—The provisions of sections 338C, 338G, and 338I shall apply to the program established in paragraph (1) to the same extent and in the same manner as such provisions apply to the National Health Service Corps Loan Repayment Program established in subpart III of part D of title III, including the applicability of provisions regarding reimbursements for increased tax liability and regarding bankruptcy.

(6) WAIVER REGARDING SCHOOL CONTRIBUTIONS.—The Secretary may waive the requirement established in paragraph (4)(B) if the Secretary determines that the requirement will impose an undue financial hardship on the school involved.

(b) FELLOWSHIPS.—

(1) IN GENERAL.—The Secretary may make grants to and enter into contracts with eligible entities to assist such entities in increasing the number of underrepresented minority individuals who are members of the faculty of such schools.

(2) APPLICATIONS.—To be eligible to receive a grant or contract under this subsection, an entity shall provide an assurance, in the application submitted by the entity, that—

(A) amounts received under such a grant or contract will be used to award a fellowship to an individual only if the individual meets the requirements of paragraphs (3) and (4); and

(B) each fellowship awarded pursuant to the grant or contract will include—

(i) a stipend in an amount not exceeding 50 percent of the regular salary of a similar faculty member for not to exceed 3 years of training; and

(ii) an allowance for other expenses, such as travel to professional meetings and costs related to specialized training.

(3) ELIGIBILITY.—To be eligible to receive a grant or contract under paragraph (1), an applicant shall demonstrate to the Secretary that such applicant has or will have the ability to—

(A) identify, recruit and select underrepresented minority individuals who have the potential for teaching, administration, or conducting research at a health professions institution;

(B) provide such individuals with the skills necessary to enable them to secure a tenured faculty position at such institution, which may include training with respect to pedagogical skills, program administration, the design and conduct of research, grants writing, and the preparation of articles suitable for publication in peer reviewed journals;

(C) provide services designed to assist such individuals in their preparation for an academic career, including the provision of counselors; and

(D) provide health services to rural or medically underserved populations.

(4) REQUIREMENTS.—To be eligible to receive a grant or contract under paragraph (1) an applicant shall—

(A) provide an assurance that such applicant will make available (directly through cash donations) $1 for every $1 of Federal funds received under this section for the fellowship;

(B) provide an assurance that institutional support will be provided for the individual for the second and third years at a level that is equal to the total amount of institutional funds provided in the year in which the grant or contract was awarded;

(C) provide an assurance that the individual that will receive the fellowship will be a member of the faculty of the applicant school; and

(D) provide an assurance that the individual that will receive the fellowship will have, at a minimum, appropriate advanced preparation (such as a master's or doctoral degree) and special skills necessary to enable such individual to teach and practice.

(5) DEFINITION.—For purposes of this subsection, the term "underrepresented minority individuals" means individuals who are members of racial or ethnic minority groups that are underrepresented in the health professions including nursing.

SEC. 739.[293c] EDUCATIONAL ASSISTANCE IN THE HEALTH PROFESSIONS REGARDING INDIVIDUALS FROM DISADVANTAGED BACKGROUNDS.

(a) IN GENERAL.—

(1) AUTHORITY FOR GRANTS.—For the purpose of assisting individuals from disadvantaged backgrounds, as determined in accordance with criteria prescribed by the Secretary, to undertake education to enter a health profession, the Secretary may make grants to and enter into contracts with schools of medi-

cine, osteopathic medicine, public health, dentistry, veterinary medicine, optometry, pharmacy, allied health, chiropractic, and podiatric medicine, public and nonprofit private schools that offer graduate programs in behavioral and mental health, programs for the training of physician assistants, and other public or private nonprofit health or educational entities to assist in meeting the costs described in paragraph (2).

(2) AUTHORIZED EXPENDITURES.—A grant or contract under paragraph (1) may be used by the entity to meet the cost of—

(A) identifying, recruiting, and selecting individuals from disadvantaged backgrounds, as so determined, for education and training in a health profession;

(B) facilitating the entry of such individuals into such a school;

(C) providing counseling, mentoring, or other services designed to assist such individuals to complete successfully their education at such a school;

(D) providing, for a period prior to the entry of such individuals into the regular course of education of such a school, preliminary education and health research training designed to assist them to complete successfully such regular course of education at such a school, or referring such individuals to institutions providing such preliminary education;

(E) publicizing existing sources of financial aid available to students in the education program of such a school or who are undertaking training necessary to qualify them to enroll in such a program;

(F) paying such scholarships as the Secretary may determine for such individuals for any period of health professions education at a health professions school;

(G) paying such stipends as the Secretary may approve for such individuals for any period of education in student-enhancement programs (other than regular courses), except that such a stipend may not be provided to an individual for more than 12 months, and such a stipend shall be in an amount determined appropriate by the Secretary (notwithstanding any other provision of law regarding the amount of stipends);

(H) carrying out programs under which such individuals gain experience regarding a career in a field of primary health care through working at facilities of public or private nonprofit community-based providers of primary health services; and

(I) conducting activities to develop a larger and more competitive applicant pool through partnerships with institutions of higher education, school districts, and other community-based entities.

(3) DEFINITION.—In this section, the term "regular course of education of such a school" as used in subparagraph (D) includes a graduate program in behavioral or mental health.

(b) REQUIREMENTS FOR AWARDS.—In making awards to eligible entities under subsection (a)(1), the Secretary shall give preference to approved applications for programs that involve a comprehensive

approach by several public or nonprofit private health or educational entities to establish, enhance and expand educational programs that will result in the development of a competitive applicant pool of individuals from disadvantaged backgrounds who desire to pursue health professions careers. In considering awards for such a comprehensive partnership approach, the following shall apply with respect to the entity involved:

(1) The entity shall have a demonstrated commitment to such approach through formal agreements that have common objectives with institutions of higher education, school districts, and other community-based entities.

(2) Such formal agreements shall reflect the coordination of educational activities and support services, increased linkages, and the consolidation of resources within a specific geographic area.

(3) The design of the educational activities involved shall provide for the establishment of a competitive health professions applicant pool of individuals from disadvantaged backgrounds by enhancing the total preparation (academic and social) of such individuals to pursue a health professions career.

(4) The programs or activities under the award shall focus on developing a culturally competent health care workforce that will serve the unserved and underserved populations within the geographic area.

(c) EQUITABLE ALLOCATION OF FINANCIAL ASSISTANCE.—The Secretary, to the extent practicable, shall ensure that services and activities under subsection (a) are adequately allocated among the various racial and ethnic populations who are from disadvantaged backgrounds.

(d) MATCHING REQUIREMENTS.—The Secretary may require that an entity that applies for a grant or contract under subsection (a), provide non-Federal matching funds, as appropriate, to ensure the institutional commitment of the entity to the projects funded under the grant or contract. As determined by the Secretary, such non-Federal matching funds may be provided directly or through donations from public or private entities and may be in cash or in-kind, fairly evaluated, including plant, equipment, or services.

SEC. 740.[293d] AUTHORIZATION OF APPROPRIATION.

(a) SCHOLARSHIPS.—There are authorized to be appropriated to carry out section 737, $51,000,000 for fiscal year 2010, and such sums as may be necessary for each of the fiscal years 2011 through 2014. Of the amount appropriated in any fiscal year, the Secretary shall ensure that not less than 16 percent shall be distributed to schools of nursing.

(b) LOAN REPAYMENTS AND FELLOWSHIPS.—For the purpose of carrying out section 738, there is authorized to be appropriated, $5,000,000 for each of the fiscal years 2010 through 2014.

(c) EDUCATIONAL ASSISTANCE IN HEALTH PROFESSIONS REGARDING INDIVIDUALS FOR DISADVANTAGED BACKGROUNDS.—For the purpose of grants and contracts under section 739(a)(1), there is authorized to be appropriated $60,000,000 for fiscal year 2010 and such sums as may be necessary for each of the fiscal years 2011 through 2014. The Secretary may use not to exceed 20 percent of

the amount appropriated for a fiscal year under this subsection to provide scholarships under section 739(a)(2)(F).

(d) REPORT.—Not later than 6 months after the date of enactment of this part, the Secretary shall prepare and submit to the appropriate committees of Congress a report concerning the efforts of the Secretary to address the need for a representative mix of individuals from historically minority health professions schools, or from institutions or other entities that historically or by geographic location have a demonstrated record of training or educating underrepresented minorities, within various health professions disciplines, on peer review councils.

SEC. 741.[293e] GRANTS FOR HEALTH PROFESSIONS EDUCATION.

(a) CULTURAL COMPETENCY, PREVENTION, AND PUBLIC HEALTH AND INDIVIDUALS WITH DISABILITY GRANTS.—

(1) IN GENERAL.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, may make awards of grants, contracts, or cooperative agreements to public and nonprofit private entities (including tribal entities) for the development, evaluation, and dissemination of research, demonstration projects, and model curricula for cultural competency, prevention, public health proficiency, reducing health disparities, and aptitude for working with individuals with disabilities training for use in health professions schools and continuing education programs, and for other purposes determined as appropriate by the Secretary.

(2) ELIGIBLE ENTITIES.—Unless specifically required otherwise in this title, the Secretary shall accept applications for grants or contracts under this section from health professions schools, academic health centers, State or local governments, or other appropriate public or private nonprofit entities (or consortia of entities, including entities promoting multidisciplinary approaches) for funding and participation in health professions training activities. The Secretary may accept applications from for-profit private entities as determined appropriate by the Secretary.

(b) COLLABORATION.—In carrying out subsection (a), the Secretary shall collaborate with health professional societies, licensing and accreditation entities, health professions schools, and experts in minority health and cultural competency, prevention, and public health and disability groups, community-based organizations, and other organizations as determined appropriate by the Secretary. The Secretary shall coordinate with curricula and research and demonstration projects developed under section 807.

(c) DISSEMINATION.—

(1) IN GENERAL.—Model curricula developed under this section shall be disseminated through the Internet Clearinghouse under section 270 and such other means as determined appropriate by the Secretary.

(2) EVALUATION.—The Secretary shall evaluate the adoption and the implementation of cultural competency, prevention, and public health, and working with individuals with a disability training curricula, and the facilitate inclusion of

these competency measures in quality measurement systems as appropriate.

(d) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section such sums as may be necessary for each of fiscal years 2010 through 2015.

PART C—TRAINING IN FAMILY MEDICINE, GENERAL INTERNAL MEDICINE, GENERAL PEDIATRICS, PHYSICIAN ASSISTANTS, GENERAL DENTISTRY, AND PEDIATRIC DENTISTRY

Subpart I—Medical Training Generally

SEC. 747.[293k] PRIMARY CARE TRAINING AND ENHANCEMENT.

(a) SUPPORT AND DEVELOPMENT OF PRIMARY CARE TRAINING PROGRAMS.—

(1) IN GENERAL.—The Secretary may make grants to, or enter into contracts with, an accredited public or nonprofit private hospital, school of medicine or osteopathic medicine, academically affiliated physician assistant training program, or a public or private nonprofit entity which the Secretary has determined is capable of carrying out such grant or contract—

(A) to plan, develop, operate, or participate in an accredited professional training program, including an accredited residency or internship program in the field of family medicine, general internal medicine, or general pediatrics for medical students, interns, residents, or practicing physicians as defined by the Secretary;

(B) to provide need-based financial assistance in the form of traineeships and fellowships to medical students, interns, residents, practicing physicians, or other medical personnel, who are participants in any such program, and who plan to specialize or work in the practice of the fields defined in subparagraph (A);

(C) to plan, develop, and operate a program for the training of physicians who plan to teach in family medicine, general internal medicine, or general pediatrics training programs;

(D) to plan, develop, and operate a program for the training of physicians teaching in community-based settings;

(E) to provide financial assistance in the form of traineeships and fellowships to physicians who are participants in any such programs and who plan to teach or conduct research in a family medicine, general internal medicine, or general pediatrics training program;

(F) to plan, develop, and operate a physician assistant education program, and for the training of individuals who will teach in programs to provide such training;

(G) to plan, develop, and operate a demonstration program that provides training in new competencies, as rec-

ommended by the Advisory Committee on Training in Primary Care Medicine and Dentistry and the National Health Care Workforce Commission established in section 5101 of the Patient Protection and Affordable Care Act, which may include—

(i) providing training to primary care physicians relevant to providing care through patient-centered medical homes (as defined by the Secretary for purposes of this section);

(ii) developing tools and curricula relevant to patient-centered medical homes; and

(iii) providing continuing education to primary care physicians relevant to patient-centered medical homes; and

(H) to plan, develop, and operate joint degree programs to provide interdisciplinary and interprofessional graduate training in public health and other health professions to provide training in environmental health, infectious disease control, disease prevention and health promotion, epidemiological studies and injury control.

(2) DURATION OF AWARDS.—The period during which payments are made to an entity from an award of a grant or contract under this subsection shall be 5 years.

(b) CAPACITY BUILDING IN PRIMARY CARE.—

(1) IN GENERAL.—The Secretary may make grants to or enter into contracts with accredited schools of medicine or osteopathic medicine to establish, maintain, or improve—

(A) academic units or programs that improve clinical teaching and research in fields defined in subsection (a)(1)(A); or

(B) programs that integrate academic administrative units in fields defined in subsection (a)(1)(A) to enhance interdisciplinary recruitment, training, and faculty development.

(2) PREFERENCE IN MAKING AWARDS UNDER THIS SUBSECTION.—In making awards of grants and contracts under paragraph (1), the Secretary shall give preference to any qualified applicant for such an award that agrees to expend the award for the purpose of—

(A) establishing academic units or programs in fields defined in subsection (a)(1)(A); or

(B) substantially expanding such units or programs.

(3) PRIORITIES IN MAKING AWARDS.—In awarding grants or contracts under paragraph (1), the Secretary shall give priority to qualified applicants that—

(A) proposes a collaborative project between academic administrative units of primary care;

(B) proposes innovative approaches to clinical teaching using models of primary care, such as the patient centered medical home, team management of chronic disease, and interprofessional integrated models of health care that incorporate transitions in health care settings and integration physical and mental health provision;

(C) have a record of training the greatest percentage of providers, or that have demonstrated significant improvements in the percentage of providers trained, who enter and remain in primary care practice;

(D) have a record of training individuals who are from underrepresented minority groups or from a rural or disadvantaged background;

(E) provide training in the care of vulnerable populations such as children, older adults, homeless individuals, victims of abuse or trauma, individuals with mental health or substance-related disorders, individuals with HIV/AIDS, and individuals with disabilities;

(F) establish formal relationships and submit joint applications with federally qualified health centers, rural health clinics, area health education centers, or clinics located in underserved areas or that serve underserved populations;

(G) teach trainees the skills to provide interprofessional, integrated care through collaboration among health professionals;

(H) provide training in enhanced communication with patients, evidence-based practice, chronic disease management, preventive care, health information technology, or other competencies as recommended by the Advisory Committee on Training in Primary Care Medicine and Dentistry and the National Health Care Workforce Commission established in section 5101 of the Patient Protection and Affordable Care Act; or

(I) provide training in cultural competency and health literacy.

(4) DURATION OF AWARDS.—The period during which payments are made to an entity from an award of a grant or contract under this subsection shall be 5 years.

(c) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—For purposes of carrying out this section (other than subsection (b)(1)(B)), there are authorized to be appropriated $125,000,000 for fiscal year 2010, and such sums as may be necessary for each of fiscal years 2011 through 2014.

(2) TRAINING PROGRAMS.—Fifteen percent of the amount appropriated pursuant to paragraph (1) in each such fiscal year shall be allocated to the physician assistant training programs described in subsection (a)(1)(F), which prepare students for practice in primary care.

(3) INTEGRATING ACADEMIC ADMINISTRATIVE UNITS.—For purposes of carrying out subsection (b)(1)(B), there are authorized to be appropriated $750,000 for each of fiscal years 2010 through 2014.

SEC. 747A.[293k–1] TRAINING OPPORTUNITIES FOR DIRECT CARE WORKERS.

(a) IN GENERAL.—The Secretary shall award grants to eligible entities to enable such entities to provide new training opportunities for direct care workers who are employed in long-term care settings such as nursing homes (as defined in section 1908(e)(1) of the Social Security Act (42 U.S.C. 1396g(e)(1)), assisted living facilities

and skilled nursing facilities, intermediate care facilities for individuals with mental retardation, home and community based settings, and any other setting the Secretary determines to be appropriate.

(b) ELIGIBILITY.—To be eligible to receive a grant under this section, an entity shall—

(1) be an institution of higher education (as defined in section 102 of the Higher Education Act of 1965 (20 U.S.C. 1002)) that—

(A) is accredited by a nationally recognized accrediting agency or association listed under section 101(c) of the Higher Education Act of 1965 (20 U.S.C. 1001(c)); and

(B) has established a public-private educational partnership with a nursing home or skilled nursing facility, agency or entity providing home and community based services to individuals with disabilities, or other long-term care provider; and

(2) submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

(c) USE OF FUNDS.—An eligible entity shall use amounts awarded under a grant under this section to provide assistance to eligible individuals to offset the cost of tuition and required fees for enrollment in academic programs provided by such entity.

(d) ELIGIBLE INDIVIDUAL.—

(1) ELIGIBILITY.—To be eligible for assistance under this section, an individual shall be enrolled in courses provided by a grantee under this subsection and maintain satisfactory academic progress in such courses.

(2) CONDITION OF ASSISTANCE.—As a condition of receiving assistance under this section, an individual shall agree that, following completion of the assistance period, the individual will work in the field of geriatrics, disability services, long term services and supports, or chronic care management for a minimum of 2 years under guidelines set by the Secretary.

(e) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $10,000,000 for the period of fiscal years 2011 through 2013.

SEC. 748.[293k–2] TRAINING IN GENERAL, PEDIATRIC, AND PUBLIC HEALTH DENTISTRY.

(a) SUPPORT AND DEVELOPMENT OF DENTAL TRAINING PROGRAMS.—

(1) IN GENERAL.—The Secretary may make grants to, or enter into contracts with, a school of dentistry, public or nonprofit private hospital, or a public or private nonprofit entity which the Secretary has determined is capable of carrying out such grant or contract—

(A) to plan, develop, and operate, or participate in, an approved professional training program in the field of general dentistry, pediatric dentistry, or public health dentistry for dental students, residents, practicing dentists, dental hygienists, or other approved primary care dental trainees, that emphasizes training for general, pediatric, or public health dentistry;

(B) to provide financial assistance to dental students, residents, practicing dentists, and dental hygiene students who are in need thereof, who are participants in any such program, and who plan to work in the practice of general, pediatric, public heath dentistry, or dental hygiene;

(C) to plan, develop, and operate a program for the training of oral health care providers who plan to teach in general, pediatric, public health dentistry, or dental hygiene;

(D) to provide financial assistance in the form of traineeships and fellowships to dentists who plan to teach or are teaching in general, pediatric, or public health dentistry;

(E) to meet the costs of projects to establish, maintain, or improve dental faculty development programs in primary care (which may be departments, divisions or other units);

(F) to meet the costs of projects to establish, maintain, or improve predoctoral and postdoctoral training in primary care programs;

(G) to create a loan repayment program for faculty in dental programs; and

(H) to provide technical assistance to pediatric training programs in developing and implementing instruction regarding the oral health status, dental care needs, and risk-based clinical disease management of all pediatric populations with an emphasis on underserved children.

(2) FACULTY LOAN REPAYMENT.—

(A) IN GENERAL.—A grant or contract under subsection (a)(1)(G) may be awarded to a program of general, pediatric, or public health dentistry described in such subsection to plan, develop, and operate a loan repayment program under which—

(i) individuals agree to serve full-time as faculty members; and

(ii) the program of general, pediatric or public health dentistry agrees to pay the principal and interest on the outstanding student loans of the individuals.

(B) MANNER OF PAYMENTS.—With respect to the payments described in subparagraph (A)(ii), upon completion by an individual of each of the first, second, third, fourth, and fifth years of service, the program shall pay an amount equal to 10, 15, 20, 25, and 30 percent, respectively, of the individual's student loan balance as calculated based on principal and interest owed at the initiation of the agreement.

(b) ELIGIBLE ENTITY.—For purposes of this subsection, entities eligible for such grants or contracts in general, pediatric, or public health dentistry shall include entities that have programs in dental or dental hygiene schools, or approved residency or advanced education programs in the practice of general, pediatric, or public health dentistry. Eligible entities may partner with schools of public health to permit the education of dental students, residents, and

dental hygiene students for a master's year in public health at a school of public health.

(c) PRIORITIES IN MAKING AWARDS.—With respect to training provided for under this section, the Secretary shall give priority in awarding grants or contracts to the following:

(1) Qualified applicants that propose collaborative projects between departments of primary care medicine and departments of general, pediatric, or public health dentistry.

(2) Qualified applicants that have a record of training the greatest percentage of providers, or that have demonstrated significant improvements in the percentage of providers, who enter and remain in general, pediatric, or public health dentistry.

(3) Qualified applicants that have a record of training individuals who are from a rural or disadvantaged background, or from underrepresented minorities.

(4) Qualified applicants that establish formal relationships with Federally qualified health centers, rural health centers, or accredited teaching facilities and that conduct training of students, residents, fellows, or faculty at the center or facility.

(5) Qualified applicants that conduct teaching programs targeting vulnerable populations such as older adults, homeless individuals, victims of abuse or trauma, individuals with mental health or substance-related disorders, individuals with disabilities, and individuals with HIV/AIDS, and in the risk-based clinical disease management of all populations.

(6) Qualified applicants that include educational activities in cultural competency and health literacy.

(7) Qualified applicants that have a high rate for placing graduates in practice settings that serve underserved areas or health disparity populations, or who achieve a significant increase in the rate of placing graduates in such settings.

(8) Qualified applicants that intend to establish a special populations oral health care education center or training program for the didactic and clinical education of dentists, dental health professionals, and dental hygienists who plan to teach oral health care for people with developmental disabilities, cognitive impairment, complex medical problems, significant physical limitations, and vulnerable elderly.

(d) APPLICATION.—An eligible entity desiring a grant under this section shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

(e) DURATION OF AWARD.—The period during which payments are made to an entity from an award of a grant or contract under subsection (a) shall be 5 years. The provision of such payments shall be subject to annual approval by the Secretary and subject to the availability of appropriations for the fiscal year involved to make the payments.

(f) AUTHORIZATIONS OF APPROPRIATIONS.—For the purpose of carrying out subsections (a) and (b), there is authorized to be appropriated $30,000,000 for fiscal year 2010 and such sums as may be necessary for each of fiscal years 2011 through 2015.

(g) CARRYOVER FUNDS.—An entity that receives an award under this section may carry over funds from 1 fiscal year to another without obtaining approval from the Secretary. In no case may any funds be carried over pursuant to the preceding sentence for more than 3 years.

SEC. 749.[293l] ADVISORY COMMITTEE ON TRAINING IN PRIMARY CARE MEDICINE AND DENTISTRY.

(a) ESTABLISHMENT.—The Secretary shall establish an advisory committee to be known as the Advisory Committee on Training in Primary Care Medicine and Dentistry (in this section referred to as the "Advisory Committee").

(b) COMPOSITION.—

(1) IN GENERAL.—The Secretary shall determine the appropriate number of individuals to serve on the Advisory Committee. Such individuals shall not be officers or employees of the Federal Government.

(2) APPOINTMENT.—Not later than 90 days after the date of enactment of this Act[7], the Secretary shall appoint the members of the Advisory Committee from among individuals who are health professionals. In making such appointments, the Secretary shall ensure a fair balance between the health professions, that at least 75 percent of the members of the Advisory Committee are health professionals, a broad geographic representation of members and a balance between urban and rural members. Members shall be appointed based on their competence, interest, and knowledge of the mission of the profession involved.

(3) MINORITY REPRESENTATION.—In appointing the members of the Advisory Committee under paragraph (2), the Secretary shall ensure the adequate representation of women and minorities.

(c) TERMS.—

(1) IN GENERAL.—A member of the Advisory Committee shall be appointed for a term of 3 years, except that of the members first appointed—

(A) ⅓ of such members shall serve for a term of 1 year;

(B) ⅓ of such members shall serve for a term of 2 years; and

(C) ⅓ of such members shall serve for a term of 3 years.

(2) VACANCIES.—

(A) IN GENERAL.—A vacancy on the Advisory Committee shall be filled in the manner in which the original appointment was made and shall be subject to any conditions which applied with respect to the original appointment.

(B) FILLING UNEXPIRED TERM.—An individual chosen to fill a vacancy shall be appointed for the unexpired term of the member replaced.

[7] So in law. The reference to "this Act" means the Public Health Service Act, which was enacted July 1, 1944. Probably should be a reference to the Health Professions Education Partnerships Act of 1998, which added section 748. That Act is Public Law 105–392, enacted November 13, 1998. (Section 102(4) of that Public Law (112 Stat. 3539) added section 748.)

(d) DUTIES.—The Advisory Committee shall—

(1) provide advice and recommendations to the Secretary concerning policy and program development and other matters of significance concerning the activities under section 747;

(2) not later than 3 years after the date of enactment of this section, and annually thereafter, prepare and submit to the Secretary, and the Committee on Labor and Human Resources of the Senate, and the Committee on Commerce of the House of Representatives, a report describing the activities of the Committee, including findings and recommendations made by the Committee concerning the activities under section 747;

(3) develop, publish, and implement performance measures for programs under this part;

(4) develop and publish guidelines for longitudinal evaluations (as described in section 761(d)(2)) for programs under this part; and

(5) recommend appropriation levels for programs under this part.

(e) MEETINGS AND DOCUMENTS.—

(1) MEETINGS.—The Advisory Committee shall meet not less than 2 times each year. Such meetings shall be held jointly with other related entities established under this title where appropriate.

(2) DOCUMENTS.—Not later than 14 days prior to the convening of a meeting under paragraph (1), the Advisory Committee shall prepare and make available an agenda of the matters to be considered by the Advisory Committee at such meeting. At any such meeting, the Advisory Council[8] shall distribute materials with respect to the issues to be addressed at the meeting. Not later than 30 days after the adjourning of such a meeting, the Advisory Committee shall prepare and make available a summary of the meeting and any actions taken by the Committee based upon the meeting.

(f) COMPENSATION AND EXPENSES.—

(1) COMPENSATION.—Each member of the Advisory Committee shall be compensated at a rate equal to the daily equivalent of the annual rate of basic pay prescribed for level IV of the Executive Schedule under section 5315 of title 5, United States Code, for each day (including travel time) during which such member is engaged in the performance of the duties of the Committee.

(2) EXPENSES.—The members of the Advisory Committee shall be allowed travel expenses, including per diem in lieu of subsistence, at rates authorized for employees of agencies under subchapter I of chapter 57 of title 5, United States Code, while away from their homes or regular places of business in the performance of services for the Committee.

(g) FACA.—The Federal Advisory Committee Act shall apply to the Advisory Committee under this section only to the extent that the provisions of such Act do not conflict with the requirements of this section.

[8] So in law. Probably should be "Advisory Committee". See section 102(4) of Public Law 105–392 (112 Stat. 3539).

SEC. 749A.[293l–1] TEACHING HEALTH CENTERS DEVELOPMENT GRANTS.

(a) PROGRAM AUTHORIZED.—The Secretary may award grants under this section to teaching health centers for the purpose of establishing new accredited or expanded primary care residency programs.

(b) AMOUNT AND DURATION.—Grants awarded under this section shall be for a term of not more than 3 years and the maximum award may not be more than $500,000.

(c) USE OF FUNDS.—Amounts provided under a grant under this section shall be used to cover the costs of—

(1) establishing or expanding a primary care residency training program described in subsection (a), including costs associated with—

(A) curriculum development;

(B) recruitment, training and retention of residents and faculty:

(C) accreditation by the Accreditation Council for Graduate Medical Education (ACGME), the American Dental Association (ADA), or the American Osteopathic Association (AOA); and

(D) faculty salaries during the development phase; and

(2) technical assistance provided by an eligible entity.

(d) APPLICATION.—A teaching health center seeking a grant under this section shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require.

(e) PREFERENCE FOR CERTAIN APPLICATIONS.—In selecting recipients for grants under this section, the Secretary shall give preference to any such application that documents an existing affiliation agreement with an area health education center program as defined in sections 751 and 799B.

(f) DEFINITIONS.—In this section:

(1) ELIGIBLE ENTITY.—The term "eligible entity" means an organization capable of providing technical assistance including an area health education center program as defined in sections 751 and 799B.

(2) PRIMARY CARE RESIDENCY PROGRAM.—The term "primary care residency program" means an approved graduate medical residency training program (as defined in section 340H) in family medicine, internal medicine, pediatrics, internal medicine-pediatrics, obstetrics and gynecology, psychiatry, general dentistry, pediatric dentistry, and geriatrics.

(3) TEACHING HEALTH CENTER.—

(A) IN GENERAL.—The term "teaching health center" means an entity that—

(i) is a community based, ambulatory patient care center; and

(ii) operates a primary care residency program.

(B) INCLUSION OF CERTAIN ENTITIES.—Such term includes the following:

(i) A Federally qualified health center (as defined in section 1905(l)(2)(B), of the Social Security Act).

(ii) A community mental health center (as defined in section 1861(ff)(3)(B) of the Social Security Act).

(iii) A rural health clinic, as defined in section 1861(aa) of the Social Security Act.

(iv) A health center operated by the Indian Health Service, an Indian tribe or tribal organization, or an urban Indian organization (as defined in section 4 of the Indian Health Care Improvement Act).

(v) An entity receiving funds under title X of the Public Health Service Act.

(g) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated, $25,000,000 for fiscal year 2010, $50,000,000 for fiscal year 2011, $50,000,000 for fiscal year 2012, and such sums as may be necessary for each fiscal year thereafter to carry out this section. Not to exceed $5,000,000 annually may be used for technical assistance program grants.

Subpart II—Training in Underserved Communities

SEC. 749B.[293m] RURAL PHYSICIAN TRAINING GRANTS.

(a) IN GENERAL.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall establish a grant program for the purposes of assisting eligible entities in recruiting students most likely to practice medicine in underserved rural communities, providing rural-focused training and experience, and increasing the number of recent allopathic and osteopathic medical school graduates who practice in underserved rural communities.

(b) ELIGIBLE ENTITIES.—In order to be eligible to receive a grant under this section, an entity shall—

(1) be a school of allopathic or osteopathic medicine accredited by a nationally recognized accrediting agency or association approved by the Secretary for this purpose, or any combination or consortium of such schools; and

(2) submit an application to the Secretary that includes a certification that such entity will use amounts provided to the institution as described in subsection (d)(1).

(c) PRIORITY.—In awarding grant funds under this section, the Secretary shall give priority to eligible entities that—

(1) demonstrate a record of successfully training students, as determined by the Secretary, who practice medicine in underserved rural communities;

(2) demonstrate that an existing academic program of the eligible entity produces a high percentage, as determined by the Secretary, of graduates from such program who practice medicine in underserved rural communities;

(3) demonstrate rural community institutional partnerships, through such mechanisms as matching or contributory funding, documented in-kind services for implementation, or existence of training partners with interprofessional expertise in community health center training locations or other similar facilities; or

(4) submit, as part of the application of the entity under subsection (b), a plan for the long-term tracking of where the graduates of such entity practice medicine.

(d) USE OF FUNDS.—

(1) ESTABLISHMENT.—An eligible entity receiving a grant under this section shall use the funds made available under such grant to establish, improve, or expand a rural-focused training program (referred to in this section as the "Program") meeting the requirements described in this subsection and to carry out such program.

(2) STRUCTURE OF PROGRAM.—An eligible entity shall—

(A) enroll no fewer than 10 students per class year into the Program; and

(B) develop criteria for admission to the Program that gives priority to students—

(i) who have originated from or lived for a period of 2 or more years in an underserved rural community; and

(ii) who express a commitment to practice medicine in an underserved rural community.

(3) CURRICULA.—The Program shall require students to enroll in didactic coursework and clinical experience particularly applicable to medical practice in underserved rural communities, including—

(A) clinical rotations in underserved rural communities, and in applicable specialties, or other coursework or clinical experience deemed appropriate by the Secretary; and

(B) in addition to core school curricula, additional coursework or training experiences focused on medical issues prevalent in underserved rural communities.

(4) RESIDENCY PLACEMENT ASSISTANCE.—Where available, the Program shall assist all students of the Program in obtaining clinical training experiences in locations with postgraduate programs offering residency training opportunities in underserved rural communities, or in local residency training programs that support and train physicians to practice in underserved rural communities.

(5) PROGRAM STUDENT COHORT SUPPORT.—The Program shall provide and require all students of the Program to participate in group activities designed to further develop, maintain, and reinforce the original commitment of such students to practice in an underserved rural community.

(e) ANNUAL REPORTING.—An eligible entity receiving a grant under this section shall submit an annual report to the Secretary on the success of the Program, based on criteria the Secretary determines appropriate, including the residency program selection of graduating students who participated in the Program.

(f) REGULATIONS.—Not later than 60 days after the date of enactment of this section, the Secretary shall by regulation define "underserved rural community" for purposes of this section.

(g) SUPPLEMENT NOT SUPPLANT.—Any eligible entity receiving funds under this section shall use such funds to supplement, not supplant, any other Federal, State, and local funds that would oth-

erwise be expended by such entity to carry out the activities described in this section.

(h) MAINTENANCE OF EFFORT.—With respect to activities for which funds awarded under this section are to be expended, the entity shall agree to maintain expenditures of non-Federal amounts for such activities at a level that is not less than the level of such expenditures maintained by the entity for the fiscal year preceding the fiscal year for which the entity receives a grant under this section.

(i) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated $4,000,000 for each of the fiscal years 2010 through 2013.

PART D—INTERDISCIPLINARY, COMMUNITY-BASED LINKAGES

SEC. 750.[294] GENERAL PROVISIONS.

(a) COLLABORATION.—To be eligible to receive assistance under this part, an academic institution shall use such assistance in collaboration with 2 or more disciplines.

(b) ACTIVITIES.—An entity shall use assistance under this part to carry out innovative demonstration projects for strategic workforce supplementation activities as needed to meet national goals for interdisciplinary, community-based linkages. Such assistance may be used consistent with this part—

(1) to develop and support training programs;

(2) for faculty development;

(3) for model demonstration programs;

(4) for the provision of stipends for fellowship trainees;

(5) to provide technical assistance; and

(6) for other activities that will produce outcomes consistent with the purposes of this part.

SEC. 751.[294a] AREA HEALTH EDUCATION CENTERS.

(a) ESTABLISHMENT OF AWARDS.—The Secretary shall make the following 2 types of awards in accordance with this section:

(1) INFRASTRUCTURE DEVELOPMENT AWARD.—The Secretary shall make awards to eligible entities to enable such entities to initiate health care workforce educational programs or to continue to carry out comparable programs that are operating at the time the award is made by planning, developing, operating, and evaluating an area health education center program.

(2) POINT OF SERVICE MAINTENANCE AND ENHANCEMENT AWARD.—The Secretary shall make awards to eligible entities to maintain and improve the effectiveness and capabilities of an existing area health education center program, and make other modifications to the program that are appropriate due to changes in demographics, needs of the populations served, or other similar issues affecting the area health education center program. For the purposes of this section, the term "Program" refers to the area health education center program.

(b) ELIGIBLE ENTITIES; APPLICATION.—

(1) ELIGIBLE ENTITIES.—

(A) INFRASTRUCTURE DEVELOPMENT.—For purposes of subsection (a)(1), the term "eligible entity" means a school of medicine or osteopathic medicine, an incorporated consortium of such schools, or the parent institutions of such a school. With respect to a State in which no area health education center program is in operation, the Secretary may award a grant or contract under subsection (a)(1) to a school of nursing.

(B) POINT OF SERVICE MAINTENANCE AND ENHANCEMENT.—For purposes of subsection (a)(2), the term "eligible entity" means an entity that has received funds under this section, is operating an area health education center program, including an area health education center or centers, and has a center or centers that are no longer eligible to receive financial assistance under subsection (a)(1).

(2) APPLICATION.—An eligible entity desiring to receive an award under this section shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

(c) USE OF FUNDS.—

(1) REQUIRED ACTIVITIES.—An eligible entity shall use amounts awarded under a grant under subsection (a)(1) or (a)(2) to carry out the following activities:

(A) Develop and implement strategies, in coordination with the applicable one-stop delivery system under section 134(c) of the Workforce Investment Act of 1998, to recruit individuals from underrepresented minority populations or from disadvantaged or rural backgrounds into health professions, and support such individuals in attaining such careers.

(B) Develop and implement strategies to foster and provide community-based training and education to individuals seeking careers in health professions within underserved areas for the purpose of developing and maintaining a diverse health care workforce that is prepared to deliver high-quality care, with an emphasis on primary care, in underserved areas or for health disparity populations, in collaboration with other Federal and State health care workforce development programs, the State workforce agency, and local workforce investment boards, and in health care safety net sites.

(C) Prepare individuals to more effectively provide health services to underserved areas and health disparity populations through field placements or preceptorships in conjunction with community-based organizations, accredited primary care residency training programs, Federally qualified health centers, rural health clinics, public health departments, or other appropriate facilities.

(D) Conduct and participate in interdisciplinary training that involves physicians, physician assistants, nurse practitioners, nurse midwives, dentists, psychologists, pharmacists, optometrists, community health workers, public and allied health professionals, or other health professionals, as practicable.

(E) Deliver or facilitate continuing education and information dissemination programs for health care professionals, with an emphasis on individuals providing care in underserved areas and for health disparity populations.

(F) Propose and implement effective program and outcomes measurement and evaluation strategies.

(G) Establish a youth public health program to expose and recruit high school students into health careers, with a focus on careers in public health.

(2) INNOVATIVE OPPORTUNITIES.—An eligible entity may use amounts awarded under a grant under subsection (a)(1) or subsection (a)(2) to carry out any of the following activities:

(A) Develop and implement innovative curricula in collaboration with community-based accredited primary care residency training programs, Federally qualified health centers, rural health clinics, behavioral and mental health facilities, public health departments, or other appropriate facilities, with the goal of increasing the number of primary care physicians and other primary care providers prepared to serve in underserved areas and health disparity populations.

(B) Coordinate community-based participatory research with academic health centers, and facilitate rapid flow and dissemination of evidence-based health care information, research results, and best practices to improve quality, efficiency, and effectiveness of health care and health care systems within community settings.

(C) Develop and implement other strategies to address identified workforce needs and increase and enhance the health care workforce in the area served by the area health education center program.

(d) REQUIREMENTS.—

(1) AREA HEALTH EDUCATION CENTER PROGRAM.—In carrying out this section, the Secretary shall ensure the following:

(A) An entity that receives an award under this section shall conduct at least 10 percent of clinical education required for medical students in community settings that are removed from the primary teaching facility of the contracting institution for grantees that operate a school of medicine or osteopathic medicine. In States in which an entity that receives an award under this section is a nursing school or its parent institution, the Secretary shall alternatively ensure that—

(i) the nursing school conducts at least 10 percent of clinical education required for nursing students in community settings that are remote from the primary teaching facility of the school; and

(ii) the entity receiving the award maintains a written agreement with a school of medicine or osteopathic medicine to place students from that school in training sites in the area health education center program area.

(B) An entity receiving funds under subsection (a)(2) does not distribute such funding to a center that is eligible to receive funding under subsection (a)(1).

(2) AREA HEALTH EDUCATION CENTER.—The Secretary shall ensure that each area health education center program includes at least 1 area health education center, and that each such center—

(A) is a public or private organization whose structure, governance, and operation is independent from the awardee and the parent institution of the awardee;

(B) is not a school of medicine or osteopathic medicine, the parent institution of such a school, or a branch campus or other subunit of a school of medicine or osteopathic medicine or its parent institution, or a consortium of such entities;

(C) designates an underserved area or population to be served by the center which is in a location removed from the main location of the teaching facilities of the schools participating in the program with such center and does not duplicate, in whole or in part, the geographic area or population served by any other center;

(D) fosters networking and collaboration among communities and between academic health centers and community-based centers;

(E) serves communities with a demonstrated need of health professionals in partnership with academic medical centers;

(F) addresses the health care workforce needs of the communities served in coordination with the public workforce investment system; and

(G) has a community-based governing or advisory board that reflects the diversity of the communities involved.

(e) MATCHING FUNDS.—With respect to the costs of operating a program through a grant under this section, to be eligible for financial assistance under this section, an entity shall make available (directly or through contributions from State, county or municipal governments, or the private sector) recurring non-Federal contributions in cash or in kind, toward such costs in an amount that is equal to not less than 50 percent of such costs. At least 25 percent of the total required non-Federal contributions shall be in cash. An entity may apply to the Secretary for a waiver of not more than 75 percent of the matching fund amount required by the entity for each of the first 3 years the entity is funded through a grant under subsection (a)(1).

(f) LIMITATION.—Not less than 75 percent of the total amount provided to an area health education center program under subsection (a)(1) or (a)(2) shall be allocated to the area health education centers participating in the program under this section. To provide needed flexibility to newly funded area health education center programs, the Secretary may waive the requirement in the sentence for the first 2 years of a new area health education center program funded under subsection (a)(1).

(g) AWARD.—An award to an entity under this section shall be not less than $250,000 annually per area health education center included in the program involved. If amounts appropriated to carry out this section are not sufficient to comply with the preceding sentence, the Secretary may reduce the per center amount provided for in such sentence as necessary, provided the distribution established in subsection (j)(2) is maintained.

(h) PROJECT TERMS.—

(1) IN GENERAL.—Except as provided in paragraph (2), the period during which payments may be made under an award under subsection (a)(1) may not exceed—

(A) in the case of a program, 12 years; or

(B) in the case of a center within a program, 6 years.

(2) EXCEPTION.—The periods described in paragraph (1) shall not apply to programs receiving point of service maintenance and enhancement awards under subsection (a)(2) to maintain existing centers and activities.

(i) INAPPLICABILITY OF PROVISION.—Notwithstanding any other provision of this title, section 791(a) shall not apply to an area health education center funded under this section.

(j) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—There is authorized to be appropriated to carry out this section $125,000,000 for each of the fiscal years 2010 through 2014.

(2) REQUIREMENTS.—Of the amounts appropriated for a fiscal year under paragraph (1)—

(A) not more than 35 percent shall be used for awards under subsection (a)(1);

(B) not less than 60 percent shall be used for awards under subsection (a)(2);

(C) not more than 1 percent shall be used for grants and contracts to implement outcomes evaluation for the area health education centers; and

(D) not more than 4 percent shall be used for grants and contracts to provide technical assistance to entities receiving awards under this section.

(3) CARRYOVER FUNDS.—An entity that receives an award under this section may carry over funds from 1 fiscal year to another without obtaining approval from the Secretary. In no case may any funds be carried over pursuant to the preceding sentence for more than 3 years.

(k) SENSE OF CONGRESS.—It is the sense of the Congress that every State have an area health education center program in effect under this section.

SEC. 752.[294b] CONTINUING EDUCATIONAL SUPPORT FOR HEALTH PROFESSIONALS SERVING IN UNDERSERVED COMMUNITIES.

(a) IN GENERAL.—The Secretary shall make grants to, and enter into contracts with, eligible entities to improve health care, increase retention, increase representation of minority faculty members, enhance the practice environment, and provide information dissemination and educational support to reduce professional isolation through the timely dissemination of research findings using relevant resources.

(b) ELIGIBLE ENTITIES.—For purposes of this section, the term "eligible entity" means an entity described in section 799(b).

(c) APPLICATION.—An eligible entity desiring to receive an award under this section shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

(d) USE OF FUNDS.—An eligible entity shall use amounts awarded under a grant or contract under this section to provide innovative supportive activities to enhance education through distance learning, continuing educational activities, collaborative conferences, and electronic and telelearning activities, with priority for primary care.

(e) AUTHORIZATION.—There is authorized to be appropriated to carry out this section $5,000,000 for each of the fiscal years 2010 through 2014, and such sums as may be necessary for each subsequent fiscal year.

SEC. 753.[294c] EDUCATION AND TRAINING RELATING TO GERIATRICS.

(a) GERIATRIC EDUCATION CENTERS.—

(1) IN GENERAL.—The Secretary shall award grants or contracts under this section to entities described in paragraphs[9] (1), (3), or (4) of section 799B, and section 801(2), for the establishment or operation of geriatric education centers.

(2) REQUIREMENTS.—A geriatric education center is a program that—

(A) improves the training of health professionals in geriatrics, including geriatric residencies, traineeships, or fellowships;

(B) develops and disseminates curricula relating to the treatment of the health problems of elderly individuals;

(C) supports the training and retraining of faculty to provide instruction in geriatrics;

(D) supports continuing education of health professionals who provide geriatric care; and

(E) provides students with clinical training in geriatrics in nursing homes, chronic and acute disease hospitals, ambulatory care centers, and senior centers.

(b) GERIATRIC TRAINING REGARDING PHYSICIANS AND DENTISTS.—

(1) IN GENERAL.—The Secretary may make grants to, and enter into contracts with, schools of medicine, schools of osteopathic medicine, teaching hospitals, and graduate medical education programs, for the purpose of providing support (including residencies, traineeships, and fellowships) for geriatric training projects to train physicians, dentists and behavioral and mental health professionals who plan to teach geriatric medicine, geriatric behavioral or mental health, or geriatric dentistry.

(2) REQUIREMENTS.—Each project for which a grant or contract is made under this subsection shall—

[9] So in law. Probably should read "paragraph".

(A) be staffed by full-time teaching physicians who have experience or training in geriatric medicine or geriatric behavioral or mental health;

(B) be staffed, or enter into an agreement with an institution staffed by full-time or part-time teaching dentists who have experience or training in geriatric dentistry;

(C) be staffed, or enter into an agreement with an institution staffed by full-time or part-time teaching behavioral mental health professionals who have experience or training in geriatric behavioral or mental health;

(D) be based in a graduate medical education program in internal medicine or family medicine or in a department of geriatrics or behavioral or mental health;

(E) provide training in geriatrics and exposure to the physical and mental disabilities of elderly individuals through a variety of service rotations, such as geriatric consultation services, acute care services, dental services, geriatric behavioral or mental health units, day and home care programs, rehabilitation services, extended care facilities, geriatric ambulatory care and comprehensive evaluation units, and community care programs for elderly individuals with intellectual disabilities; and

(F) provide training in geriatrics through one or both of the training options described in subparagraphs (A) and (B) of paragraph (3).

(3) TRAINING OPTIONS.—The training options referred to in subparagraph (F) of paragraph (2) shall be as follows:

(A) A 1-year retraining program in geriatrics for—

(i) physicians who are faculty members in departments of internal medicine, family medicine, gynecology, geriatrics, and behavioral or mental health at schools of medicine and osteopathic medicine;

(ii) dentists who are faculty members at schools of dentistry or at hospital departments of dentistry; and

(iii) behavioral or mental health professionals who are faculty members in departments of behavioral or mental health; and

(B) A 2-year internal medicine or family medicine fellowship program providing emphasis in geriatrics, which shall be designed to provide training in clinical geriatrics and geriatrics research for—

(i) physicians who have completed graduate medical education programs in internal medicine, family medicine, behavioral or mental health, neurology, gynecology, or rehabilitation medicine;

(ii) dentists who have demonstrated a commitment to an academic career and who have completed postdoctoral dental training, including postdoctoral dental education programs or who have relevant advanced training or experience; and

(iii) behavioral or mental health professionals who have completed graduate medical education programs in behavioral or mental health.

(4) DEFINITIONS.—For purposes of this subsection:

(A) The term "graduate medical education program" means a program sponsored by a school of medicine, a school of osteopathic medicine, a hospital, or a public or private institution that—

(i) offers postgraduate medical training in the specialties and subspecialties of medicine; and

(ii) has been accredited by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association through its Committee on Postdoctoral Training.

(B) The term "post-doctoral dental education program" means a program sponsored by a school of dentistry, a hospital, or a public or private institution that—

(i) offers post-doctoral training in the specialties of dentistry, advanced education in general dentistry, or a dental general practice residency; and

(ii) has been accredited by the Commission on Dental Accreditation.

(c) GERIATRIC FACULTY FELLOWSHIPS.—

(1) ESTABLISHMENT OF PROGRAM.—The Secretary shall establish a program to provide Geriatric Academic Career Awards to eligible individuals to promote the career development of such individuals as academic geriatricians.

(2) ELIGIBLE INDIVIDUALS.—To be eligible to receive an Award under paragraph (1), an individual shall—

(A) be board certified or board eligible in internal medicine, family practice, psychiatry, or licensed dentistry, or have completed any required training in a discipline and employed in an accredited health professions school that is approved by the Secretary;

(B) have completed an approved fellowship program in geriatrics or have completed specialty training in geriatrics as required by the discipline and any addition geriatrics training as required by the Secretary; and

(C) have a junior (non-tenured) faculty appointment at an accredited (as determined by the Secretary) school of medicine, osteopathic medicine, nursing, social work, psychology, dentistry, pharmacy, or other allied health disciplines in an accredited health professions school that is approved by the Secretary.

(3) LIMITATIONS.—No Award under paragraph (1) may be made to an eligible individual unless the individual—

(A) has submitted to the Secretary an application, at such time, in such manner, and containing such information as the Secretary may require, and the Secretary has approved such application;

(B) provides, in such form and manner as the Secretary may require, assurances that the individual will meet the service requirement described in paragraph (6); and

(C) provides, in such form and manner as the Secretary may require, assurances that the individual has a full-time faculty appointment in a health professions institution and documented commitment from such institution

to spend 75 percent of the total time of such individual on teaching and developing skills in interdisciplinary education in geriatrics.

(4) MAINTENANCE OF EFFORT.—An eligible individual that receives an Award under paragraph (1) shall provide assurances to the Secretary that funds provided to the eligible individual under this subsection will be used only to supplement, not to supplant, the amount of Federal, State, and local funds otherwise expended by the eligible individual.

(5) AMOUNT AND TERM.—

(A) AMOUNT.—The amount of an Award under this section for individuals who are physicians shall equal $50,000 for fiscal year 1998, adjusted for subsequent fiscal years to reflect the increase in the Consumer Price Index. The Secretary shall determine the amount of an Award under this section for individuals who are not physicians.

(B) TERM.—The term of any Award made under this subsection shall not exceed 5 years.

(C) PAYMENT TO INSTITUTION.—The Secretary shall make payments to institutions which include schools of medicine, osteopathic medicine, nursing, social work, psychology, dentistry, and pharmacy, or other allied health discipline in an accredited health professions school that is approved by the Secretary.

(6) SERVICE REQUIREMENT.—An individual who receives an Award under this subsection shall provide training in clinical geriatrics, including the training of interdisciplinary teams of health care professionals. The provision of such training shall constitute at least 75 percent of the obligations of such individual under the Award.

(d) GERIATRIC WORKFORCE DEVELOPMENT.—

(1) IN GENERAL.—The Secretary shall award grants or contracts under this subsection to entities that operate a geriatric education center pursuant to subsection (a)(1).

(2) APPLICATION.—To be eligible for an award under paragraph (1), an entity described in such paragraph shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

(3) USE OF FUNDS.—Amounts awarded under a grant or contract under paragraph (1) shall be used to—

(A) carry out the fellowship program described in paragraph (4); and

(B) carry out 1 of the 2 activities described in paragraph (5).

(4) FELLOWSHIP PROGRAM.—

(A) IN GENERAL.—Pursuant to paragraph (3), a geriatric education center that receives an award under this subsection shall use such funds to offer short-term intensive courses (referred to in this subsection as a "fellowship") that focus on geriatrics, chronic care management, and long-term care that provide supplemental training for faculty members in medical schools and other health professions schools with programs in psychology, pharmacy, nursing, social work, dentistry, public health, allied health,

or other health disciplines, as approved by the Secretary. Such a fellowship shall be open to current faculty, and appropriately credentialed volunteer faculty and practitioners, who do not have formal training in geriatrics, to upgrade their knowledge and clinical skills for the care of older adults and adults with functional limitations and to enhance their interdisciplinary teaching skills.

(B) LOCATION.—A fellowship shall be offered either at the geriatric education center that is sponsoring the course, in collaboration with other geriatric education centers, or at medical schools, schools of dentistry, schools of nursing, schools of pharmacy, schools of social work, graduate programs in psychology, or allied health and other health professions schools approved by the Secretary with which the geriatric education centers are affiliated.

(C) CME CREDIT.—Participation in a fellowship under this paragraph shall be accepted with respect to complying with continuing health profession education requirements. As a condition of such acceptance, the recipient shall agree to subsequently provide a minimum of 18 hours of voluntary instructional support through a geriatric education center that is providing clinical training to students or trainees in long-term care settings.

(5) ADDITIONAL REQUIRED ACTIVITIES DESCRIBED.—Pursuant to paragraph (3), a geriatric education center that receives an award under this subsection shall use such funds to carry out 1 of the following 2 activities.

(A) FAMILY CAREGIVER AND DIRECT CARE PROVIDER TRAINING.—A geriatric education center that receives an award under this subsection shall offer at least 2 courses each year, at no charge or nominal cost, to family caregivers and direct care providers that are designed to provide practical training for supporting frail elders and individuals with disabilities. The Secretary shall require such Centers to work with appropriate community partners to develop training program content and to publicize the availability of training courses in their service areas. All family caregiver and direct care provider training programs shall include instruction on the management of psychological and behavioral aspects of dementia, communication techniques for working with individuals who have dementia, and the appropriate, safe, and effective use of medications for older adults.

(B) INCORPORATION OF BEST PRACTICES.—A geriatric education center that receives an award under this subsection shall develop and include material on depression and other mental disorders common among older adults, medication safety issues for older adults, and management of the psychological and behavioral aspects of dementia and communication techniques with individuals who have dementia in all training courses, where appropriate.

(6) TARGETS.—A geriatric education center that receives an award under this subsection shall meet targets approved by the Secretary for providing geriatric training to a certain num-

ber of faculty or practitioners during the term of the award, as well as other parameters established by the Secretary.

(7) AMOUNT OF AWARD.—An award under this subsection shall be in an amount of $150,000. Not more than 24 geriatric education centers may receive an award under this subsection.

(8) MAINTENANCE OF EFFORT.—A geriatric education center that receives an award under this subsection shall provide assurances to the Secretary that funds provided to the geriatric education center under this subsection will be used only to supplement, not to supplant, the amount of Federal, State, and local funds otherwise expended by the geriatric education center.

(9) AUTHORIZATION OF APPROPRIATIONS.—In addition to any other funding available to carry out this section, there is authorized to be appropriated to carry out this subsection, $10,800,000 for the period of fiscal year 2011 through 2014.

(e) GERIATRIC CAREER INCENTIVE AWARDS.—

(1) IN GENERAL.—The Secretary shall award grants or contracts under this section to individuals described in paragraph (2) to foster greater interest among a variety of health professionals in entering the field of geriatrics, long-term care, and chronic care management.

(2) ELIGIBLE INDIVIDUALS.—To be eligible to received an award under paragraph (1), an individual shall—

(A) be an advanced practice nurse, a clinical social worker, a pharmacist, or student of psychology who is pursuing a doctorate or other advanced degree in geriatrics or related fields in an accredited health professions school; and

(B) submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

(3) CONDITION OF AWARD.—As a condition of receiving an award under this subsection, an individual shall agree that, following completion of the award period, the individual will teach or practice in the field of geriatrics, long-term care, or chronic care management for a minimum of 5 years under guidelines set by the Secretary.

(4) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this subsection, $10,000,000 for the period of fiscal years 2011 through 2013.

SEC. 754.[294d] QUENTIN N. BURDICK PROGRAM FOR RURAL INTERDISCIPLINARY TRAINING.

(a) GRANTS.—The Secretary may make grants or contracts under this section to help entities fund authorized activities under an application approved under subsection (c).

(b) USE OF AMOUNTS.—

(1) IN GENERAL.—Amounts provided under subsection (a) shall be used by the recipients to fund interdisciplinary training projects designed to—

(A) use new and innovative methods to train health care practitioners to provide services in rural areas;

(B) demonstrate and evaluate innovative interdisciplinary methods and models designed to provide access to cost-effective comprehensive health care;

(C) deliver health care services to individuals residing in rural areas;

(D) enhance the amount of relevant research conducted concerning health care issues in rural areas; and

(E) increase the recruitment and retention of health care practitioners from rural areas and make rural practice a more attractive career choice for health care practitioners.

(2) METHODS.—A recipient of funds under subsection (a) may use various methods in carrying out the projects described in paragraph (1), including—

(A) the distribution of stipends to students of eligible applicants;

(B) the establishment of a post-doctoral fellowship program;

(C) the training of faculty in the economic and logistical problems confronting rural health care delivery systems; or

(D) the purchase or rental of transportation and telecommunication equipment where the need for such equipment due to unique characteristics of the rural area is demonstrated by the recipient.

(3) ADMINISTRATION.—

(A) IN GENERAL.—An applicant shall not use more than 10 percent of the funds made available to such applicant under subsection (a) for administrative expenses.

(B) TRAINING.—Not more than 10 percent of the individuals receiving training with funds made available to an applicant under subsection (a) shall be trained as doctors of medicine or doctors of osteopathy.

(C) LIMITATION.—An institution that receives a grant under this section shall use amounts received under such grant to supplement, not supplant, amounts made available by such institution for activities of the type described in subsection (b)(1) in the fiscal year preceding the year for which the grant is received.

(c) APPLICATIONS.—Applications submitted for assistance under this section shall—

(1) be jointly submitted by at least two eligible applicants with the express purpose of assisting individuals in academic institutions in establishing long-term collaborative relationships with health care providers in rural areas; and

(2) designate a rural health care agency or agencies for clinical treatment or training, including hospitals, community health centers, migrant health centers, rural health clinics, community behavioral and mental health centers, long-term care facilities, Native Hawaiian health centers, or facilities operated by the Indian Health Service or an Indian tribe or tribal organization or Indian organization under a contract with the Indian Health Service under the Indian Self-Determination Act.

(d) DEFINITIONS.—For the purposes of this section, the term "rural" means geographic areas that are located outside of standard metropolitan statistical areas.

SEC. 755.[294e] ALLIED HEALTH AND OTHER DISCIPLINES.

(a) IN GENERAL.—The Secretary may make grants or contracts under this section to help entities fund activities of the type described in subsection (b).

(b) ACTIVITIES.—Activities of the type described in this subsection include the following:

(1) Assisting entities in meeting the costs associated with expanding or establishing programs that will increase the number of individuals trained in allied health professions. Programs and activities funded under this paragraph may include—

(A) those that expand enrollments in allied health professions with the greatest shortages or whose services are most needed by the elderly;

(B) those that provide rapid transition training programs in allied health fields to individuals who have baccalaureate degrees in health-related sciences;

(C) those that establish community-based allied health training programs that link academic centers to rural clinical settings;

(D) those that provide career advancement training for practicing allied health professionals;

(E) those that expand or establish clinical training sites for allied health professionals in medically underserved or rural communities in order to increase the number of individuals trained;

(F) those that develop curriculum that will emphasize knowledge and practice in the areas of prevention and health promotion, geriatrics, long-term care, home health and hospice care, and ethics;

(G) those that expand or establish interdisciplinary training programs that promote the effectiveness of allied health practitioners in geriatric assessment and the rehabilitation of the elderly;

(H) those that expand or establish demonstration centers to emphasize innovative models to link allied health clinical practice, education, and research;

(I) those that provide financial assistance (in the form of traineeships) to students who are participants in any such program; and

(i) who plan to pursue a career in an allied health field that has a demonstrated personnel shortage; and

(ii) who agree upon completion of the training program to practice in a medically underserved community;

that shall be utilized to assist in the payment of all or part of the costs associated with tuition, fees and such other stipends as the Secretary may consider necessary; and

(J) those to meet the costs of projects to plan, develop, and operate or maintain graduate programs in behavioral and mental health practice.

(2) Planning and implementing projects in preventive and primary care training for podiatric physicians in approved or provisionally approved residency programs that shall provide financial assistance in the form of traineeships to residents who participate in such projects and who plan to specialize in primary care.

(3) Carrying out demonstration projects in which chiropractors and physicians collaborate to identify and provide effective treatment for spinal and lower-back conditions.

SEC. 756.[294e–1] MENTAL AND BEHAVIORAL HEALTH EDUCATION AND TRAINING GRANTS.

(a) GRANTS AUTHORIZED.—The Secretary may award grants to eligible institutions of higher education to support the recruitment of students for, and education and clinical experience of the students in—

(1) baccalaureate, master's, and doctoral degree programs of social work, as well as the development of faculty in social work;

(2) accredited master's, doctoral, internship, and post-doctoral residency programs of psychology for the development and implementation of interdisciplinary training of psychology graduate students for providing behavioral and mental health services, including substance abuse prevention and treatment services;

(3) accredited institutions of higher education or accredited professional training programs that are establishing or expanding internships or other field placement programs in child and adolescent mental health in psychiatry, psychology, school psychology, behavioral pediatrics, psychiatric nursing, social work, school social work, substance abuse prevention and treatment, marriage and family therapy, school counseling, or professional counseling; and

(4) State-licensed mental health nonprofit and for-profit organizations to enable such organizations to pay for programs for preservice or in-service training of paraprofessional child and adolescent mental health workers.

(b) ELIGIBILITY REQUIREMENTS.—To be eligible for a grant under this section, an institution shall demonstrate—

(1) participation in the institutions' programs of individuals and groups from different racial, ethnic, cultural, geographic, religious, linguistic, and class backgrounds, and different genders and sexual orientations;

(2) knowledge and understanding of the concerns of the individuals and groups described in subsection (a);

(3) any internship or other field placement program assisted under the grant will prioritize cultural and linguistic competency;

(4) the institution will provide to the Secretary such data, assurances, and information as the Secretary may require; and

(5) with respect to any violation of the agreement between the Secretary and the institution, the institution will pay such

liquidated damages as prescribed by the Secretary by regulation.

(c) INSTITUTIONAL REQUIREMENT.—For grants authorized under subsection (a)(1), at least 4 of the grant recipients shall be historically black colleges or universities or other minority-serving institutions.

(d) PRIORITY.—

(1) In selecting the grant recipients in social work under subsection (a)(1), the Secretary shall give priority to applicants that—

(A) are accredited by the Council on Social Work Education;

(B) have a graduation rate of not less than 80 percent for social work students; and

(C) exhibit an ability to recruit social workers from and place social workers in areas with a high need and high demand population.

(2) In selecting the grant recipients in graduate psychology under subsection (a)(2), the Secretary shall give priority to institutions in which training focuses on the needs of vulnerable groups such as older adults and children, individuals with mental health or substance-related disorders, victims of abuse or trauma and of combat stress disorders such as posttraumatic stress disorder and traumatic brain injuries, homeless individuals, chronically ill persons, and their families.

(3) In selecting the grant recipients in training programs in child and adolescent mental health under subsections (a)(3) and (a)(4), the Secretary shall give priority to applicants that—

(A) have demonstrated the ability to collect data on the number of students trained in child and adolescent mental health and the populations served by such students after graduation or completion of preservice or in-service training;

(B) have demonstrated familiarity with evidence-based methods in child and adolescent mental health services, including substance abuse prevention and treatment services;

(C) have programs designed to increase the number of professionals and paraprofessionals serving high-priority populations and to applicants who come from high-priority communities and plan to serve medically underserved populations, in health professional shortage areas, or in medically underserved areas;

(D) offer curriculum taught collaboratively with a family on the consumer and family lived experience or the importance of family-professional or family-paraprofessional partnerships; and

(E) provide services through a community mental health program described in section 1913(b)(1).

(e) AUTHORIZATION OF APPROPRIATION.—For the fiscal years 2010 through 2013, there is authorized to be appropriated to carry out this section—

(1) $8,000,000 for training in social work in subsection (a)(1);

(2) $12,000,000 for training in graduate psychology in subsection (a)(2), of which not less than $10,000,000 shall be allocated for doctoral, postdoctoral, and internship level training;

(3) $10,000,000 for training in professional child and adolescent mental health in subsection (a)(3); and

(4) $5,000,000 for training in paraprofessional child and adolescent work in subsection (a)(4).

SEC. 757.[294f] ADVISORY COMMITTEE ON INTERDISCIPLINARY, COMMUNITY-BASED LINKAGES.

(a) ESTABLISHMENT.—The Secretary shall establish an advisory committee to be known as the Advisory Committee on Interdisciplinary, Community-Based Linkages (in this section referred to as the "Advisory Committee").

(b) COMPOSITION.—

(1) IN GENERAL.—The Secretary shall determine the appropriate number of individuals to serve on the Advisory Committee. Such individuals shall not be officers or employees of the Federal Government.

(2) APPOINTMENT.—Not later than 90 days after the date of enactment of this Act[10], the Secretary shall appoint the members of the Advisory Committee from among individuals who are health professionals from schools of the types described in sections 751(b)(1)(A), 753(b), and 755(b). In making such appointments, the Secretary shall ensure a fair balance between the health professions, that at least 75 percent of the members of the Advisory Committee are health professionals, a broad geographic representation of members and a balance between urban and rural members. Members shall be appointed based on their competence, interest, and knowledge of the mission of the profession involved.

(3) MINORITY REPRESENTATION.—In appointing the members of the Advisory Committee under paragraph (2), the Secretary shall ensure the adequate representation of women and minorities.

(c) TERMS.—

(1) IN GENERAL.—A member of the Advisory Committee shall be appointed for a term of 3 years, except that of the members first appointed—

(A) ⅓ of the members shall serve for a term of 1 year;

(B) ⅓ of the members shall serve for a term of 2 years; and

(C) ⅓ of the members shall serve for a term of 3 years.

(2) VACANCIES.—

(A) IN GENERAL.—A vacancy on the Advisory Committee shall be filled in the manner in which the original appointment was made and shall be subject to any condi-

[10] So in law. The reference to "this Act" means the Public Health Service Act, which was enacted July 1, 1944. Probably should be a reference to the Health Professions Education Partnerships Act of 1998, which added section 756. That Act is Public Law 105–392, enacted November 13, 1998. (Section 103 of that Public Law (112 Stat. 3541) added section 756.)

tions which applied with respect to the original appointment.

(B) FILLING UNEXPIRED TERM.—An individual chosen to fill a vacancy shall be appointed for the unexpired term of the member replaced.

(d) DUTIES.—The Advisory Committee shall—

(1) provide advice and recommendations to the Secretary concerning policy and program development and other matters of significance concerning the activities under this part;

(2) not later than 3 years after the date of enactment of this section, and annually thereafter, prepare and submit to the Secretary, and the Committee on Labor and Human Resources of the Senate, and the Committee on Commerce of the House of Representatives, a report describing the activities of the Committee, including findings and recommendations made by the Committee concerning the activities under this part;

(3) develop, publish, and implement performance measures for programs under this part;

(4) develop and publish guidelines for longitudinal evaluations (as described in section 761(d)(2)) for programs under this part; and

(5) recommend appropriation levels for programs under this part.

(e) MEETINGS AND DOCUMENTS.—

(1) MEETINGS.—The Advisory Committee shall meet not less than 3 times each year. Such meetings shall be held jointly with other related entities established under this title where appropriate.

(2) DOCUMENTS.—Not later than 14 days prior to the convening of a meeting under paragraph (1), the Advisory Committee shall prepare and make available an agenda of the matters to be considered by the Advisory Committee at such meeting. At any such meeting, the Advisory Council[11] shall distribute materials with respect to the issues to be addressed at the meeting. Not later than 30 days after the adjourning of such a meeting, the Advisory Committee shall prepare and make available a summary of the meeting and any actions taken by the Committee based upon the meeting.

(f) COMPENSATION AND EXPENSES.—

(1) COMPENSATION.—Each member of the Advisory Committee shall be compensated at a rate equal to the daily equivalent of the annual rate of basic pay prescribed for level IV of the Executive Schedule under section 5315 of title 5, United States Code, for each day (including travel time) during which such member is engaged in the performance of the duties of the Committee.

(2) EXPENSES.—The members of the Advisory Committee shall be allowed travel expenses, including per diem in lieu of subsistence, at rates authorized for employees of agencies under subchapter I of chapter 57 of title 5, United States Code,

[11] So in law. Probably should be "Advisory Committee". See section 103 of Public Law 105–392 (112 Stat. 3541).

while away from their homes or regular places of business in the performance of services for the Committee.

(g) FACA.—The Federal Advisory Committee Act shall apply to the Advisory Committee under this section only to the extent that the provisions of such Act do not conflict with the requirements of this section.

[Note: Section 758 was repealed by section 501(b)(2) of Public Law 113–4; enacted March 7, 2013, 127 Stat. 54.]

SEC. 759.[294i] PROGRAM FOR EDUCATION AND TRAINING IN PAIN CARE.

(a) IN GENERAL.—The Secretary may make awards of grants, cooperative agreements, and contracts to health professions schools, hospices, and other public and private entities for the development and implementation of programs to provide education and training to health care professionals in pain care.

(b) CERTAIN TOPICS.—An award may be made under subsection (a) only if the applicant for the award agrees that the program carried out with the award will include information and education on—

(1) recognized means for assessing, diagnosing, treating, and managing pain and related signs and symptoms, including the medically appropriate use of controlled substances;

(2) applicable laws, regulations, rules, and policies on controlled substances, including the degree to which misconceptions and concerns regarding such laws, regulations, rules, and policies, or the enforcement thereof, may create barriers to patient access to appropriate and effective pain care;

(3) interdisciplinary approaches to the delivery of pain care, including delivery through specialized centers providing comprehensive pain care treatment expertise;

(4) cultural, linguistic, literacy, geographic, and other barriers to care in underserved populations; and

(5) recent findings, developments, and improvements in the provision of pain care.

(c) EVALUATION OF PROGRAMS.—The Secretary shall (directly or through grants or contracts) provide for the evaluation of programs implemented under subsection (a) in order to determine the effect of such programs on knowledge and practice of pain care.

(d) PAIN CARE DEFINED.—For purposes of this section the term "pain care" means the assessment, diagnosis, treatment, or management of acute or chronic pain regardless of causation or body location.

(e) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, such sums as may be necessary for each of the fiscal years 2010 through 2012. Amounts appropriated under this subsection shall remain available until expended.

PART E—HEALTH PROFESSIONS AND PUBLIC HEALTH WORKFORCE

Subpart 1—Health Professions Workforce Information and Analysis

SEC. 761.[294n] HEALTH PROFESSIONS WORKFORCE INFORMATION AND ANALYSIS.

(a) PURPOSE.—It is the purpose of this section to—

(1) provide for the development of information describing the health professions workforce and the analysis of workforce related issues; and

(2) provide necessary information for decision-making regarding future directions in health professions and nursing programs in response to societal and professional needs.

(b) NATIONAL CENTER FOR HEALTH CARE WORKFORCE ANALYSIS.—

(1) ESTABLISHMENT.—The Secretary shall establish the National Center for Health Workforce Analysis (referred to in this section as the "National Center").

(2) PURPOSES.—The National Center, in coordination to the extent practicable with the National Health Care Workforce Commission (established in section 5101 of the Patient Protection and Affordable Care Act), and relevant regional and State centers and agencies, shall—

(A) provide for the development of information describing and analyzing the health care workforce and workforce related issues;

(B) carry out the activities under section 792(a);

(C) annually evaluate programs under this title;

(D) develop and publish performance measures and benchmarks for programs under this title; and

(E) establish, maintain, and publicize a national Internet registry of each grant awarded under this title and a database to collect data from longitudinal evaluations (as described in subsection (d)(2)) on performance measures (as developed under sections 749(d)(3), 757(d)(3), and 762(a)(3)).

(3) COLLABORATION AND DATA SHARING.—

(A) IN GENERAL.—The National Center shall collaborate with Federal agencies and relevant professional and educational organizations or societies for the purpose of linking data regarding grants awarded under this title.

(B) CONTRACTS FOR HEALTH WORKFORCE ANALYSIS.—For the purpose of carrying out the activities described in subparagraph (A), the National Center may enter into contracts with relevant professional and educational organizations or societies.

(c) STATE AND REGIONAL CENTERS FOR HEALTH WORKFORCE ANALYSIS.—

(1) IN GENERAL.—The Secretary shall award grants to, or enter into contracts with, eligible entities for purposes of—

(A) collecting, analyzing, and reporting data regarding programs under this title to the National Center and to the public; and

(B) providing technical assistance to local and regional entities on the collection, analysis, and reporting of data.

(2) ELIGIBLE ENTITIES.—To be eligible for a grant or contract under this subsection, an entity shall—

(A) be a State, a State workforce investment board, a public health or health professions school, an academic health center, or an appropriate public or private nonprofit entity; and

(B) submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

(d) INCREASE IN GRANTS FOR LONGITUDINAL EVALUATIONS.—

(1) IN GENERAL.—The Secretary shall increase the amount awarded to an eligible entity under this title for a longitudinal evaluation of individuals who have received education, training, or financial assistance from programs under this title.

(2) CAPABILITY.—A longitudinal evaluation shall be capable of—

(A) studying practice patterns; and

(B) collecting and reporting data on performance measures developed under sections 749(d)(3), 757(d)(3), and 762(a)(3).

(3) GUIDELINES.—A longitudinal evaluation shall comply with guidelines issued under sections 749(d)(4), 757(d)(4), and 762(a)(4).

(4) ELIGIBLE ENTITIES.—To be eligible to obtain an increase under this section, an entity shall be a recipient of a grant or contract under this title.

(e) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—

(A) NATIONAL CENTER.—To carry out subsection (b), there are authorized to be appropriated $7,500,000 for each of fiscal years 2010 through 2014.

(B) STATE AND REGIONAL CENTERS.—To carry out subsection (c), there are authorized to be appropriated $4,500,000 for each of fiscal years 2010 through 2014.

(C) GRANTS FOR LONGITUDINAL EVALUATIONS.—To carry out subsection (d), there are authorized to be appropriated such sums as may be necessary for fiscal years 2010 through 2014.

(2) RESERVATION.—Of the amounts appropriated under subsection (a)[12] for a fiscal year, the Secretary shall reserve not less than $600,000 for conducting health professions research and for carrying out data collection and analysis in accordance with section 792.

[12] The reference to "subsection (a)" in subsection (e)(2) probably should read "paragraph (1)". Paragraph (4) of section 5103(a) of PL 111–148 probably should have been designated as a subparagraph (B) of paragraph (3) of such section. As such, the amendment instruction in paragraph (4) to strike "subsection (a)" and insert "paragraph (1)" could not be executed since it did not specify to which subsection to carry out the amendment.

(3) AVAILABILITY OF ADDITIONAL FUNDS.—Amounts otherwise appropriated for programs or activities under this title may be used for activities under subsection (b) with respect to the programs or activities from which such amounts were made available.

SEC. 762.[294o] ADVISORY COUNCIL ON GRADUATE MEDICAL EDUCATION.

(a) ESTABLISHMENT; DUTIES.—There is established the Council on Graduate Medical Education (in this section referred to as the "Council"). The Council shall—

(1) make recommendations to the Secretary of Health and Human Services (in this section referred to as the "Secretary"), and to the Committee on Labor and Human Resources of the Senate, and the Committee on Energy and Commerce of the House of Representatives, with respect to—

(A) the supply and distribution of physicians in the United States;

(B) current and future shortages or excesses of physicians in medical and surgical specialties and subspecialties;

(C) issues relating to foreign medical school graduates;

(D) appropriate Federal policies with respect to the matters specified in subparagraphs (A), (B), and (C), including policies concerning changes in the financing of undergraduate and graduate medical education programs and changes in the types of medical education training in graduate medical education programs;

(E) appropriate efforts to be carried out by hospitals, schools of medicine, schools of osteopathic medicine, and accrediting bodies with respect to the matters specified in subparagraphs (A), (B), and (C), including efforts for changes in undergraduate and graduate medical education programs; and

(F) deficiencies in, and needs for improvements in, existing data bases concerning the supply and distribution of, and postgraduate training programs for, physicians in the United States and steps that should be taken to eliminate those deficiencies;

(2) encourage entities providing graduate medical education to conduct activities to voluntarily achieve the recommendations of the Council under paragraph (1)(E);

(3) develop, publish, and implement performance measures for programs under this title, except for programs under part C or D;

(4) develop and publish guidelines for longitudinal evaluations (as described in section 761(d)(2)) for programs under this title, except for programs under part C or D; and

(5) recommend appropriation levels for programs under this title, except for programs under part C or D.

(b) COMPOSITION.—The Council shall be composed of—

(1) the Assistant Secretary for Health or the designee of the Assistant Secretary;

(2) the Administrator of the Health Care Financing Administration;

(3) the Chief Medical Director of the Department of Veterans Affairs;

(4) 6 members appointed by the Secretary to include representatives of practicing primary care physicians, national and specialty physician organizations, foreign medical graduates, and medical student and house staff associations;

(5) 4 members appointed by the Secretary to include representatives of schools of medicine and osteopathic medicine and public and private teaching hospitals; and

(6) 4 members appointed by the Secretary to include representatives of health insurers, business, and labor.

(c) TERMS OF APPOINTED MEMBERS.—

(1) IN GENERAL; STAGGERED ROTATION.—Members of the Council appointed under paragraphs (4), (5), and (6) of subsection (b) shall be appointed for a term of 4 years, except that the term of office of the members first appointed shall expire, as designated by the Secretary at the time of appointment, 4 at the end of 1 year, 4 at the end of 2 years, 3 at the end of 3 years, and 3 at the end of 4 years.

(2) DATE CERTAIN FOR APPOINTMENT.—The Secretary shall appoint the first members to the Council under paragraphs (4), (5), and (6) of subsection (b) within 60 days after the date of enactment of this section.

(d) CHAIR.—The Council shall elect one of its members as Chairman of the Council.

(e) QUORUM.—Nine members of the Council shall constitute a quorum, but a lesser number may hold hearings.

(f) VACANCIES.—Any vacancy in the Council shall not affect its power to function.

(g) COMPENSATION.—Each member of the Council who is not otherwise employed by the United States Government shall receive compensation at a rate equal to the daily rate prescribed for GS–18 under the General Schedule under section 5332 of title 5, United States Code, for each day, including traveltime, such member is engaged in the actual performance of duties as a member of the Council. A member of the Council who is an officer or employee of the United States Government shall serve without additional compensation. All members of the Council shall be reimbursed for travel, subsistence, and other necessary expenses incurred by them in the performance of their duties.

(h) CERTAIN AUTHORITIES AND DUTIES.—

(1) AUTHORITIES.—In order to carry out the provisions of this section, the Council is authorized to—

(A) collect such information, hold such hearings, and sit and act at such times and places, either as a whole or by subcommittee, and request the attendance and testimony of such witnesses and the production of such books, records, correspondence, memoranda, papers, and documents as the Council or such subcommittee may consider available; and

(B) request the cooperation and assistance of Federal departments, agencies, and instrumentalities, and such departments, agencies, and instrumentalities are authorized to provide such cooperation and assistance.

(2) COORDINATION OF ACTIVITIES.—The Council shall coordinate its activities with the activities of the Secretary under section 792 of the Public Health Service Act. The Secretary shall, in cooperation with the Council and pursuant to the recommendations of the Council, take such steps as are practicable to eliminate deficiencies in the data base established under such section 792 and shall make available in its reports such comprehensive data sets as are developed pursuant to this section.

(i) REQUIREMENT REGARDING REPORTS.—In the reports required under subsection (a), the Council shall specify its activities during the period for which the report is made.

(j) FINAL REPORT.—Not later than April 1, 2002, the Council shall submit a final report under subsection (a).

(k) TERMINATION.—The Council shall terminate September 30, 2003[13].

(l) FUNDING.—Amounts otherwise appropriated under this title may be utilized by the Secretary to support the activities of the Council.

SEC. 763.[294p] PEDIATRIC RHEUMATOLOGY.

(a) IN GENERAL.—The Secretary, acting through the appropriate agencies, shall evaluate whether the number of pediatric rheumatologists is sufficient to address the health care needs of children with arthritis and related conditions, and if the Secretary determines that the number is not sufficient, shall develop strategies to help address the shortfall.

(b) REPORT TO CONGRESS.—Not later than October 1, 2001, the Secretary shall submit to the Congress a report describing the results of the evaluation under subsection (a), and as applicable, the strategies developed under such subsection.

(c) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005.

Subpart 2—Public Health Workforce

SEC. 765.[295] GENERAL PROVISIONS.

(a) IN GENERAL.—The Secretary may award grants or contracts to eligible entities to increase the number of individuals in the public health workforce, to enhance the quality of such workforce, and to enhance the ability of the workforce to meet national, State, and local health care needs.

(b) ELIGIBILITY.—To be eligible to receive a grant or contract under subsection (a) an entity shall—

(1) be—

(A) a health professions school, including an accredited school or program of public health, health administration,

[13] Appropriations Acts for the Department of Health and Human Services for fiscal years 2004 and 2005 provided for the continued operation of the Council. See section 219 of division E of Public Law 108–199 (118 Stat. 255) and section 218 of division F of Public Law 108–447 (118 Stat. 3141). Each of such sections refers to "the Council on Graduate Education established by section 301 of Public Law 102–408". Such section 301 was transferred to the Public Health Service Act as section 762 above by section 104(b) of Public Law 105–392 (112 Stat. 3552).

preventive medicine, or dental public health or a school providing health management programs;

(B) an academic health center;

(C) a State or local government; or

(D) any other appropriate public or private nonprofit entity; and

(2) prepare and submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

(c) PREFERENCE.—In awarding grants or contracts under this section the Secretary may grant a preference to entities—

(1) serving individuals who are from disadvantaged backgrounds (including underrepresented racial and ethnic minorities); and

(2) graduating large proportions of individuals who serve in underserved communities.

(d) ACTIVITIES.—Amounts provided under a grant or contract awarded under this section may be used for—

(1) the costs of planning, developing, or operating demonstration training programs;

(2) faculty development;

(3) trainee support;

(4) technical assistance;

(5) to meet the costs of projects—

(A) to plan and develop new residency training programs and to maintain or improve existing residency training programs in preventive medicine and dental public health, that have available full-time faculty members with training and experience in the fields of preventive medicine and dental public health; and

(B) to provide financial assistance to residency trainees enrolled in such programs;

(6) the retraining of existing public health workers as well as for increasing the supply of new practitioners to address priority public health, preventive medicine, public health dentistry, and health administration needs;

(7) preparing public health professionals for employment at the State and community levels;

(8) public health workforce loan repayment programs; or

(9) other activities that may produce outcomes that are consistent with the purposes of this section.

(e) TRAINEESHIPS.—

(1) IN GENERAL.—With respect to amounts used under this section for the training of health professionals, such training programs shall be designed to—

(A) make public health education more accessible to the public and private health workforce;

(B) increase the relevance of public health academic preparation to public health practice in the future;

(C) provide education or training for students from traditional on-campus programs in practice-based sites; or

(D) develop educational methods and distance-based approaches or technology that address adult learning requirements and increase knowledge and skills related to

community-based cultural diversity in public health education.

(2) SEVERE SHORTAGE DISCIPLINES.—Amounts provided under grants or contracts under this section may be used for the operation of programs designed to award traineeships to students in accredited schools of public health who enter educational programs in fields where there is a severe shortage of public health professionals, including epidemiology, biostatistics, environmental health, toxicology, public health nursing, nutrition, preventive medicine, maternal and child health, and behavioral and mental health professions.

SEC. 766.[295a] PUBLIC HEALTH TRAINING CENTERS.

(a) IN GENERAL.—The Secretary may make grants or contracts for the operation of public health training centers.

(b) ELIGIBLE ENTITIES.—

(1) IN GENERAL.—A public health training center shall be an accredited school of public health, or another public or nonprofit private institution accredited for the provision of graduate or specialized training in public health, that plans, develops, operates, and evaluates projects that are in furtherance of the goals established by the Secretary for the year 2000 in the areas of preventive medicine, health promotion and disease prevention, or improving access to and quality of health services in medically underserved communities.

(2) PREFERENCE.—In awarding grants or contracts under this section the Secretary shall give preference to accredited schools of public health.

(c) CERTAIN REQUIREMENTS.—With respect to a public health training center, an award may not be made under subsection (a) unless the program agrees that it—

(1) will establish or strengthen field placements for students in public or nonprofit private health agencies or organizations;

(2) will involve faculty members and students in collaborative projects to enhance public health services to medically underserved communities;

(3) will specifically designate a geographic area or medically underserved population to be served by the center that shall be in a location removed from the main location of the teaching facility of the school that is participating in the program with such center; and

(4) will assess the health personnel needs of the area to be served by the center and assist in the planning and development of training programs to meet such needs.

SEC. 767.[295b] PUBLIC HEALTH TRAINEESHIPS.

(a) IN GENERAL.—The Secretary may make grants to accredited schools of public health, and to other public or nonprofit private institutions accredited for the provision of graduate or specialized training in public health, for the purpose of assisting such schools and institutions in providing traineeships to individuals described in subsection (b)(3).

(b) CERTAIN REQUIREMENTS.—

(1) AMOUNT.—The amount of any grant under this section shall be determined by the Secretary.

(2) USE OF GRANT.—Traineeships awarded under grants made under subsection (a) shall provide for tuition and fees and such stipends and allowances (including travel and subsistence expenses and dependency allowances) for the trainees as the Secretary may deem necessary.

(3) ELIGIBLE INDIVIDUALS.—The individuals referred to in subsection (a) are individuals who are pursuing a course of study in a health professions field in which there is a severe shortage of health professionals (which fields include the fields of epidemiology, environmental health, biostatistics, toxicology, nutrition, and maternal and child health).

SEC. 768.[295c] PREVENTIVE MEDICINE AND PUBLIC HEALTH TRAINING GRANT PROGRAM.

(a) GRANTS.—The Secretary, acting through the Administrator of the Health Resources and Services Administration and in consultation with the Director of the Centers for Disease Control and Prevention, shall award grants to, or enter into contracts with, eligible entities to provide training to graduate medical residents in preventive medicine specialties.

(b) ELIGIBILITY.—To be eligible for a grant or contract under subsection (a), an entity shall be—

(1) an accredited school of public health or school of medicine or osteopathic medicine;

(2) an accredited public or private nonprofit hospital;

(3) a State, local, or tribal health department; or

(4) a consortium of 2 or more entities described in paragraphs (1) through (3).

(c) USE OF FUNDS.—Amounts received under a grant or contract under this section shall be used to—

(1) plan, develop (including the development of curricula), operate, or participate in an accredited residency or internship program in preventive medicine or public health;

(2) defray the costs of practicum experiences, as required in such a program; and

(3) establish, maintain, or improve—

(A) academic administrative units (including departments, divisions, or other appropriate units) in preventive medicine and public health; or

(B) programs that improve clinical teaching in preventive medicine and public health.

(d) REPORT.—The Secretary shall submit to the Congress an annual report on the program carried out under this section.

SEC. 769.[295d] HEALTH ADMINISTRATION TRAINEESHIPS AND SPECIAL PROJECTS.

(a) IN GENERAL.—The Secretary may make grants to State or local governments (that have in effect preventive medical and dental public health residency programs) or public or nonprofit private educational entities (including graduate schools of social work and business schools that have health management programs) that offer a program described in subsection (b)—

(1) to provide traineeships for students enrolled in such a program; and

(2) to assist accredited programs health administration in the development or improvement of programs to prepare students for employment with public or nonprofit private entities.

(b) RELEVANT PROGRAMS.—The program referred to in subsection (a) is an accredited program in health administration, hospital administration, or health policy analysis and planning, which program is accredited by a body or bodies approved for such purpose by the Secretary of Education and which meets such other quality standards as the Secretary of Health and Human Services by regulation may prescribe.

(c) PREFERENCE IN MAKING GRANTS.—In making grants under subsection (a), the Secretary shall give preference to qualified applicants that meet the following conditions:

(1) Not less than 25 percent of the graduates of the applicant are engaged in full-time practice settings in medically underserved communities.

(2) The applicant recruits and admits students from medically underserved communities.

(3) For the purpose of training students, the applicant has established relationships with public and nonprofit providers of health care in the community involved.

(4) In training students, the applicant emphasizes employment with public or nonprofit private entities.

(d) CERTAIN PROVISIONS REGARDING TRAINEESHIPS.—

(1) USE OF GRANT.—Traineeships awarded under grants made under subsection (a) shall provide for tuition and fees and such stipends and allowances (including travel and subsistence expenses and dependency allowances) for the trainees as the Secretary may deem necessary.

(2) PREFERENCE FOR CERTAIN STUDENTS.—Each entity applying for a grant under subsection (a) for traineeships shall assure to the satisfaction of the Secretary that the entity will give priority to awarding the traineeships to students who demonstrate a commitment to employment with public or nonprofit private entities in the fields with respect to which the traineeships are awarded.

SEC. 770.[295e] AUTHORIZATION OF APPROPRIATIONS.

(a) IN GENERAL.—For the purpose of carrying out this subpart, there is authorized to be appropriated $43,000,000 for fiscal year 2011, and such sums as may be necessary for each of the fiscal years 2012 through 2015.

(b) LIMITATION REGARDING CERTAIN PROGRAM.—In obligating amounts appropriated under subsection (a), the Secretary may not obligate more than 30 percent for carrying out section 767.

Subpart 3—Recruitment and Retention Programs

SEC. 775.[295f] INVESTMENT IN TOMORROW'S PEDIATRIC HEALTH CARE WORKFORCE.

(a) ESTABLISHMENT.—The Secretary shall establish and carry out a pediatric specialty loan repayment program under which the

eligible individual agrees to be employed full-time for a specified period (which shall not be less than 2 years) in providing pediatric medical subspecialty, pediatric surgical specialty, or child and adolescent mental and behavioral health care, including substance abuse prevention and treatment services.

(b) PROGRAM ADMINISTRATION.—Through the program established under this section, the Secretary shall enter into contracts with qualified health professionals under which—

(1) such qualified health professionals will agree to provide pediatric medical subspecialty, pediatric surgical specialty, or child and adolescent mental and behavioral health care in an area with a shortage of the specified pediatric subspecialty that has a sufficient pediatric population to support such pediatric subspecialty, as determined by the Secretary; and

(2) the Secretary agrees to make payments on the principal and interest of undergraduate, graduate, or graduate medical education loans of professionals described in paragraph (1) of not more than $35,000 a year for each year of agreed upon service under such paragraph for a period of not more than 3 years during the qualified health professional's—

(A) participation in an accredited pediatric medical subspecialty, pediatric surgical specialty, or child and adolescent mental health subspecialty residency or fellowship; or

(B) employment as a pediatric medical subspecialist, pediatric surgical specialist, or child and adolescent mental health professional serving an area or population described in such paragraph.

(c) IN GENERAL.—

(1) ELIGIBLE INDIVIDUALS.—

(A) PEDIATRIC MEDICAL SPECIALISTS AND PEDIATRIC SURGICAL SPECIALISTS.—For purposes of contracts with respect to pediatric medical specialists and pediatric surgical specialists, the term "qualified health professional" means a licensed physician who—

(i) is entering or receiving training in an accredited pediatric medical subspecialty or pediatric surgical specialty residency or fellowship; or

(ii) has completed (but not prior to the end of the calendar year in which this section is enacted) the training described in subparagraph (B).

(B) CHILD AND ADOLESCENT MENTAL AND BEHAVIORAL HEALTH.—For purposes of contracts with respect to child and adolescent mental and behavioral health care, the term "qualified health professional" means a health care professional who—

(i) has received specialized training or clinical experience in child and adolescent mental health in psychiatry, psychology, school psychology, behavioral pediatrics, psychiatric nursing, social work, school social work, substance abuse disorder prevention and treatment, marriage and family therapy, school counseling, or professional counseling;

(ii) has a license or certification in a State to practice allopathic medicine, osteopathic medicine, psychology, school psychology, psychiatric nursing, social work, school social work, marriage and family therapy, school counseling, or professional counseling; or

(iii) is a mental health service professional who completed (but not before the end of the calendar year in which this section is enacted) specialized training or clinical experience in child and adolescent mental health described in clause (i).

(2) ADDITIONAL ELIGIBILITY REQUIREMENTS.—The Secretary may not enter into a contract under this subsection with an eligible individual unless—

(A) the individual agrees to work in, or for a provider serving, a health professional shortage area or medically underserved area, or to serve a medically underserved population;

(B) the individual is a United States citizen or a permanent legal United States resident; and

(C) if the individual is enrolled in a graduate program, the program is accredited, and the individual has an acceptable level of academic standing (as determined by the Secretary).

(d) PRIORITY.—In entering into contracts under this subsection, the Secretary shall give priority to applicants who—

(1) are or will be working in a school or other pre-kindergarten, elementary, or secondary education setting;

(2) have familiarity with evidence-based methods and cultural and linguistic competence health care services; and

(3) demonstrate financial need.

(e) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated $30,000,000 for each of fiscal years 2010 through 2014 to carry out subsection (c)(1)(A) and $20,000,000 for each of fiscal years 2010 through 2013 to carry out subsection (c)(1)(B).

SEC. 776.[295f–1] PUBLIC HEALTH WORKFORCE LOAN REPAYMENT PROGRAM.

(a) ESTABLISHMENT.—The Secretary shall establish the Public Health Workforce Loan Repayment Program (referred to in this section as the "Program") to assure an adequate supply of public health professionals to eliminate critical public health workforce shortages in Federal, State, local, and tribal public health agencies.

(b) ELIGIBILITY.—To be eligible to participate in the Program, an individual shall—

(1)(A) be accepted for enrollment, or be enrolled, as a student in an accredited academic educational institution in a State or territory in the final year of a course of study or program leading to a public health or health professions degree or certificate; and have accepted employment with a Federal, State, local, or tribal public health agency, or a related training fellowship, as recognized by the Secretary, to commence upon graduation; [14]

[14] So in law. There should probably be an "or" at the end of subparagraph (A).

(B)(i) have graduated, during the preceding 10-year period, from an accredited educational institution in a State or territory and received a public health or health professions degree or certificate; and

(ii) be employed by, or have accepted employment with, a Federal, State, local, or tribal public health agency or a related training fellowship, as recognized by the Secretary;

(2) be a United States citizen; and

(3)(A) submit an application to the Secretary to participate in the Program;

(B) execute a written contract as required in subsection (c); and

(4) not have received, for the same service, a reduction of loan obligations under section 455(m), 428J, 428K, 428L, or 460 of the Higher Education Act of 1965.

(c) CONTRACT.—The written contract (referred to in this section as the "written contract") between the Secretary and an individual shall contain—

(1) an agreement on the part of the Secretary that the Secretary will repay on behalf of the individual loans incurred by the individual in the pursuit of the relevant degree or certificate in accordance with the terms of the contract;

(2) an agreement on the part of the individual that the individual will serve in the full-time employment of a Federal, State, local, or tribal public health agency or a related fellowship program in a position related to the course of study or program for which the contract was awarded for a period of time (referred to in this section as the "period of obligated service") equal to the greater of—

(A) 3 years; or

(B) such longer period of time as determined appropriate by the Secretary and the individual;

(3) an agreement, as appropriate, on the part of the individual to relocate to a priority service area (as determined by the Secretary) in exchange for an additional loan repayment incentive amount to be determined by the Secretary;

(4) a provision that any financial obligation of the United States arising out of a contract entered into under this section and any obligation of the individual that is conditioned thereon, is contingent on funds being appropriated for loan repayments under this section;

(5) a statement of the damages to which the United States is entitled, under this section for the individual's breach of the contract; and

(6) such other statements of the rights and liabilities of the Secretary and of the individual, not inconsistent with this section.

(d) PAYMENTS.—

(1) IN GENERAL.—A loan repayment provided for an individual under a written contract under the Program shall consist of payment, in accordance with paragraph (2), on behalf of the individual of the principal, interest, and related expenses on government and commercial loans received by the individual regarding the undergraduate or graduate education of

the individual (or both), which loans were made for tuition expenses incurred by the individual.

(2) PAYMENTS FOR YEARS SERVED.—For each year of obligated service that an individual contracts to serve under subsection (c) the Secretary may pay up to $35,000 on behalf of the individual for loans described in paragraph (1). With respect to participants under the Program whose total eligible loans are less than $105,000, the Secretary shall pay an amount that does not exceed ⅓ of the eligible loan balance for each year of obligated service of the individual.

(3) TAX LIABILITY.—For the purpose of providing reimbursements for tax liability resulting from payments under paragraph (2) on behalf of an individual, the Secretary shall, in addition to such payments, make payments to the individual in an amount not to exceed 39 percent of the total amount of loan repayments made for the taxable year involved.

(e) POSTPONING OBLIGATED SERVICE.—With respect to an individual receiving a degree or certificate from a health professions or other related school, the date of the initiation of the period of obligated service may be postponed as approved by the Secretary.

(f) BREACH OF CONTRACT.—An individual who fails to comply with the contract entered into under subsection (c) shall be subject to the same financial penalties as provided for under section 338E for breaches of loan repayment contracts under section 338B.

(g) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $195,000,000 for fiscal year 2010, and such sums as may be necessary for each of fiscal years 2011 through 2015.

SEC. 777.[295f–2] TRAINING FOR MID-CAREER PUBLIC AND ALLIED HEALTH PROFESSIONALS.

(a) IN GENERAL.—The Secretary may make grants to, or enter into contracts with, any eligible entity to award scholarships to eligible individuals to enroll in degree or professional training programs for the purpose of enabling mid-career professionals in the public health and allied health workforce to receive additional training in the field of public health and allied health.

(b) ELIGIBILITY.—

(1) ELIGIBLE ENTITY.—The term "eligible entity" indicates an accredited educational institution that offers a course of study, certificate program, or professional training program in public or allied health or a related discipline, as determined by the Secretary

(2) ELIGIBLE INDIVIDUALS.—The term "eligible individuals" includes those individuals employed in public and allied health positions at the Federal, State, tribal, or local level who are interested in retaining or upgrading their education.

(c) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $60,000,000 for fiscal year 2010 and such sums as may be necessary for each of fiscal years 2011 through 2015. Fifty percent of appropriated funds shall be allotted to public health mid-career professionals and 50 percent shall be allotted to allied health mid-career professionals.

SEC. 778.[295f–3] FELLOWSHIP TRAINING IN APPLIED PUBLIC HEALTH EPIDEMIOLOGY, PUBLIC HEALTH LABORATORY SCIENCE, PUBLIC HEALTH INFORMATICS, AND EXPANSION OF THE EPIDEMIC INTELLIGENCE SERVICE.

(a) IN GENERAL.—The Secretary may carry out activities to address documented workforce shortages in State and local health departments in the critical areas of applied public health epidemiology and public health laboratory science and informatics and may expand the Epidemic Intelligence Service.

(b) SPECIFIC USES.—In carrying out subsection (a), the Secretary shall provide for the expansion of existing fellowship programs operated through the Centers for Disease Control and Prevention in a manner that is designed to alleviate shortages of the type described in subsection (a).

(c) OTHER PROGRAMS.—The Secretary may provide for the expansion of other applied epidemiology training programs that meet objectives similar to the objectives of the programs described in subsection (b).

(d) WORK OBLIGATION.—Participation in fellowship training programs under this section shall be deemed to be service for purposes of satisfying work obligations stipulated in contracts under section 338I(j).

(e) GENERAL SUPPORT.—Amounts may be used from grants awarded under this section to expand the Public Health Informatics Fellowship Program at the Centers for Disease Control and Prevention to better support all public health systems at all levels of government.

(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $39,500,000 for each of fiscal years 2010 through 2013, of which—

(1) $5,000,000 shall be made available in each such fiscal year for epidemiology fellowship training program activities under subsections (b) and (c);

(2) $5,000,000 shall be made available in each such fiscal year for laboratory fellowship training programs under subsection (b);

(3) $5,000,000 shall be made available in each such fiscal year for the Public Health Informatics Fellowship Program under subsection (e); and

(4) $24,500,000 shall be made available for expanding the Epidemic Intelligence Service under subsection (a).

PART F—GENERAL PROVISIONS

SEC. 791.[295j] PREFERENCES AND REQUIRED INFORMATION IN CERTAIN PROGRAMS.

(a) PREFERENCES IN MAKING AWARDS.—

(1) IN GENERAL.—Subject to paragraph (2), in making awards of grants or contracts under any of sections 747 and 750, the Secretary shall give preference to any qualified applicant that—

(A) has a high rate for placing graduates in practice settings having the principal focus of serving residents of medically underserved communities;

(B) during the 2-year period preceding the fiscal year for which such an award is sought, has achieved a significant increase in the rate of placing graduates in such settings; or

(C) utilizes a longitudinal evaluation (as described in section 761(d)(2)) and reports data from such system to the national workforce database (as established under section 761(b)(2)(E)).

(2) LIMITATION REGARDING PEER REVIEW.—For purposes of paragraph (1), the Secretary may not give an applicant preference if the proposal of the applicant is ranked at or below the 20th percentile of proposals that have been recommended for approval by peer review groups.

(b) DEFINITION.—For purposes of this section, the term "graduate" means, unless otherwise specified, an individual who has successfully completed all training and residency requirements necessary for full certification in the health profession selected by the individual.

(c) EXCEPTIONS FOR NEW PROGRAMS.—

(1) IN GENERAL.—To permit new programs to compete equitably for funding under this section, those new programs that meet at least 4 of the criteria described in paragraph (3) shall qualify for a funding preference under this section.

(2) DEFINITION.—As used in this subsection, the term "new program" means any program that has graduated less than three classes. Upon graduating at least three classes, a program shall have the capability to provide the information necessary to qualify the program for the general funding preferences described in subsection (a).

(3) CRITERIA.—The criteria referred to in paragraph (1) are the following:

(A) The mission statement of the program identifies a specific purpose of the program as being the preparation of health professionals to serve underserved populations.

(B) The curriculum of the program includes content which will help to prepare practitioners to serve underserved populations.

(C) Substantial clinical training experience is required under the program in medically underserved communities.

(D) A minimum of 20 percent of the clinical faculty of the program spend at least 50 percent of their time providing or supervising care in medically underserved communities.

(E) The entire program or a substantial portion of the program is physically located in a medically underserved community.

(F) Student assistance, which is linked to service in medically underserved communities following graduation, is available to the students in the program.

(G) The program provides a placement mechanism for deploying graduates to medically underserved communities.

SEC. 792.[295k] HEALTH PROFESSIONS DATA.

(a) IN GENERAL.—The Secretary shall establish a program, including a uniform health professions data reporting system, to collect, compile, and analyze data on health professions personnel which program shall initially include data respecting all physicians and dentists in the States. The Secretary is authorized to expand the program to include, whenever he determines it necessary, the collection, compilation, and analysis of data respecting pharmacists, optometrists, podiatrists, veterinarians, public health personnel, audiologists, speech pathologists, health care administration personnel, nurses, allied health personnel, medical technologists, chiropractors, clinical psychologists, professional counselors, and any other health personnel in States designated by the Secretary to be included in the program. Such data shall include data respecting the training, licensure status (including permanent, temporary, partial, limited, or institutional), place or places of practice, professional specialty, practice characteristics, place and date of birth, sex, and socioeconomic background of health professions personnel and such other demographic information regarding health professions personnel as the Secretary may require.

(b) CERTAIN AUTHORITIES AND REQUIREMENTS.—

(1) SOURCES OF INFORMATION.—In carrying out subsection (a), the Secretary shall collect available information from appropriate local, State, and Federal agencies and other appropriate sources.

(2) CONTRACTS FOR STUDIES OF HEALTH PROFESSIONS.—The Secretary shall conduct or enter into contracts for the conduct of analytic and descriptive studies of the health professions, including evaluations and projections of the supply of, and requirements for, the health professions by specialty and geographic location. Such studies shall include studies determining by specialty and geographic location the number of health professionals (including allied health professionals and health care administration personnel) who are members of minority groups, including Hispanics, and studies providing by specialty and geographic location evaluations and projections of the supply of, and requirements for, health professionals (including allied health professionals and health care administration personnel) to serve minority groups, including Hispanics.

(3) GRANTS AND CONTRACTS REGARDING STATES.—The Secretary is authorized to make grants and to enter into contracts with States (or an appropriate nonprofit private entity in any State) for the purpose of participating in the program established under subsection (a). The Secretary shall determine the amount and scope of any such grant or contract. To be eligible for a grant or contract under this paragraph a State or entity shall submit an application in such form and manner and containing such information as the Secretary shall require. Such application shall include reasonable assurance, satisfactory to the Secretary, that—

(A) such State (or nonprofit entity within a State) will establish a program of mandatory annual registration of the health professions personnel described in subsection (a) who reside or practice in such State and of health insti-

tutions licensed by such State, which registration shall include such information as the Secretary shall determine to be appropriate;

(B) such State or entity shall collect such information and report it to the Secretary in such form and manner as the Secretary shall prescribe; and

(C) such State or entity shall comply with the requirements of subsection (e).

(d)[15] REPORTS TO CONGRESS.—The Secretary shall submit to the Congress on October 1, 1993, and biennially thereafter, the following reports:

(1) A comprehensive report regarding the status of health personnel according to profession, including a report regarding the analytic and descriptive studies conducted under this section.

(2) A comprehensive report regarding applicants to, and students enrolled in, programs and institutions for the training of health personnel, including descriptions and analyses of student indebtedness, student need for financial assistance, financial resources to meet the needs of students, student career choices such as practice specialty and geographic location and the relationship, if any, between student indebtedness and career choices.

(e)[16] REQUIREMENTS REGARDING PERSONAL DATA.—

(1) IN GENERAL.—The Secretary and each program entity shall in securing and maintaining any record of individually identifiable personal data (hereinafter in this subsection referred to as "personal data") for purposes of this section—

(A) inform any individual who is asked to supply personal data whether he is legally required, or may refuse, to supply such data and inform him of any specific consequences, known to the Secretary or program entity, as the case may be, of providing or not providing such data;

(B) upon request, inform any individual if he is the subject of personal data secured or maintained by the Secretary or program entity, as the case may be, and make the data available to him in a form comprehensible to him;

(C) assure that no use is made of personal data which use is not within the purposes of this section unless an informed consent has been obtained from the individual who is the subject of such data; and

(D) upon request, inform any individual of the use being made of personal data respecting such individual and of the identity of the individuals and entities which will use the data and their relationship to the programs under this section.

(2) CONSENT AS PRECONDITION TO DISCLOSURE.—Any entity which maintains a record of personal data and which receives a request from the Secretary or a program entity for such data for purposes of this section shall not transfer any such data to the Secretary or to a program entity unless the individual

[15] So in law. Probably should be redesignated as (c).
[16] So in law. Probably should be redesignated as (d).

whose personal data is to be so transferred gives an informed consent for such transfer.

(3) DISCLOSURE BY SECRETARY.—

(A) Notwithstanding any other provision of law, personal data collected by the Secretary or any program entity under this section may not be made available or disclosed by the Secretary or any program entity to any person other than the individual who is the subject of such data unless (i) such person requires such data for purposes of this section, or (ii) in response to a demand for such data made by means of compulsory legal process. Any individual who is the subject of personal data made available or disclosed under clause (ii) shall be notified of the demand for such data.

(B) Subject to all applicable laws regarding confidentiality, only the data collected by the Secretary under this section which is not personal data shall be made available to bona fide researchers and policy analysts (including the Congress) for the purposes of assisting in the conduct of studies respecting health professions personnel.

(4) DEFINITION.—For purposes of this subsection, the term "program entity" means any public or private entity which collects, compiles, or analyzes health professions data under a grant, contract, or other arrangement with the Secretary under this section.

(g)[17] TECHNICAL ASSISTANCE.—The Secretary shall provide technical assistance to the States and political subdivisions thereof in the development of systems (including model laws) concerning confidentiality and comparability of data collected pursuant to this section.

(h)[18] GRANTS AND CONTRACTS REGARDING NONPROFIT ENTITIES.—

(1) IN GENERAL.—In carrying out subsection (a), the Secretary may make grants, or enter into contracts and cooperative agreements with, and provide technical assistance to, any nonprofit entity in order to establish a uniform allied health professions data reporting system to collect, compile, and analyze data on the allied health professions personnel.

(2) REPORTS.—With respect to reports required in subsection (d), each such report made on or after October 1, 1991, shall include a description and analysis of data collected pursuant to paragraph (1).

SEC. 794.[19] [295m] PROHIBITION AGAINST DISCRIMINATION ON BASIS OF SEX.

The Secretary may not make a grant, loan guarantee, or interest subsidy payment under this title to, or for the benefit of, any school of medicine, osteopathic medicine, dentistry, veterinary medicine, optometry, pharmacy, podiatric medicine, or public health or any training center for allied health personnel, or graduate program in clinical psychology, unless the application for the grant,

[17] So in law. Probably should be redesignated as (e).
[18] So in law. Probably should be redesignated as (f).
[19] Section 793 was repealed by section 106(a)(2)(C) of Public Law 105–392 (112 Stat. 3557).

loan guarantee, or interest subsidy payment contains assurances satisfactory to the Secretary that the school or training center will not discriminate on the basis of sex in the admission of individuals to its training programs. The Secretary may not enter into a contract under this title with any such school or training center unless the school, training center, or graduate program furnishes assurances satisfactory to the Secretary that it will not discriminate on the basis of sex in the admission of individuals to its training programs. In the case of a school of medicine which—

(1) on the date of the enactment of this sentence is in the process of changing its status as an institution which admits only female students to that of an institution which admits students without regard to their sex, and

(2) is carrying out such change in accordance with a plan approved by the Secretary,

the provisions of the preceding sentences of this section shall apply only with respect to a grant, contract, loan guarantee, or interest subsidy to, or for the benefit of such a school for a fiscal year beginning after June 30, 1979.

SEC. 796.[20][295n–1] APPLICATION.

(a) IN GENERAL.—To be eligible to receive a grant or contract under this title, an eligible entity shall prepare and submit to the Secretary an application that meets the requirements of this section, at such time, in such manner, and containing such information as the Secretary may require.

(b) PLAN.—An application submitted under this section shall contain the plan of the applicant for carrying out a project with amounts received under this title. Such plan shall be consistent with relevant Federal, State, or regional health professions program plans.

(c) PERFORMANCE OUTCOME STANDARDS.—An application submitted under this section shall contain a specification by the applicant entity of performance outcome standards that the project to be funded under the grant or contract will be measured against. Such standards shall address relevant health workforce needs that the project will meet. The recipient of a grant or contract under this section shall meet the standards set forth in the grant or contract application.

(d) LINKAGES.—An application submitted under this section shall contain a description of the linkages with relevant educational and health care entities, including training programs for other health professionals as appropriate, that the project to be funded under the grant or contract will establish. To the extent practicable, grantees under this section shall establish linkages with health care providers who provide care for underserved communities and populations.

SEC. 797.[295n–2] USE OF FUNDS.

(a) IN GENERAL.—Amounts provided under a grant or contract awarded under this title may be used for training program development and support, faculty development, model demonstrations, trainee support including tuition, books, program fees and reason-

[20] Section 795 was repealed by section 101(b)(1) of Public Law 105–392 (112 Stat. 3537).

able living expenses during the period of training, technical assistance, workforce analysis, dissemination of information, and exploring new policy directions, as appropriate to meet recognized health workforce objectives, in accordance with this title.

(b) MAINTENANCE OF EFFORT.—With respect to activities for which a grant awarded under this title is to be expended, the entity shall agree to maintain expenditures of non-Federal amounts for such activities at a level that is not less than the level of such expenditures maintained by the entity for the fiscal year preceding the fiscal year for which the entity receives such a grant.

SEC. 798.[295o] MATCHING REQUIREMENT.

The Secretary may require that an entity that applies for a grant or contract under this title provide non-Federal matching funds, as appropriate, to ensure the institutional commitment of the entity to the projects funded under the grant. As determined by the Secretary, such non-Federal matching funds may be provided directly or through donations from public or private entities and may be in cash or in-kind, fairly evaluated, including plant, equipment, or services.

SEC. 799.[295o–1] GENERALLY APPLICABLE PROVISIONS.

(a) AWARDING OF GRANTS AND CONTRACTS.—The Secretary shall ensure that grants and contracts under this title are awarded on a competitive basis, as appropriate, to carry out innovative demonstration projects or provide for strategic workforce supplementation activities as needed to meet health workforce goals and in accordance with this title. Contracts may be entered into under this title with public or private entities as may be necessary.

(b) ELIGIBLE ENTITIES.—Unless specifically required otherwise in this title, the Secretary shall accept applications for grants or contracts under this title from health professions schools, academic health centers, State or local governments, or other appropriate public or private nonprofit entities for funding and participation in health professions and nursing training activities. The Secretary may accept applications from for-profit private entities if determined appropriate by the Secretary.

(c) INFORMATION REQUIREMENTS.—

(1) IN GENERAL.—Recipients of grants and contracts under this title shall meet information requirements as specified by the Secretary.

(2) DATA COLLECTION.—The Secretary shall establish procedures to ensure that, with respect to any data collection required under this title, such data is collected in a manner that takes into account age, sex, race, and ethnicity.

(3) USE OF FUNDS.—The Secretary shall establish procedures to permit the use of amounts appropriated under this title to be used for data collection purposes.

(4) EVALUATIONS.—The Secretary shall establish procedures to ensure the annual evaluation of programs and projects operated by recipients of grants or contracts under this title. Such procedures shall ensure that continued funding for such programs and projects will be conditioned upon a demonstration that satisfactory progress has been made by the pro-

gram or project in meeting the objectives of the program or project.

(d) TRAINING PROGRAMS.—Training programs conducted with amounts received under this title shall meet applicable accreditation and quality standards.

(e) DURATION OF ASSISTANCE.—

(1) IN GENERAL.—Subject to paragraph (2), in the case of an award to an entity of a grant, cooperative agreement, or contract under this title, the period during which payments are made to the entity under the award may not exceed 5 years. The provision of payments under the award shall be subject to annual approval by the Secretary of the payments and subject to the availability of appropriations for the fiscal year involved to make the payments. This paragraph may not be construed as limiting the number of awards under the program involved that may be made to the entity.

(2) LIMITATION.—In the case of an award to an entity of a grant, cooperative agreement, or contract under this title, paragraph (1) shall apply only to the extent not inconsistent with any other provision of this title that relates to the period during which payments may be made under the award.

(f) PEER REVIEW REGARDING CERTAIN PROGRAMS.—

(1) IN GENERAL.—Each application for a grant under this title, except any scholarship or loan program, including those under sections[21] 701, 721, or 723, shall be submitted to a peer review group for an evaluation of the merits of the proposals made in the application. The Secretary may not approve such an application unless a peer review group has recommended the application for approval.

(2) COMPOSITION.—Each peer review group under this subsection shall be composed principally of individuals who are not officers or employees of the Federal Government. In providing for the establishment of peer review groups and procedures, the Secretary shall ensure sex, racial, ethnic, and geographic balance among the membership of such groups.

(3) ADMINISTRATION.—This subsection shall be carried out by the Secretary acting through the Administrator of the Health Resources and Services Administration.

(g) PREFERENCE OR PRIORITY CONSIDERATIONS.—In considering a preference or priority for funding which is based on outcome measures for an eligible entity under this title, the Secretary may also consider the future ability of the eligible entity to meet the outcome preference or priority through improvements in the eligible entity's program design.

(h) ANALYTIC ACTIVITIES.—The Secretary shall ensure that—

(1) cross-cutting workforce analytical activities are carried out as part of the workforce information and analysis activities under section 761; and

(2) discipline-specific workforce information and analytical activities are carried out as part of—

(A) the community-based linkage program under part D; and

[21] So in law. Probably should read "section".

(B) the health workforce development program under subpart 2 of part E.

(i) OSTEOPATHIC SCHOOLS.—For purposes of this title, any reference to—

(1) medical schools shall include osteopathic medical schools; and

(2) medical students shall include osteopathic medical students.

SEC. 799A.[295o–2] TECHNICAL ASSISTANCE.

Funds appropriated under this title may be used by the Secretary to provide technical assistance in relation to any of the authorities under this title.

SEC. 799B.[295p] DEFINITIONS.

For purposes of this title:

(1)(A) The terms "school of medicine", "school of dentistry", "school of osteopathic medicine", "school of pharmacy", "school of optometry", "school of podiatric medicine", "school of veterinary medicine", "school of public health", and "school of chiropractic" mean an accredited public or nonprofit private school in a State that provides training leading, respectively, to a degree of doctor of medicine, a degree of doctor of dentistry or an equivalent degree, a degree of doctor of osteopathy, a degree of bachelor of science in pharmacy or an equivalent degree or a degree of doctor of pharmacy or an equivalent degree, a degree of doctor of optometry or an equivalent degree, a degree of doctor of podiatric medicine or an equivalent degree, a degree of doctor of veterinary medicine or an equivalent degree, a graduate degree in public health or an equivalent degree, and a degree of doctor of chiropractic or an equivalent degree, and including advanced training related to such training provided by any such school.

(B) The terms "graduate program in health administration" and "graduate program in clinical psychology" mean an accredited graduate program in a public or nonprofit private institution in a State that provides training leading, respectively, to a graduate degree in health administration or an equivalent degree and a doctoral degree in clinical psychology or an equivalent degree.

(C) The terms "graduate program in clinical social work" and "graduate program in marriage and family therapy" and "graduate program in professional counseling" mean an accredited graduate program in a public or nonprofit private institution in a State that provides training, respectively, in a concentration in health or mental health care leading to a graduate degree in social work and a concentration leading to a graduate degree in marriage and family therapy and a concentration leading to a graduate degree in counseling.

(D)[22] The term "graduate program in behavioral health and mental health practice" means a graduate program in clin-

[22] Section 108(a)(2) of Public Law 105–392 (112 Stat. 3560) provides that paragraph (1)(D) is amended by inserting "behavioral health and mental health practice," before "clinical". The

Continued

ical psychology, clinical social work, professional counseling, or marriage and family therapy.

(E) The term "accredited", when applied to a school of medicine, osteopathic medicine, dentistry, veterinary medicine, optometry, podiatry, pharmacy, public health, or chiropractic, or a graduate program in health administration, clinical psychology, clinical social work, professional counseling, or marriage and family therapy, means a school or program that is accredited by a recognized body or bodies approved for such purpose by the Secretary of Education, except that a new school or program that, by reason of an insufficient period of operation, is not, at the time of application for a grant or contract under this title, eligible for accreditation by such a recognized body or bodies, shall be deemed accredited for purposes of this title, if the Secretary of Education finds, after consultation with the appropriate accreditation body or bodies, that there is reasonable assurance that the school or program will meet the accreditation standards of such body or bodies prior to the beginning of the academic year following the normal graduation date of the first entering class in such school or program.

(2) The term "teaching facilities" means areas dedicated for use by students, faculty, or administrative or maintenance personnel for clinical purposes, research activities, libraries, classrooms, offices, auditoriums, dining areas, student activities, or other related purposes necessary for, and appropriate to, the conduct of comprehensive programs of education. Such term includes interim facilities but does not include off-site improvements or living quarters.

(3) PHYSICIAN ASSISTANT EDUCATION PROGRAM.—The term "physician assistant education program" means an educational program in a public or private institution in a State that—

(A) has as its objective the education of individuals who, upon completion of their studies in the program, be qualified to provide primary care medical services with the supervision of a physician; and

(B) is accredited by the Accreditation Review Commission on Education for the Physician Assistant.

(4) The term "school of allied health" means a public or nonprofit private college, junior college, or university or hospital-based educational entity that—

(A) provides, or can provide, programs of education to enable individuals to become allied health professionals or to provide additional training for allied health professionals;

(B) provides training for not less than a total of twenty persons in the allied health curricula (except that this subparagraph shall not apply to any hospital-based educational entity);

(C) includes or is affiliated with a teaching hospital; and

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amendment cannot be executed because the amendment does not specify to which instance of the term "clinical" the amendment applies.

(D) is accredited by a recognized body or bodies approved for such purposes by the Secretary of Education, or which provides to the Secretary satisfactory assurance by such accrediting body or bodies that reasonable progress is being made toward accreditation.

(5) The term "allied health professionals" means a health professional (other than a registered nurse or physician assistant)—

(A) who has received a certificate, an associate's degree, a bachelor's degree, a master's degree, a doctoral degree, or postbaccalaureate training, in a science relating to health care;

(B) who shares in the responsibility for the delivery of health care services or related services, including—

(i) services relating to the identification, evaluation, and prevention of disease and disorders;

(ii) dietary and nutrition services;

(iii) health promotion services;

(iv) rehabilitation services; or

(v) health systems management services; and

(C) who has not received a degree of doctor of medicine, a degree of doctor of osteopathy, a degree of doctor of dentistry or an equivalent degree, a degree of doctor of veterinary medicine or an equivalent degree, a degree of doctor of optometry or an equivalent degree, a degree of doctor of podiatric medicine or an equivalent degree, a degree of bachelor of science in pharmacy or an equivalent degree, a degree of doctor of pharmacy or an equivalent degree, a graduate degree in public health or an equivalent degree, a degree of doctor of chiropractic or an equivalent degree, a graduate degree in health administration or an equivalent degree, a doctoral degree in clinical psychology or an equivalent degree, or a degree in social work or an equivalent degree or a degree in counseling or an equivalent degree.

(6) The term "medically underserved community" means an urban or rural area or population that—

(A) is eligible for designation under section 332 as a health professional shortage area;

(B)[23] is eligible to be served by a migrant health center under section 329, a community health center under section 330, a grantee under section 330(h) (relating to homeless individuals), or a grantee under section 340A (relating to residents of public housing);

(C) has a shortage of personal health services, as determined under criteria issued by the Secretary under section 1861(aa)(2) of the Social Security Act (relating to rural health clinics); or

(D) is designated by a State Governor (in consultation with the medical community) as a shortage area or medically underserved community.

[23] See footnote for section 224(g)(1)(G)(ii).

(7) The term "Department" means the Department of Health and Human Services.

(8) The term "nonprofit" refers to the status of an entity owned and operated by one or more corporations or associations no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual.

(9) The term "State" includes, in addition to the several States, only the District of Columbia, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, the Virgin Islands, Guam, American Samoa, and the Trust Territory of the Pacific Islands.

(10)(A) Subject to subparagraph (B), the term "underrepresented minorities" means, with respect to a health profession, racial and ethnic populations that are underrepresented in the health profession relative to the number of individuals who are members of the population involved.

(B) For purposes of subparagraph (A), Asian individuals shall be considered by the various subpopulations of such individuals.

(11) The term "psychologist" means an individual who—

(A) holds a doctoral degree in psychology; and

(B) is licensed or certified on the basis of the doctoral degree in psychology, by the State in which the individual practices, at the independent practice level of psychology to furnish diagnostic, assessment, preventive, and therapeutic services directly to individuals.

(12) AREA HEALTH EDUCATION CENTER.—The term "area health education center" means a public or nonprofit private organization that has a cooperative agreement or contract in effect with an entity that has received an award under subsection (a)(1) or (a)(2) of section 751, satisfies the requirements in section 751(d)(1), and has as one of its principal functions the operation of an area health education center. Appropriate organizations may include hospitals, health organizations with accredited primary care training programs, accredited physician assistant educational programs associated with a college or university, and universities or colleges not operating a school of medicine or osteopathic medicine.

(13) AREA HEALTH EDUCATION CENTER PROGRAM.—The term "area health education center program" means cooperative program consisting of an entity that has received an award under subsection (a)(1) or (a)(2) of section 751 for the purpose of planning, developing, operating, and evaluating an area health education center program and one or more area health education centers, which carries out the required activities described in section 751(c), satisfies the program requirements in such section, has as one of its principal functions identifying and implementing strategies and activities that address health care workforce needs in its service area, in coordination with the local workforce investment boards.

(14) CLINICAL SOCIAL WORKER.—The term "clinical social worker" has the meaning given the term in section 1861(hh)(1) of the Social Security Act (42 U.S.C. 1395x(hh)(1)).

(15) CULTURAL COMPETENCY.—The term "cultural competency" shall be defined by the Secretary in a manner consistent with section 1707(d)(3).

(16) DIRECT CARE WORKER.—The term "direct care worker" has the meaning given that term in the 2010 Standard Occupational Classifications of the Department of Labor for Home Health Aides [31–1011], Psychiatric Aides [31–1013], Nursing Assistants [31–1014], and Personal Care Aides [39–9021].

(17) FEDERALLY QUALIFIED HEALTH CENTER.—The term "Federally qualified health center" has the meaning given that term in section 1861(aa) of the Social Security Act (42 U.S.C. 1395x(aa)).

(18) FRONTIER HEALTH PROFESSIONAL SHORTAGE AREA.—The term "frontier health professional shortage area" means an area—

(A) with a population density less than 6 persons per square mile within the service area; and

(B) with respect to which the distance or time for the population to access care is excessive.

(19) GRADUATE PSYCHOLOGY.—The term "graduate psychology" means an accredited program in professional psychology.

(20) HEALTH DISPARITY POPULATION.—The term "health disparity population" has the meaning given such term in section 903(d)(1).

(21) HEALTH LITERACY.—The term "health literacy" means the degree to which an individual has the capacity to obtain, communicate, process, and understand health information and services in order to make appropriate health decisions.

(22) MENTAL HEALTH SERVICE PROFESSIONAL.—The term "mental health service professional" means an individual with a graduate or postgraduate degree from an accredited institution of higher education in psychiatry, psychology, school psychology, behavioral pediatrics, psychiatric nursing, social work, school social work, substance abuse disorder prevention and treatment, marriage and family counseling, school counseling, or professional counseling.

(23) ONE-STOP DELIVERY SYSTEM CENTER.—The term "one-stop delivery system" means a one-stop delivery system described in section 134(c) of the Workforce Investment Act of 1998 (29 U.S.C. 2864(c)).

(24) PARAPROFESSIONAL CHILD AND ADOLESCENT MENTAL HEALTH WORKER.—The term "paraprofessional child and adolescent mental health worker" means an individual who is not a mental or behavioral health service professional, but who works at the first stage of contact with children and families who are seeking mental or behavioral health services, including substance abuse prevention and treatment services.

(25) RACIAL AND ETHNIC MINORITY GROUP; RACIAL AND ETHNIC MINORITY POPULATION.—The terms "racial and ethnic minority group" and "racial and ethnic minority population" have the meaning given the term "racial and ethnic minority group" in section 1707.

(26) RURAL HEALTH CLINIC.—The term "rural health clinic" has the meaning given that term in section 1861(aa) of the Social Security Act (42 U.S.C. 1395x(aa)).

PUBLIC HEALTH SERVICE ACT

As Amended Through P.L. 112–240, Enacted January 2, 2013

TITLE VIII—NURSING WORKFORCE DEVELOPMENT

PART A—GENERAL PROVISIONS

SEC. 801.[296] DEFINITIONS.

As used in this title:

(1) ELIGIBLE ENTITIES.—The term "eligible entities" means schools of nursing, nursing centers, academic health centers, State or local governments, and other public or private nonprofit entities determined appropriate by the Secretary that submit to the Secretary an application in accordance with section 802.

(2) SCHOOL OF NURSING.—The term "school of nursing" means an accredited (as defined in paragraph 6) collegiate, associate degree, or diploma school of nursing in a State where graduates are—

(A) authorized to sit for the National Council Licensure EXamination-Registered Nurse (NCLEX–RN); or

(B) licensed registered nurses who will receive a graduate or equivalent degree or training to become an advanced education nurse as defined by section 811(b).

(3) COLLEGIATE SCHOOL OF NURSING.—The term "collegiate school of nursing" means a department, division, or other administrative unit in a college or university which provides primarily or exclusively a program of education in professional nursing and related subjects leading to the degree of bachelor of arts, bachelor of science, bachelor of nursing, or to an equivalent degree, or to a graduate degree in nursing, or to an equivalent degree, and including advanced training related to such program of education provided by such school, but only if such program, or such unit, college or university is accredited.

(4) ASSOCIATE DEGREE SCHOOL OF NURSING.—The term "associate degree school of nursing" means a department, division, or other administrative unit in a junior college, community college, college, or university which provides primarily or exclusively a two-year program of education in professional nursing and allied subjects leading to an associate degree in nursing or to an equivalent degree, but only if such program, or such unit, college, or university is accredited.

(5) DIPLOMA SCHOOL OF NURSING.—The term "diploma school of nursing" means a school affiliated with a hospital or university, or an independent school, which provides primarily

or exclusively a program of education in professional nursing and allied subjects leading to a diploma or to equivalent indicia that such program has been satisfactorily completed, but only if such program, or such affiliated school or such hospital or university or such independent school is accredited.

(6) ACCREDITED.—

(A) IN GENERAL.—Except as provided in subparagraph (B), the term "accredited" when applied to any program of nurse education means a program accredited by a recognized body or bodies, or by a State agency, approved for such purpose by the Secretary of Education and when applied to a hospital, school, college, or university (or a unit thereof) means a hospital, school, college, or university (or a unit thereof) which is accredited by a recognized body or bodies, or by a State agency, approved for such purpose by the Secretary of Education. For the purpose of this paragraph, the Secretary of Education shall publish a list of recognized accrediting bodies, and of State agencies, which the Secretary of Education determines to be reliable authority as to the quality of education offered.

(B) NEW PROGRAMS.—A new program of nursing that, by reason of an insufficient period of operation, is not, at the time of the submission of an application for a grant or contract under this title, eligible for accreditation by such a recognized body or bodies or State agency, shall be deemed accredited for purposes of this title if the Secretary of Education finds, after consultation with the appropriate accreditation body or bodies, that there is reasonable assurance that the program will meet the accreditation standards of such body or bodies prior to the beginning of the academic year following the normal graduation date of students of the first entering class in such a program.

(7) NONPROFIT.—The term "nonprofit" as applied to any school, agency, organization, or institution means one which is a corporation or association, or is owned and operated by one or more corporations or associations, no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual.

(8) STATE.—The term "State" means a State, the Commonwealth of Puerto Rico, the District of Columbia, the Commonwealth of the Northern Mariana Islands, Guam, American Samoa, the Virgin Islands, or the Trust Territory of the Pacific Islands.

(9) AMBULATORY SURGICAL CENTER.—The term "ambulatory surgical center" has the meaning applicable to such term under title XVIII of the Social Security Act.

(10) FEDERALLY QUALIFIED HEALTH CENTER.—The term "Federally qualified health center" has the meaning given such term under section 1861(aa)(4) of the Social Security Act.

(11) HEALTH CARE FACILITY.—The term "health care facility" means an Indian Health Service health center, a Native Hawaiian health center, a hospital, a Federally qualified health center, a rural health clinic, a nursing home, a home health agency, a hospice program, a public health clinic, a

State or local department of public health, a skilled nursing facility, an ambulatory surgical center, or any other facility designated by the Secretary.

(12) HOME HEALTH AGENCY.—The term "home health agency" has the meaning given such term in section 1861(o) of the Social Security Act.

(13) HOSPICE PROGRAM.—The term "hospice program" has the meaning given such term in section 1861(dd)(2) of the Social Security Act.

(14) RURAL HEALTH CLINIC.—The term "rural health clinic" has the meaning given such term in section 1861(aa)(2) of the Social Security Act.

(15) SKILLED NURSING FACILITY.—The term "skilled nursing facility" has the meaning given such term in section 1819(a) of the Social Security Act.

(16) ACCELERATED NURSING DEGREE PROGRAM.—The term "accelerated nursing degree program" means a program of education in professional nursing offered by an accredited school of nursing in which an individual holding a bachelors degree in another discipline receives a BSN or MSN degree in an accelerated time frame as determined by the accredited school of nursing.

(17) BRIDGE OR DEGREE COMPLETION PROGRAM.—The term "bridge or degree completion program" means a program of education in professional nursing offered by an accredited school of nursing, as defined in paragraph (2), that leads to a baccalaureate degree in nursing. Such programs may include, Registered Nurse (RN) to Bachelor's of Science of Nursing (BSN) programs, RN to MSN (Master of Science of Nursing) programs, or BSN to Doctoral programs.

SEC. 802.[296a] APPLICATION.

(a) IN GENERAL.—To be eligible to receive a grant or contract under this title, an eligible entity shall prepare and submit to the Secretary an application that meets the requirements of this section, at such time, in such manner, and containing such information as the Secretary may require.

(b) PLAN.—An application submitted under this section shall contain the plan of the applicant for carrying out a project with amounts received under this title. Such plan shall be consistent with relevant Federal, State, or regional program plans.

(c) PERFORMANCE OUTCOME STANDARDS.—An application submitted under this section shall contain a specification by the applicant entity of performance outcome standards that the project to be funded under the grant or contract will be measured against. Such standards shall address relevant national nursing needs that the project will meet. The recipient of a grant or contract under this section shall meet the standards set forth in the grant or contract application.

(d) LINKAGES.—An application submitted under this section shall contain a description of the linkages with relevant educational and health care entities, including training programs for other health professionals as appropriate, that the project to be funded under the grant or contract will establish.

SEC. 803.[296b] USE OF FUNDS.

(a) IN GENERAL.—Amounts provided under a grant or contract awarded under this title may be used for training program development and support, faculty development, model demonstrations, trainee support including tuition, books, program fees and reasonable living expenses during the period of training, technical assistance, workforce analysis, and dissemination of information, as appropriate to meet recognized nursing objectives, in accordance with this title.

(b) MAINTENANCE OF EFFORT.—With respect to activities for which a grant awarded under this title is to be expended, the entity shall agree to maintain expenditures of non-Federal amounts for such activities at a level that is not less than the level of such expenditures maintained by the entity for the fiscal year preceding the fiscal year for which the entity receives such a grant.

SEC. 804.[296c] MATCHING REQUIREMENT.

The Secretary may require that an entity that applies for a grant or contract under this title provide non-Federal matching funds, as appropriate, to ensure the institutional commitment of the entity to the projects funded under the grant. Such non-Federal matching funds may be provided directly or through donations from public or private entities and may be in cash or in-kind, fairly evaluated, including plant, equipment, or services.

SEC. 805.[296d] PREFERENCE.

In awarding grants or contracts under this title, the Secretary shall give preference to applicants with projects that will substantially benefit rural or underserved populations, or help meet public health nursing needs in State or local health departments.

SEC. 806.[296e] GENERALLY APPLICABLE PROVISIONS.

(a) AWARDING OF GRANTS AND CONTRACTS.—The Secretary shall ensure that grants and contracts under this title are awarded on a competitive basis, as appropriate, to carry out innovative demonstration projects or provide for strategic workforce supplementation activities as needed to meet national nursing service goals and in accordance with this title. Contracts may be entered into under this title with public or private entities as determined necessary by the Secretary.

(b) INFORMATION REQUIREMENTS.—

(1) IN GENERAL.—Recipients of grants and contracts under this title shall meet information requirements as specified by the Secretary.

(2) EVALUATIONS.—The Secretary shall establish procedures to ensure the annual evaluation of programs and projects operated by recipients of grants under this title. Such procedures shall ensure that continued funding for such programs and projects will be conditioned upon a demonstration that satisfactory progress has been made by the program or project in meeting the objectives of the program or project.

(c) TRAINING PROGRAMS.—Training programs conducted with amounts received under this title shall meet applicable accreditation and quality standards.

(d) DURATION OF ASSISTANCE.—

(1) IN GENERAL.—Subject to paragraph (2), in the case of an award to an entity of a grant, cooperative agreement, or contract under this title, the period during which payments are made to the entity under the award may not exceed 5 years. The provision of payments under the award shall be subject to annual approval by the Secretary of the payments and subject to the availability of appropriations for the fiscal year involved to make the payments. This paragraph may not be construed as limiting the number of awards under the program involved that may be made to the entity.

(2) LIMITATION.—In the case of an award to an entity of a grant, cooperative agreement, or contract under this title, paragraph (1) shall apply only to the extent not inconsistent with any other provision of this title that relates to the period during which payments may be made under the award.

(e) PEER REVIEW REGARDING CERTAIN PROGRAMS.—

(1) IN GENERAL.—Each application for a grant under this title, except advanced nurse traineeship grants under section 811(a)(2), shall be submitted to a peer review group for an evaluation of the merits of the proposals made in the application. The Secretary may not approve such an application unless a peer review group has recommended the application for approval.

(2) COMPOSITION.—Each peer review group under this subsection shall be composed principally of individuals who are not officers or employees of the Federal Government. In providing for the establishment of peer review groups and procedures, the Secretary shall, except as otherwise provided, ensure sex, racial, ethnic, and geographic representation among the membership of such groups.

(3) ADMINISTRATION.—This subsection shall be carried out by the Secretary acting through the Administrator of the Health Resources and Services Administration.

(f) ANALYTIC ACTIVITIES.—The Secretary shall ensure that—

(1) cross-cutting workforce analytical activities are carried out as part of the workforce information and analysis activities under this title; and

(2) discipline-specific workforce information is developed and analytical activities are carried out as part of—

(A) the advanced education nursing activities under part B;

(B) the workforce diversity activities under part C; and

(C) basic nursing education and practice activities under part D.

(g) STATE AND REGIONAL PRIORITIES.—Activities under grants or contracts under this title shall, to the extent practicable, be consistent with related Federal, State, or regional nursing professions program plans and priorities.

(h) FILING OF APPLICATIONS.—

(1) IN GENERAL.—Applications for grants or contracts under this title may be submitted by health professions schools, schools of nursing, academic health centers, State or local governments, or other appropriate public or private non-

profit entities as determined appropriate by the Secretary in accordance with this title.

(2) FOR-PROFIT ENTITIES.—Notwithstanding paragraph (1), a for-profit entity may be eligible for a grant or contract under this title as determined appropriate by the Secretary.

SEC. 807.[296e–1] GRANTS FOR HEALTH PROFESSIONS EDUCATION.

(a) CULTURAL COMPETENCY, PREVENTION, AND PUBLIC HEALTH AND INDIVIDUALS WITH DISABILITY GRANTS.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, may make awards of grants, contracts, or cooperative agreements to eligible entities for the development, evaluation, and dissemination of research, demonstration projects, and model curricula for cultural competency, prevention, public health proficiency, reducing health disparities, and aptitude for working with individuals with disabilities training for use in health professions schools and continuing education programs, and for other purposes determined as appropriate by the Secretary. Grants under this section shall be the same as provided in section 741.

(b) COLLABORATION.—In carrying out subsection (a), the Secretary shall collaborate with the entities described in section 741(b). The Secretary shall coordinate with curricula and research and demonstration projects developed under such section 741.

(c) DISSEMINATION.—Model curricula developed under this section shall be disseminated and evaluated in the same manner as model curricula developed under section 741, as described in subsection (c) of such section.

(d) AUTHORIZATION OF APPROPRIATIONS.—There are to be appropriated to carry out this section such sums as may be necessary for each of the fiscal years 2010 through 2015.

SEC. 808.[296f] TECHNICAL ASSISTANCE.

Funds appropriated under this title may be used by the Secretary to provide technical assistance in relation to any of the authorities under this title.

PROHIBITION AGAINST DISCRIMINATION BY SCHOOLS ON THE BASIS OF SEX.

SEC. 809.[296g] The Secretary may not make a grant, loan guarantee, or interest subsidy payment under this title to, or for the benefit of, any school of nursing unless the application for the grant, loan guarantee, or interest subsidy payment contains assurances satisfactory to the Secretary that the school will not discriminate on the basis of sex in the admission of individuals to its training programs. The Secretary may not enter into a contract under this title with any school unless the school furnishes assurances satisfactory to the Secretary that it will not discriminate on the basis of sex in the admission of individuals to its training programs.

PART B—NURSE PRACTITIONERS, NURSE MIDWIVES, NURSE ANESTHETISTS, AND OTHER ADVANCED EDUCATION NURSES

SEC. 811.[296j] ADVANCED EDUCATION NURSING GRANTS.

(a) IN GENERAL.—The Secretary may award grants to and enter into contracts with eligible entities to meet the costs of—

(1) projects that support the enhancement of advanced nursing education and practice; and

(2) traineeships for individuals in advanced nursing education programs.

(b) DEFINITION OF ADVANCED EDUCATION NURSES.—For purposes of this section, the term "advanced education nurses" means individuals trained in advanced degree programs including individuals in combined R.N./Master's degree programs, post-nursing master's certificate programs, or, in the case of nurse midwives, in certificate programs in existence on the date that is one day prior to the date of enactment of this section, to serve as nurse practitioners, clinical nurse specialists, nurse midwives, nurse anesthetists, nurse educators, nurse administrators, or public health nurses, or in other nurse specialties determined by the Secretary to require advanced education.

(c) AUTHORIZED NURSE PRACTITIONER.—Nurse practitioner programs eligible for support under this section are educational programs for registered nurses (irrespective of the type of school of nursing in which the nurses received their training) that—

(1) meet guidelines prescribed by the Secretary; and

(2) have as their objective the education of nurses who will upon completion of their studies in such programs, be qualified to effectively provide primary health care, including primary health care in homes and in ambulatory care facilities, long-term care facilities, acute care, and other health care settings.

(d) AUTHORIZED NURSE-MIDWIFERY PROGRAMS.—Midwifery programs that are eligible for support under this section are educational programs that—

(1) have as their objective the education of midwives; and

(2) are accredited by the American College of Nurse-Midwives Accreditation Commission for Midwifery Education.

(e) AUTHORIZED NURSE ANESTHESIA PROGRAMS.—Nurse anesthesia programs eligible for support under this section are education programs that—

(1) provide registered nurses with full-time anesthetist education; and

(2) are accredited by the Council on Accreditation of Nurse Anesthesia Educational Programs.

(f) OTHER AUTHORIZED EDUCATIONAL PROGRAMS.—The Secretary shall prescribe guidelines as appropriate for other advanced nurse education programs eligible for support under this section.

(g) TRAINEESHIPS.—

(1) IN GENERAL.—The Secretary may not award a grant to an applicant under subsection (a) unless the applicant involved agrees that traineeships provided with the grant will only pay all or part of the costs of—

(A) the tuition, books, and fees of the program of advanced nurse education with respect to which the traineeship is provided; and

(B) the reasonable living expenses of the individual during the period for which the traineeship is provided.

(2) SPECIAL CONSIDERATION.—In making awards of grants and contracts under subsection (a)(2), the Secretary shall give special consideration to an eligible entity that agrees to expend the award to train advanced education nurses who will practice in health professional shortage areas designated under section 332.

PART C—INCREASING NURSING WORKFORCE DIVERSITY

SEC. 821.[296m] WORKFORCE DIVERSITY GRANTS.

(a)[1] IN GENERAL.—

(1) AUTHORITY.—The Secretary may award grants to and enter into contracts with eligible entities to meet the costs of special projects to increase nursing education opportunities for individuals who are from disadvantaged backgrounds (including racial and ethnic minorities underrepresented among registered nurses) by providing student scholarships or stipends, stipends for diploma or associate degree nurses to enter a bridge or degree completion program, student scholarships or stipends for accelerated nursing degree programs, pre-entry preparation, advanced education preparation, and retention activities.

(b) GUIDANCE.—In carrying out subsection (a), the Secretary shall take into consideration the recommendations of the National Advisory Council on Nurse Education and Practice and consult with nursing associations including the National Coalition of Ethnic Minority Nurse Associations, American Nurses Association, the National League for Nursing, the American Association of Colleges of Nursing, the National Black Nurses Association, the National Association of Hispanic Nurses, the Association of Asian American and Pacific Islander Nurses, the Native American Indian and Alaskan Nurses Association, and the National Council of State Boards of Nursing, and other organizations determined appropriate by the Secretary.

(c) REQUIRED INFORMATION AND CONDITIONS FOR AWARD RECIPIENTS.—

(1) IN GENERAL.—Recipients of awards under this section may be required, where requested, to report to the Secretary concerning the annual admission, retention, and graduation rates for individuals from disadvantaged backgrounds and ethnic and racial minorities in the school or schools involved in the projects.

(2) FALLING RATES.—If any of the rates reported under paragraph (1) fall below the average of the two previous years,

[1] So in law. There is no paragraph (2) in subsection (a).

the grant or contract recipient shall provide the Secretary with plans for immediately improving such rates.

(3) INELIGIBILITY.—A recipient described in paragraph (2) shall be ineligible for continued funding under this section if the plan of the recipient fails to improve the rates within the 1-year period beginning on the date such plan is implemented.

PART D—STRENGTHENING CAPACITY FOR BASIC NURSE EDUCATION AND PRACTICE

SEC. 831.[296p] NURSE EDUCATION, PRACTICE, AND QUALITY GRANTS.

(a) EDUCATION PRIORITY AREAS.—The Secretary may award grants to or enter into contracts with eligible entities for—

(1) expanding the enrollment in baccalaureate nursing programs; or

(2) providing education in new technologies, including distance learning methodologies.

(b) PRACTICE PRIORITY AREAS.—The Secretary may award grants to or enter into contracts with eligible entities for—

(1) establishing or expanding nursing practice arrangements in noninstitutional settings to demonstrate methods to improve access to primary health care in medically underserved communities;

(2) providing care for underserved populations and other high-risk groups such as the elderly, individuals with HIV/AIDS, substance abusers, the homeless, and victims of domestic violence;

(3) providing coordinated care, and other skills needed to practice in existing and emerging organized health care systems; or

(4) developing cultural competencies among nurses.

(c) RETENTION PRIORITY AREAS.—The Secretary may award grants to and enter into contracts with eligible entities to enhance the nursing workforce by initiating and maintaining nurse retention programs pursuant to paragraph (1) or (2).

(1) GRANTS FOR CAREER LADDER PROGRAMS.—The Secretary may award grants to and enter into contracts with eligible entities for programs—

(A) to promote career advancement for nursing personnel in a variety of training settings, cross training or specialty training among diverse population groups, and the advancement of individuals including to become professional nurses, advanced education nurses, licensed practical nurses, certified nurse assistants, and home health aides; and

(B) to assist individuals in obtaining education and training required to enter the nursing profession and advance within such profession, such as by providing career counseling and mentoring.

(2) ENHANCING PATIENT CARE DELIVERY SYSTEMS.—

(A) GRANTS.—The Secretary may award grants to eligible entities to improve the retention of nurses and enhance patient care that is directly related to nursing ac-

tivities by enhancing collaboration and communication among nurses and other health care professionals, and by promoting nurse involvement in the organizational and clinical decisionmaking processes of a health care facility.

(B) PREFERENCE.—In making awards of grants under this paragraph, the Secretary shall give a preference to applicants that have not previously received an award under this paragraph.

(C) CONTINUATION OF AN AWARD.—The Secretary shall make continuation of any award under this paragraph beyond the second year of such award contingent on the recipient of such award having demonstrated to the Secretary measurable and substantive improvement in nurse retention or patient care.

(d) OTHER PRIORITY AREAS.—The Secretary may award grants to or enter into contracts with eligible entities to address other areas that are of high priority to nurse education, practice, and retention, as determined by the Secretary.

(e) PREFERENCE.—For purposes of any amount of funds appropriated to carry out this section for fiscal year 2003, 2004, or 2005 that is in excess of the amount of funds appropriated to carry out this section for fiscal year 2002, the Secretary shall give preference to awarding grants or entering into contracts under subsections (a)(2) and (c).

(f) REPORT.—The Secretary shall submit to the Congress before the end of each fiscal year a report on the grants awarded and the contracts entered into under this section. Each such report shall identify the overall number of such grants and contracts and provide an explanation of why each such grant or contract will meet the priority need of the nursing workforce.

(g) ELIGIBLE ENTITY.—For purposes of this section, the term "eligible entity" includes a school of nursing, as defined in section 801(2),,[2] a health care facility, or a partnership of such a school and facility.

(h) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section such sums as may be necessary for each of fiscal years 2010 through 2014.

SEC. 831A.[296p–1] NURSE RETENTION GRANTS.

(a) RETENTION PRIORITY AREAS.—The Secretary may award grants to, and enter into contracts with, eligible entities to enhance the nursing workforce by initiating and maintaining nurse retention programs pursuant to subsection (b) or (c).

(b) GRANTS FOR CAREER LADDER PROGRAM.—The Secretary may award grants to, and enter into contracts with, eligible entities for programs—

(1) to promote career advancement for individuals including licensed practical nurses, licensed vocational nurses, certified nurse assistants, home health aides, diploma degree or associate degree nurses, to become baccalaureate prepared registered nurses or advanced education nurses in order to meet the needs of the registered nurse workforce;

[2] So in law.

(2) developing and implementing internships and residency programs in collaboration with an accredited school of nursing, as defined by section 801(2), to encourage mentoring and the development of specialties; or

(3) to assist individuals in obtaining education and training required to enter the nursing profession and advance within such profession.

(c) ENHANCING PATIENT CARE DELIVERY SYSTEMS.—

(1) GRANTS.—The Secretary may award grants to eligible entities to improve the retention of nurses and enhance patient care that is directly related to nursing activities by enhancing collaboration and communication among nurses and other health care professionals, and by promoting nurse involvement in the organizational and clinical decision-making processes of a health care facility.

(2) PRIORITY.—In making awards of grants under this subsection, the Secretary shall give preference to applicants that have not previously received an award under this subsection (or section 831(c) as such section existed on the day before the date of enactment of this section).

(3) CONTINUATION OF AN AWARD.—The Secretary shall make continuation of any award under this subsection beyond the second year of such award contingent on the recipient of such award having demonstrated to the Secretary measurable and substantive improvement in nurse retention or patient care.

(d) OTHER PRIORITY AREAS.—The Secretary may award grants to, or enter into contracts with, eligible entities to address other areas that are of high priority to nurse retention, as determined by the Secretary.

(e) REPORT.—The Secretary shall submit to the Congress before the end of each fiscal year a report on the grants awarded and the contracts entered into under this section. Each such report shall identify the overall number of such grants and contracts and provide an explanation of why each such grant or contract will meet the priority need of the nursing workforce.

(f) ELIGIBLE ENTITY.—For purposes of this section, the term "eligible entity" includes an accredited school of nursing, as defined by section 801(2), a health care facility, or a partnership of such a school and facility.

(g) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section such sums as may be necessary for each of fiscal years 2010 through 2012.

PART E—STUDENT LOANS [3]

LOAN AGREEMENTS.

SEC. 835.[297a] (a) The Secretary is authorized to enter into an agreement for the establishment and operation of a student loan

[3] Section 936(e) of Public Law 94–63 repealed a section of this title that provided for a revolving fund. This former section was section 827. With respect to the revolving fund, such section 936(e) provided as follows: "The nurse training fund created within the Treasury by section

Continued

fund in accordance with this part with any public or nonprofit private school of nursing which is located in a State.

(b) Each agreement entered into under this section shall—

(1) provide for establishment of a student loan fund by the school;

(2) provide for deposit in the fund, except as provided in section 871, of (A) the Federal capital contributions paid from allotments under section 838 to the school by the Secretary, (B) an additional amount from other sources equal to not less than one-ninth of such Federal capital contributions, (C) collections of principal and interest on loans made from the fund, (D) collections pursuant to section 836(f), and (E) any other earnings of the fund;

(3) provide that the fund, except as provided in section 871, shall be used only for loans to students of the school in accordance with the agreement and for costs of collection of such loans and interest thereon;

(4) provide that loans may be made from such fund only to students pursuing a full-time or half-time course of study at the school leading to a baccalaureate or associate degree in nursing or an equivalent degree or a diploma in nursing, or to a graduate degree in nursing; and

(5) contain such other provisions as are necessary to protect the financial interests of the United States.

(c)(1) Any standard established by the Secretary by regulation for the collection by schools of nursing of loans made pursuant to loan agreements under this part shall provide that the failure of any such school to collect such loans shall be measured in accordance with this subsection. With respect to the student loan fund established pursuant to such agreements, this subsection may not be construed to require such schools to reimburse such loan fund for loans that became uncollectable prior to 1983.

(2) The measurement of a school's failure to collect loans made under this part shall be the ratio (stated as a percentage) that the defaulted principal amount outstanding of such school bears to the matured loans of such school.

(3) For purposes of this subsection—

(A) the term "default" means the failure of a borrower of a loan made under this part to—

(i) make an installment payment when due; or

(ii) comply with any other term of the promissory note for such loan,

except that a loan made under this part shall not be considered to be in default if the loan is discharged in bankruptcy or if the school reasonably concludes from written contacts with the borrower that the borrower intends to repay the loan;

827(d)(1) of the Act shall remain available to the Secretary of Health, Education, and Welfare for the purpose of meeting his responsibilities respecting participations in obligations acquired under section 827 of the Act. The Secretary shall continue to deposit in such fund all amounts received by him as interest payments or repayments of principal on loans under such section 827. If at any time the Secretary determines the moneys in the funds exceed the present and any reasonable prospective further requirements of such fund, such excess may be transferred to the general fund of the Treasury.". Such section further provided that "[t]here are authorized to be appropriated without fiscal year limitation such sums as may be necessary to enable the Secretary to make payments under agreements entered into under section 827(b) of the Act before ".

(B) the term "defaulted principal amount outstanding" means the total amount borrowed from the loan fund of a school that has reached the repayment stage (minus any principal amount repaid or cancelled) on loans—

(i) repayable monthly and in default for at least 120 days; and

(ii) repayable less frequently than monthly and in default for at least 180 days;

(C) the term "grace period" means the period of nine months beginning on the date on which the borrower ceases to pursue a full-time or half-time course of study at a school of nursing; and

(D) the term "matured loans" means the total principal amount of all loans made by a school of nursing under this part minus the total principal amount of loans made by such school to students who are—

(i) enrolled in a full-time or half-time course of study at such school; or

(ii) in their grace period.

LOAN PROVISIONS.

SEC. 836.[297b] (a) The total of the loans for any academic year (or its equivalent, as determined under regulations of the Secretary) made by schools of nursing from loan funds established pursuant to agreements under this part may not exceed $3,300 in the case of any student, except that for the final two academic years of the program involved, such total may not exceed $5,200. The aggregate of the loans for all years from such funds may not exceed $17,000 in the case of any student during fiscal years 2010 and 2011. After fiscal year 2011, such amounts shall be adjusted to provide for a cost-of-attendance increase for the yearly loan rate and the aggregate of the loans.

(b) Loans from any such student loan fund by any school shall be made on such terms and conditions as the school may determine; subject, however, to such conditions, limitations, and requirements as the Secretary may prescribe (by regulation or in the agreement with the school) with a view to preventing impairment of the capital of such fund to the maximum extent practicable in the light of the objective of enabling the student to complete his course of study; and except that—

(1) such a loan may be made only to a student who (A) is in need of the amount of the loan to pursue a full-time or half-time course of study at the school leading to a baccalaureate or associate degree in nursing or an equivalent degree, or a diploma in nursing, or a graduate degree in nursing, (B) is capable, in the opinion of the school, of maintaining good standing in such course of study, and (C) with respect to any student enrolling in the school after June 30, 2000, is of financial need (as defined in regulations issued by the Secretary);

(2) such a loan shall be repayable in equal or graduated periodic installments (with the right of the borrower to accelerate repayment) over the ten-year period which begins nine months after the student ceases to pursue a full-time or half-

time course of study at a school of nursing, excluding from such 10-year period all (A) periods (up to three years) of (i) active duty performed by the borrower as a member of a uniformed service, or (ii) service as a volunteer under the Peace Corps Act, (B) periods (up to ten years) during which the borrower is pursuing a full-time or half-time course of study at a collegiate school of nursing leading to baccalaureate degree in nursing or an equivalent degree, or to graduate degree in nursing, or is otherwise pursuing advanced professional training in nursing (or training to be a nurse anesthetist), and (C) such additional periods under the terms of paragraph (8) of this subsection;

(3) in the case of a student who received such a loan before September 29, 1995, an amount up to 85 per centum of any such loan made before such date (plus interest thereon) shall be canceled for full-time employment as a professional nurse (including teaching in any of the fields of nurse training and service as an administrator, supervisor, or consultant in any of the fields of nursing) in any public or nonprofit private agency, institution, or organization (including neighborhood health centers), at the rate of 15 per centum of the amount of such loan (plus interest) unpaid on the first day of such service for each of the first, second, and third complete year of such service, and 20 per centum of such amount (plus interest) for each complete fourth and fifth year of such service;

(4) the liability to repay the unpaid balance of such loan and accrued interest thereon shall be canceled upon the death of the borrower, or if the Secretary determines that he has become permanently and totally disabled;

(5) such a loan shall bear interest on the unpaid balance of the loan, computed only for periods during which the loan is repayable, at the rate of 5 percent per annum;

(6) such a loan shall be made without security or endorsement, except that if the borrower is a minor and the note or other evidence of obligation executed by him would not, under the applicable law, create a binding obligation, either security or endorsement may be required;

(7) no note or other evidence of any such loan may be transferred or assigned by the school making the loan except that, if the borrower transfers to another school participating in the program under this part, such note or other evidence of a loan may be transferred to such other school; and

(8) pursuant to uniform criteria established by the Secretary, the repayment period established under paragraph (2) for any student borrower who during the repayment period failed to make consecutive payments and who, during the last 12 months of the repayment period, has made at least 12 consecutive payments may be extended for a period not to exceed 10 years.

(c) Where all or any part of a loan, or interest, is canceled under this section, the Secretary shall pay to the school an amount equal to the school's proportionate share of the canceled portion, as determined by the Secretary.

(d) Any loan for any year by a school from a student loan fund established pursuant to an agreement under this part shall be made in such installments as may be provided in regulations of the Secretary or such agreement and, upon notice to the Secretary by the school that any recipient of a loan is failing to maintain satisfactory standing, any or all further installments of his loans shall be withheld, as may be appropriate.

(e) An agreement under this part with any school shall include provisions designed to make loans from the student loan fund established thereunder reasonably available (to the extent of the available funds in such fund) to all eligible students in the school in need thereof.

(f) Subject to regulations of the Secretary and in accordance with this section, a school shall assess a charge with respect to a loan from the loan fund established pursuant to an agreement under this part for failure of the borrower to pay all or any part of an installment when it is due and, in the case of a borrower who is entitled to deferment of the loan under subsection (b)(2) or cancellation of part or all of the loan under subsection (b)(3), for any failure to file timely and satisfactory evidence of such entitlement. No such charge may be made if the payment of such installment or the filing of such evidence is made within 60 days after the date on which such installment or filing is due. The amount of any such charge may not exceed an amount equal to 6 percent of the amount of such installment. The school may elect to add the amount of any such charge to the principal amount of the loan as of the first day after the day on which such installment or evidence was due, or to make the amount of the charge payable to the school not later than the due date of the next installment after receipt by the borrower of notice of the assessment of the charge.

(g) A school may provide in accordance with regulations of the Secretary, that during the repayment period of a loan from a loan fund established pursuant to an agreement under this part payments of principal and interest by the borrower with respect to all the outstanding loans made to him from loan funds so established shall be at a rate equal to not less than $40 per month.

(h) Notwithstanding the amendment made by section 6(b) of the Nurse Training Act of 1971 to this section—

(A) any person who obtained one or more loans from a loan fund established under this part, who before the date of the enactment of the Nurse Training Act of 1971 became eligible for cancellation of all or part of such loans (including accrued interest) under this section (as in effect on the day before such date), and who on such date was not engaged in a service for which loan cancellation was authorized under this section (as so in effect), may at any time elect to receive such cancellation in accordance with this subsection (as so in effect); and

(B) in the case of any person who obtained one or more loans from a loan fund established under this part and who on such date was engaged in a service for which cancellation of all or part of such loans (including accrued interest) was authorized under this section (as so in effect), this section (as so in effect) shall continue to apply to such person for purposes

of providing such loan cancellation until he terminates such service.

(i) Upon application by a person who received and is under an obligation to repay, any loan made to such person as a nursing student, the Secretary may undertake to repay (without liability to the applicant) all or any part of such loan, and any interest or portion thereof outstanding thereon, upon his determination, pursuant to regulations establishing criteria therefor, that the applicant—

(1) failed to complete the nursing studies with respect to which such loan was made;

(2) is in exceptionally needy circumstances; and

(3) has not resumed, or cannot reasonably be expected to resume, such nursing studies within two years following the date upon which the applicant terminated the studies with respect to which such loan was made.

(j) The Secretary is authorized to attempt to collect any loan which was made under this part, which is in default, and which was referred to the Secretary by a school of nursing with which the Secretary has an agreement under this part, on behalf of that school under such terms and conditions as the Secretary may prescribe (including reimbursement from the school's student loan fund for expenses the Secretary may reasonably incur in attempting collection), but only if the school has complied with such requirements as the Secretary may specify by regulation with respect to the collection of loans under this part. A loan so referred shall be treated as a debt subject to section 5514 of title 5, United States Code. Amounts collected shall be deposited in the school's student loan fund. Whenever the Secretary desires the institution of a civil action regarding any such loan, the Secretary shall refer the matter to the Attorney General for appropriate action.

(k)[4] ELIMINATION OF STATUTE OF LIMITATION FOR LOAN COLLECTIONS.—

(1) PURPOSE.—It is the purpose of this subsection to ensure that obligations to repay loans under this section are enforced without regard to any Federal or State statutory, regulatory, or administrative limitation on the period within which debts may be enforced.

(2) PROHIBITION.—Notwithstanding any other provision of Federal or State law, no limitation shall terminate the period within which suit may be filed, a judgment may be enforced, or an offset, garnishment, or other action may be initiated or taken by a school of nursing that has an agreement with the Secretary pursuant to section 835 that is seeking the repayment of the amount due from a borrower on a loan made under this part after the default of the borrower on such loan.

[4] Paragraph (2) of section 133(c) of Public Law 105–392 provides as follows: "The amendment made by paragraph (1) shall be effective with respect to actions pending on or after the date of enactment of this Act.".

ALLOTMENTS AND PAYMENTS OF FEDERAL CAPITAL CONTRIBUTIONS.

SEC. 838.[5] [297d] (a)(1) The Secretary shall from time to time set dates by which schools of nursing in a State must file applications for Federal capital contributions.

(2)(A) If the total of the amounts requested for any fiscal year in such applications exceeds the total amount appropriated under section 837[6] for that fiscal year, the allotment from such total amount to the loan fund of each school of nursing shall be reduced to whichever of the following is the smaller:

(i) The amount requested in its application.

(ii) An amount which bears the same ratio to the total amount appropriated as the number of students estimated by the Secretary to be enrolled on a full-time basis in such school during such fiscal year bears to the estimated total number of students enrolled in all such schools on a full-time basis during such year.

(B) Amounts remaining after allotment under subparagraph (A) shall be reallotted in accordance with clause (ii) of such subparagraph among schools whose applications requested more than the amounts so allotted to their loan funds, but with such adjustments as may be necessary to prevent the total allotted to any such school's loan fund under this paragraph and paragraph (3) from exceeding the total so requested by it.

(3) Funds which, pursuant to section 839(c) or pursuant to a loan agreement under section 835, are returned to the Secretary in any fiscal year, shall be available for allotment until expended. Funds described in the preceding sentence shall be allotted among schools of nursing in such manner as the Secretary determines will best carry out this part.

(b) Allotments to a loan fund of a school shall be paid to it from time to time in such installments as the Secretary determines will not result in unnecessary accumulations in the loan fund at such school.

(c) The Federal capital contributions to a loan fund of a school under this part shall be paid to it from time to time in such installments as the Secretary determines will not result in unnecessary accumulations in the loan fund at such school.

DISTRIBUTION OF ASSETS FROM LOAN FUNDS.

SEC. 839.[297e] (a) If a school terminates a loan fund established under an agreement pursuant to section 835(b), or if the Secretary for good cause terminates the agreement with the school, there shall be a capital distribution as follows:

(1) The Secretary shall first be paid an amount which bears the same ratio to such balance in such fund on the date of termination of the fund as the total amount of the Federal capital contributions to such fund by the Secretary pursuant to section 835(b)(2)(A) bears to the total amount in such fund derived from such Federal capital contributions and from funds deposited therein pursuant to section 835(b)(2)(B).

[5] Section 837 was repealed by section 123(3) of Public Law 105–392 (112 Stat. 3562).
[6] Section 837 was repealed by section 123(3) of Public Law 105–392 (112 Stat. 3562).

(2) The remainder of such balance shall be paid to the school.

(b) If a capital distribution is made under subsection (a), the school involved shall, after such capital distribution, pay to the Secretary, not less often than quarterly, the same proportionate share of amounts received by the school in payment of principal or interest on loans made from the loan fund established under section 835(b) as determined by the Secretary under subsection (a).

(c)(1) Within 90 days after the termination of any agreement with a school under section 835 or the termination in any other manner of a school's participation in the loan program under this subpart[7], such school shall pay to the Secretary from the balance of the loan fund of such school established under section 835, an amount which bears the same ratio to the balance in such fund on the date of such termination as the total amount of the Federal capital contributions to such fund by the Secretary pursuant to section 835(b)(2)(A) bears to the total amount in such fund on such date derived from such Federal capital contributions and from funds deposited in the fund pursuant to section 835(b)(2)(B). The remainder of such balance shall be paid to the school.

(2) A school to which paragraph (1) applies shall pay to the Secretary after the date on which payment is made under such paragraph and not less than quarterly, the same proportionate share of amounts received by the school after the date of termination referred to in paragraph (1) in payment of principal or interest on loans made from the loan fund as was determined for the Secretary under such paragraph.

ADMINISTRATIVE PROVISIONS.

SEC. 840.**[**297g**]** The Secretary may agree to modifications of agreements made under this part, and may compromise, waive, or release any right, title, claim, or demand of the United States arising or acquired under this part.

PROCEDURES FOR APPEAL OF TERMINATIONS.

SEC. 842.[8]**[**297i**]** In any case in which the Secretary intends to terminate an agreement with a school of nursing under this part, the Secretary shall provide the school with a written notice specifying such intention and stating that the school may request a formal hearing with respect to such termination. If the school requests such a hearing within 30 days after the receipt of such notice, the Secretary shall provide such school with a hearing conducted by an administrative law judge.

LOAN REPAYMENT AND SCHOLARSHIP PROGRAMS.

SEC. 846.[9]**[**297n**]** (a) IN GENERAL.—In the case of any individual—

[7] So in law. Probably should read "part".

[8] There is no section 841 between sections 840 and 842. Section 5310(b)(7) of Public Law 111–148 redesignates section 841 as section 871. Such amendment also redesignates part F as part I and transfers part I (as redesignated) to the end of this title.

[9] Title VIII does not contain a section 843 or 844. A section 845 appears in part G on page 810.

(1) who has received a baccalaureate or associate degree in nursing (or an equivalent degree), a diploma in nursing, or a graduate degree in nursing;

(2) who obtained (A) one or more loans from a loan fund established under subpart II[10], or (B) any other educational loan for nurse training costs; and

(3) who enters into an agreement with the Secretary to serve as nurse for a period of not less than two years at a health care facility with a critical shortage of nurses, or in a accredited school of nursing, as defined by section 801(2), as nurse faculty;

the Secretary shall make payments in accordance with subsection (b), for and on behalf of that individual, on the principal of and interest on any loan of that individual described in paragraph (2) of this subsection which is outstanding on the date the individual begins the service specified in the agreement described in paragraph (3) of this subsection. After fiscal year 2007, the Secretary may not, pursuant to any agreement entered into under this subsection, assign a nurse to any private entity unless that entity is nonprofit.

(b) MANNER OF PAYMENTS.—The payments described in subsection (a) shall be made by the Secretary as follows:

(1) Upon completion by the individual for whom the payments are to be made of the first year of the service specified in the agreement entered into with the Secretary under subsection (a), the Secretary shall pay 30 percent of the principal of, and the interest on each loan of such individual described in subsection (a)(2) which is outstanding on the date he began such practice.

(2) Upon completion by that individual of the second year of such service, the Secretary shall pay another 30 percent of the principal of, and the interest on each such loan.

(3) Upon completion by that individual of a third year of such service, the Secretary shall pay another 25 percent of the principal of, and the interest on each such loan.

(c) PAYMENT BY DUE DATE.—Notwithstanding the requirement of completion of practice specified in subsection (b), the Secretary shall, on or before the due date thereof, pay any loan or loan installment which may fall due within the period of service for which the borrower may receive payments under this subsection, upon the declaration of such borrower, at such times and in such manner as the Secretary may prescribe (and supported by such other evidence as the Secretary may reasonably require), that the borrower is then serving as described by subsection (a)(3), and that the borrower will continue to so serve for the period required (in the absence of this subsection) to entitle the borrower to have made the payments provided by this subsection for such period; except that not more than 85 percent of the principal of any such loan shall be paid pursuant to this subsection.

(d) SCHOLARSHIP PROGRAM.—

(1) IN GENERAL.—The Secretary shall (for fiscal years 2003 and 2004) and may (for fiscal years thereafter) carry out a program of entering into contracts with eligible individuals under

[10] So in law. Probably should read "part".

which such individuals agree to serve as nurses for a period of not less than 2 years at a health care facility with a critical shortage of nurses, in consideration of the Federal Government agreeing to provide to the individuals scholarships for attendance at schools of nursing.

(2) ELIGIBLE INDIVIDUALS.—In this subsection, the term "eligible individual" means an individual who is enrolled or accepted for enrollment as a full-time or part-time student in a school of nursing.

(3) SERVICE REQUIREMENT.—

(A) IN GENERAL.—The Secretary may not enter into a contract with an eligible individual under this subsection unless the individual agrees to serve as a nurse at a health care facility with a critical shortage of nurses for a period of full-time service of not less than 2 years, or for a period of part-time service in accordance with subparagraph (B).

(B) PART-TIME SERVICE.—An individual may complete the period of service described in subparagraph (A) on a part-time basis if the individual has a written agreement that—

(i) is entered into by the facility and the individual and is approved by the Secretary; and

(ii) provides that the period of obligated service will be extended so that the aggregate amount of service performed will equal the amount of service that would be performed through a period of full-time service of not less than 2 years.

(4) APPLICABILITY OF CERTAIN PROVISIONS.—The provisions of subpart III of part D of title III shall, except as inconsistent with this section, apply to the program established in paragraph (1) in the same manner and to the same extent as such provisions apply to the National Health Service Corps Scholarship Program established in such subpart.

(e) PREFERENCES REGARDING PARTICIPANTS.—In entering into agreements under subsection (a) or (d), the Secretary shall give preference to qualified applicants with the greatest financial need.

(f) BREACH OF AGREEMENT.—The Secretary may make payments under subsection (a) on behalf of an individual only if the agreement under such subsection provides that section 860(c) is applicable to the individual.

(g) BREACH OF AGREEMENT.—

(1) IN GENERAL.—In the case of any program under this section under which an individual makes an agreement to provide health services for a period of time in accordance with such program in consideration of receiving an award of Federal funds regarding education as a nurse (including an award for the repayment of loans), the following applies if the agreement provides that this subsection is applicable:

(A) In the case of a program under this section that makes an award of Federal funds for attending an accredited program of nursing (in this section referred to as a "nursing program"), the individual is liable to the Federal Government for the amount of such award (including

amounts provided for expenses related to such attendance), and for interest on such amount at the maximum legal prevailing rate, if the individual—

(i) fails to maintain an acceptable level of academic standing in the nursing program (as indicated by the program in accordance with requirements established by the Secretary);

(ii) is dismissed from the nursing program for disciplinary reasons; or

(iii) voluntarily terminates the nursing program.

(B) The individual is liable to the Federal Government for the amount of such award (including amounts provided for expenses related to such attendance), and for interest on such amount at the maximum legal prevailing rate, if the individual fails to provide health services in accordance with the program under this section for the period of time applicable under the program.

(2) WAIVER OR SUSPENSION OF LIABILITY.—In the case of an individual or health facility making an agreement for purposes of paragraph (1), the Secretary shall provide for the waiver or suspension of liability under such subsection if compliance by the individual or the health facility, as the case may be, with the agreements involved is impossible, or would involve extreme hardship to the individual or facility, and if enforcement of the agreements with respect to the individual or facility would be unconscionable.

(3) DATE CERTAIN FOR RECOVERY.—Subject to paragraph (2), any amount that the Federal Government is entitled to recover under paragraph (1) shall be paid to the United States not later than the expiration of the 3-year period beginning on the date the United States becomes so entitled.

(4) AVAILABILITY.—Amounts recovered under paragraph (1) with respect to a program under this section shall be available for the purposes of such program, and shall remain available for such purposes until expended.

(h) REPORTS.—Not later than 18 months after the date of enactment of the Nurse Reinvestment Act, and annually thereafter, the Secretary shall prepare and submit to the Congress a report describing the programs carried out under this section, including statements regarding—

(1) the number of enrollees, scholarships, loan repayments, and grant recipients;

(2) the number of graduates;

(3) the amount of scholarship payments and loan repayments made;

(4) which educational institution the recipients attended;

(5) the number and placement location of the scholarship and loan repayment recipients at health care facilities with a critical shortage of nurses;

(6) the default rate and actions required;

(7) the amount of outstanding default funds of both the scholarship and loan repayment programs;

(8) to the extent that it can be determined, the reason for the default;

(9) the demographics of the individuals participating in the scholarship and loan repayment programs;

(10) justification for the allocation of funds between the scholarship and loan repayment programs; and

(11) an evaluation of the overall costs and benefits of the programs.

(i) FUNDING.—

(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of payments under agreements entered into under subsection (a) or (d), there are authorized to be appropriated such sums as may be necessary for each of fiscal years 2003 through 2007.

(2) ALLOCATIONS.—Of the amounts appropriated under paragraph (1), the Secretary may, as determined appropriate by the Secretary, allocate amounts between the program under subsection (a) and the program under subsection (d).

NURSE FACULTY LOAN PROGRAM.

SEC. 846A.[297n–1] (a) SCHOOL OF NURSING STUDENT LOAN FUND.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, may enter into an agreement with any accredited school of nursing for the establishment and operation of a student loan fund in accordance with this section, to increase the number of qualified nursing faculty.

(b) AGREEMENTS.—Each agreement entered into under subsection (a) shall—

(1) provide for the establishment of a student loan fund by the school involved;

(2) provide for deposit in the fund of—

(A) the Federal capital contributions to the fund;

(B) an amount equal to not less than one-ninth of such Federal capital contributions, contributed by such school;

(C) collections of principal and interest on loans made from the fund; and

(D) any other earnings of the fund;

(3) provide that the fund will be used only for loans to students of the school in accordance with subsection (c) and for costs of collection of such loans and interest thereon;

(4) provide that loans may be made from such fund only to students pursuing a full-time course of study or, at the discretion of the Secretary, a part-time course of study in an advanced degree program described in section 811(b); and

(5) contain such other provisions as are necessary to protect the financial interests of the United States.

(c) LOAN PROVISIONS.—Loans from any student loan fund established by a school pursuant to an agreement under subsection (a) shall be made to an individual on such terms and conditions as the school may determine, except that—

(1) such terms and conditions are subject to any conditions, limitations, and requirements prescribed by the Secretary;

(2) in the case of any individual, the total of the loans for any academic year made by schools of nursing from loan funds established pursuant to agreements under subsection (a) may

not exceed $35,500, during fiscal years 2010 and 2011 fiscal years (after fiscal year 2011, such amounts shall be adjusted to provide for a cost-of-attendance increase for the yearly loan rate and the aggregate loan;

(3) an amount up to 85 percent of any such loan (plus interest thereon) shall be canceled by the school as follows:

(A) upon completion by the individual of each of the first, second, and third year of full-time employment, required by the loan agreement entered into under this subsection, as a faculty member in an accredited a[11] school of nursing, the school shall cancel 20 percent of the principle of, and the interest on, the amount of such loan unpaid on the first day of such employment; and

(B) upon completion by the individual of the fourth year of full-time employment, required by the loan agreement entered into under this subsection, as a faculty member in a school of nursing, the school shall cancel 25 percent of the principle of, and the interest on, the amount of such loan unpaid on the first day of such employment;

(4) such a loan may be used to pay the cost of tuition, fees, books, laboratory expenses, and other reasonable education expenses;

(5) such a loan shall be repayable in equal or graduated periodic installments (with the right of the borrower to accelerate repayment) over the 10-year period that begins 9 months after the individual ceases to pursue a course of study at a school of nursing; and

(6) such a loan shall—

(A) beginning on the date that is 3 months after the individual ceases to pursue a course of study at a school of nursing, bear interest on the unpaid balance of the loan at the rate of 3 percent per annum; or

(B) subject to subsection (e), if the school of nursing determines that the individual will not complete such course of study or serve as a faculty member as required under the loan agreement under this subsection, bear interest on the unpaid balance of the loan at the prevailing market rate.

(d) PAYMENT OF PROPORTIONATE SHARE.—Where all or any part of a loan, or interest, is canceled under this section, the Secretary shall pay to the school an amount equal to the school's proportionate share of the canceled portion, as determined by the Secretary.

(e) REVIEW BY SECRETARY.—At the request of the individual involved, the Secretary may review any determination by an accredited school of nursing under subsection (c)(6)(B).

(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section such sums as may be necessary for each of fiscal years 2010 through 2014.

[11] So in law. Probably should read "...as a faculty member in an accredited school of nursing...".

SEC. 847.[297o] ELIGIBLE INDIVIDUAL STUDENT LOAN REPAYMENT.

(a) IN GENERAL.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, may enter into an agreement with eligible individuals for the repayment of education loans, in accordance with this section, to increase the number of qualified nursing faculty.

(b) AGREEMENTS.—Each agreement entered into under this subsection shall require that the eligible individual shall serve as a full-time member of the faculty of an accredited school of nursing, for a total period, in the aggregate, of at least 4 years during the 6-year period beginning on the later of—

(1) the date on which the individual receives a master's or doctorate nursing degree from an accredited school of nursing; or

(2) the date on which the individual enters into an agreement under this subsection.

(c) AGREEMENT PROVISIONS.—Agreements entered into pursuant to subsection (b) shall be entered into on such terms and conditions as the Secretary may determine, except that—

(1) not more than 10 months after the date on which the 6-year period described under subsection (b) begins, but in no case before the individual starts as a full-time member of the faculty of an accredited school of nursing the Secretary shall begin making payments, for and on behalf of that individual, on the outstanding principal of, and interest on, any loan of that individual obtained to pay for such degree;

(2) for an individual who has completed a master's in nursing or equivalent degree in nursing—

(A) payments may not exceed $10,000 per calendar year; and

(B) total payments may not exceed $40,000 during the 2010 and 2011 fiscal years (after fiscal year 2011, such amounts shall be adjusted to provide for a cost-of-attendance increase for the yearly loan rate and the aggregate loan); and

(3) for an individual who has completed a doctorate or equivalent degree in nursing—

(A) payments may not exceed $20,000 per calendar year; and

(B) total payments may not exceed $80,000 during the 2010 and 2011 fiscal years (adjusted for subsequent fiscal years as provided for in the same manner as in paragraph (2)(B)).

(d) BREACH OF AGREEMENT.—

(1) IN GENERAL.—In the case of any agreement made under subsection (b), the individual is liable to the Federal Government for the total amount paid by the Secretary under such agreement, and for interest on such amount at the maximum legal prevailing rate, if the individual fails to meet the agreement terms required under such subsection.

(2) WAIVER OR SUSPENSION OF LIABILITY.—In the case of an individual making an agreement for purposes of paragraph (1), the Secretary shall provide for the waiver or suspension of liability under such paragraph if compliance by the individual

with the agreement involved is impossible or would involve extreme hardship to the individual or if enforcement of the agreement with respect to the individual would be unconscionable.

(3) DATE CERTAIN FOR RECOVERY.—Subject to paragraph (2), any amount that the Federal Government is entitled to recover under paragraph (1) shall be paid to the United States not later than the expiration of the 3-year period beginning on the date the United States becomes so entitled.

(4) AVAILABILITY.—Amounts recovered under paragraph (1) shall be available to the Secretary for making loan repayments under this section and shall remain available for such purpose until expended.

(e) ELIGIBLE INDIVIDUAL DEFINED.—For purposes of this section, the term "eligible individual" means an individual who—

(1) is a United States citizen, national, or lawful permanent resident;

(2) holds an unencumbered license as a registered nurse; and

(3) has either already completed a master's or doctorate nursing program at an accredited school of nursing or is currently enrolled on a full-time or part-time basis in such a program.

(f) PRIORITY.—For the purposes of this section and section 846A, funding priority will be awarded to School of Nursing Student Loans that support doctoral nursing students or Individual Student Loan Repayment that support doctoral nursing students.

(g) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section such sums as may be necessary for each of fiscal years 2010 through 2014.

PART F—NATIONAL ADVISORY COUNCIL ON NURSE EDUCATION AND PRACTICE

SEC. 851.[297t] NATIONAL ADVISORY COUNCIL ON NURSE EDUCATION AND PRACTICE.

(a) ESTABLISHMENT.—The Secretary shall establish an advisory council to be known as the National Advisory Council on Nurse Education and Practice (in this section referred to as the "Advisory Council").

(b) COMPOSITION.—

(1) IN GENERAL.—The Advisory Council shall be composed of—

(A) not less than 21, nor more than 23 individuals, who are not officers or employees of the Federal Government, appointed by the Secretary without regard to the Federal civil service laws, of which—

(i) 2 shall be selected from full-time students enrolled in schools of nursing;

(ii) 2 shall be selected from the general public;

(iii) 2 shall be selected from practicing professional nurses; and

(iv) 9 shall be selected from among the leading authorities in the various fields of nursing, higher, secondary education, and associate degree schools of

nursing, and from representatives of advanced education nursing groups (such as nurse practitioners, nurse midwives, and nurse anesthetists), hospitals, and other institutions and organizations which provide nursing services; and

(B) the Secretary (or the delegate of the Secretary (who shall be an ex officio member and shall serve as the Chairperson)).

(2) APPOINTMENT.—Not later than 90 days after the date of enactment of this Act[12], the Secretary shall appoint the members of the Advisory Council and each such member shall serve a 4 year term. In making such appointments, the Secretary shall ensure a fair balance between the nursing professions, a broad geographic representation of members and a balance between urban and rural members. Members shall be appointed based on their competence, interest, and knowledge of the mission of the profession involved. A majority of the members shall be nurses.

(3) MINORITY REPRESENTATION.—In appointing the members of the Advisory Council under paragraph (1), the Secretary shall ensure the adequate representation of minorities.

(c) VACANCIES.—

(1) IN GENERAL.—A vacancy on the Advisory Council shall be filled in the manner in which the original appointment was made and shall be subject to any conditions which applied with respect to the original appointment.

(2) FILLING UNEXPIRED TERM.—An individual chosen to fill a vacancy shall be appointed for the unexpired term of the member replaced.

(d) DUTIES.—The Advisory Council shall—

(1) provide advice and recommendations to the Secretary and Congress concerning policy matters arising in the administration of this title, including the range of issues relating to the nurse workforce, education, and practice improvement;

(2) provide advice to the Secretary and Congress in the preparation of general regulations and with respect to policy matters arising in the administration of this title, including the range of issues relating to nurse supply, education and practice improvement; and

(3) not later than 3 years after the date of enactment of this section, and annually thereafter, prepare and submit to the Secretary, the Committee on Labor and Human Resources of the Senate, and the Committee on Commerce of the House of Representatives, a report describing the activities of the Council, including findings and recommendations made by the Council concerning the activities under this title.

(e) MEETINGS AND DOCUMENTS.—

(1) MEETINGS.—The Advisory Council shall meet not less than 2 times each year. Such meetings shall be held jointly

[12] So in law. The reference to "this Act" means the Public Health Service Act, which was enacted July 1, 1944. Probably should be a reference to the Health Professions Education Partnerships Act of 1998, which added section 845. That Act is Public Law 105–392, enacted November 13, 1998. (Section 123(5) of that Public Law (112 Stat. 3569) added section 845.)

with other related entities established under this title where appropriate.

(2) DOCUMENTS.—Not later than 14 days prior to the convening of a meeting under paragraph (1), the Advisory Council shall prepare and make available an agenda of the matters to be considered by the Advisory Council at such meeting. At any such meeting, the Advisory Council shall distribute materials with respect to the issues to be addressed at the meeting. Not later than 30 days after the adjourning of such a meeting, the Advisory Council shall prepare and make available a summary of the meeting and any actions taken by the Council based upon the meeting.

(f) COMPENSATION AND EXPENSES.—

(1) COMPENSATION.—Each member of the Advisory Council shall be compensated at a rate equal to the daily equivalent of the annual rate of basic pay prescribed for level IV of the Executive Schedule under section 5315 of title 5, United States Code, for each day (including travel time) during which such member is engaged in the performance of the duties of the Council. All members of the Council who are officers or employees of the United States shall serve without compensation in addition to that received for their services as officers or employees of the United States.

(2) EXPENSES.—The members of the Advisory Council shall be allowed travel expenses, including per diem in lieu of subsistence, at rates authorized for employees of agencies under subchapter I of chapter 57 of title 5, United States Code, while away from their homes or regular places of business in the performance of services for the Council.

(g) FUNDING.—Amounts appropriated under this title may be utilized by the Secretary to support the nurse education and practice activities of the Council.

(h) FACA.—The Federal Advisory Committee Act shall apply to the Advisory Committee under this section only to the extent that the provisions of such Act do not conflict with the requirements of this section.

PART G—PUBLIC SERVICE ANNOUNCEMENTS

SEC. 861.[297w] PUBLIC SERVICE ANNOUNCEMENTS.

(a) IN GENERAL.—The Secretary shall develop and issue public service announcements that advertise and promote the nursing profession, highlight the advantages and rewards of nursing, and encourage individuals to enter the nursing profession.

(b) METHOD.—The public service announcements described in subsection (a) shall be broadcast through appropriate media outlets, including television or radio, in a manner intended to reach as wide and diverse an audience as possible.

(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section such sums as may be necessary for each of fiscal years 2003 through 2007.

SEC. 862.[297x] STATE AND LOCAL PUBLIC SERVICE ANNOUNCEMENTS.

(a) IN GENERAL.—The Secretary may award grants to eligible entities to support State and local advertising campaigns through appropriate media outlets to promote the nursing profession, highlight the advantages and rewards of nursing, and encourage individuals from disadvantaged backgrounds to enter the nursing profession.

(b) USE OF FUNDS.—An eligible entity that receives a grant under subsection (a) shall use funds received through such grant to acquire local television and radio time, place advertisements in local newspapers, or post information on billboards or on the Internet in a manner intended to reach as wide and diverse an audience as possible, in order to—

(1) advertise and promote the nursing profession;

(2) promote nursing education programs;

(3) inform the public of financial assistance regarding such education programs;

(4) highlight individuals in the community who are practicing nursing in order to recruit new nurses; or

(5) provide any other information to recruit individuals for the nursing profession.

(c) LIMITATION.—An eligible entity that receives a grant under subsection (a) shall not use funds received through such grant to advertise particular employment opportunities.

(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section such sums as may be necessary for each of fiscal years 2003 through 2007.

PART H—COMPREHENSIVE GERIATRIC EDUCATION

SEC. 865.[298] COMPREHENSIVE GERIATRIC EDUCATION.

(a) PROGRAM AUTHORIZED.—The Secretary shall award grants to eligible entities to develop and implement, in coordination with programs under section 753, programs and initiatives to train and educate individuals in providing geriatric care for the elderly.

(b) USE OF FUNDS.—An eligible entity that receives a grant under subsection (a) shall use funds under such grant to—

(1) provide training to individuals who will provide geriatric care for the elderly;

(2) develop and disseminate curricula relating to the treatment of the health problems of elderly individuals;

(3) train faculty members in geriatrics;

(4) provide continuing education to individuals who provide geriatric care; or

(5) establish traineeships for individuals who are preparing for advanced education nursing degrees in geriatric nursing, long-term care, gero-psychiatric nursing or other nursing areas that specialize in the care of the elderly population.

(c) APPLICATION.—An eligible entity desiring a grant under subsection (a) shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may reasonably require.

(d) ELIGIBLE ENTITY.—For purposes of this section, the term "eligible entity" includes a school of nursing, a health care facility, a program leading to certification as a certified nurse assistant, a partnership of such a school and facility, or a partnership of such a program and facility.

(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section such sums as may be necessary for each of fiscal years 2010 through 2014.

PART I—FUNDING

SEC. 871.[298d] AUTHORIZATION OF APPROPRIATIONS.

For the purpose of carrying out parts B, C, and D (subject to section 851(g)), there are authorized to be appropriated $338,000,000 for fiscal year 2010, and such sums as may be necessary for each of the fiscal years 2011 through 2016.

December 13, 2013

PUBLIC HEALTH SERVICE ACT

As Amended Through P.L. 112–240, Enacted January 2, 2013

TITLE IX—AGENCY FOR HEALTHCARE RESEARCH AND QUALITY [1]

PART A—ESTABLISHMENT AND GENERAL DUTIES

SEC. 901.[299] MISSION AND DUTIES.

(a) IN GENERAL.—There is established within the Public Health Service an agency to be known as the Agency for Healthcare Research and Quality, which shall be headed by a director appointed by the Secretary. The Secretary shall carry out this title acting through the Director.

(b) MISSION.—The purpose of the Agency is to enhance the quality, appropriateness, and effectiveness of health services, and access to such services, through the establishment of a broad base of scientific research and through the promotion of improvements in clinical and health system practices, including the prevention of diseases and other health conditions. The Agency shall promote health care quality improvement by conducting and supporting—

(1) research that develops and presents scientific evidence regarding all aspects of health care, including—

(A) the development and assessment of methods for enhancing patient participation in their own care and for facilitating shared patient-physician decision-making;

(B) the outcomes, effectiveness, and cost-effectiveness of health care practices, including preventive measures and long-term care;

(C) existing and innovative technologies;

(D) the costs and utilization of, and access to health care;

(E) the ways in which health care services are organized, delivered, and financed and the interaction and impact of these factors on the quality of patient care;

(F) methods for measuring quality and strategies for improving quality; and

(G) ways in which patients, consumers, purchasers, and practitioners acquire new information about best practices and health benefits, the determinants and impact of their use of this information;

[1] Section 2 of Public Law 106–129 (113 Stat. 1653) designated the Agency as the Agency for Healthcare Research and Quality. Formerly it was designated as the Agency for Health Care Policy and Research. See section 6103 of Public Law 101–239 (103 Stat. 2189).

(2) the synthesis and dissemination of available scientific evidence for use by patients, consumers, practitioners, providers, purchasers, policy makers, and educators; and

(3) initiatives to advance private and public efforts to improve health care quality.

(c) REQUIREMENTS WITH RESPECT TO RURAL AND INNER-CITY AREAS AND PRIORITY POPULATIONS.—

(1) RESEARCH, EVALUATIONS AND DEMONSTRATION PROJECTS.—In carrying out this title, the Director shall conduct and support research and evaluations, and support demonstration projects, with respect to—

(A) the delivery of health care in inner-city areas, and in rural areas (including frontier areas); and

(B) health care for priority populations, which shall include—

(i) low-income groups;

(ii) minority groups;

(iii) women;

(iv) children;

(v) the elderly; and

(vi) individuals with special health care needs, including individuals with disabilities and individuals who need chronic care or end-of-life health care.

(2) PROCESS TO ENSURE APPROPRIATE RESEARCH.—The Director shall establish a process to ensure that the requirements of paragraph (1) are reflected in the overall portfolio of research conducted and supported by the Agency.

(3) OFFICE OF PRIORITY POPULATIONS.—The Director shall establish an Office of Priority Populations to assist in carrying out the requirements of paragraph (1).

SEC. 902.[299a] GENERAL AUTHORITIES.

(a) IN GENERAL.—In carrying out section 901(b), the Director shall conduct and support research, evaluations, and training, support demonstration projects, research networks, and multidisciplinary centers, provide technical assistance, and disseminate information on health care and on systems for the delivery of such care, including activities with respect to—

(1) the quality, effectiveness, efficiency, appropriateness and value of health care services;

(2) quality measurement and improvement;

(3) the outcomes, cost, cost-effectiveness, and use of health care services and access to such services;

(4) clinical practice, including primary care and practice-oriented research;

(5) health care technologies, facilities, and equipment;

(6) health care costs, productivity, organization, and market forces;

(7) health promotion and disease prevention, including clinical preventive services;

(8) health statistics, surveys, database development, and epidemiology; and

(9) medical liability.

(b) HEALTH SERVICES TRAINING GRANTS.—

(1) IN GENERAL.—The Director may provide training grants in the field of health services research related to activities authorized under subsection (a), to include pre- and post-doctoral fellowships and training programs, young investigator awards, and other programs and activities as appropriate. In carrying out this subsection, the Director shall make use of funds made available under section 487(d)(3) as well as other appropriated funds.

(2) REQUIREMENTS.—In developing priorities for the allocation of training funds under this subsection, the Director shall take into consideration shortages in the number of trained researchers who are addressing health care issues for the priority populations identified in section 901(c)(1)(B) and in addition, shall take into consideration indications of long-term commitment, amongst applicants for training funds, to addressing health care needs of the priority populations.

(c) MULTIDISCIPLINARY CENTERS.—The Director may provide financial assistance to assist in meeting the costs of planning and establishing new centers, and operating existing and new centers, for multidisciplinary health services research, demonstration projects, evaluations, training, and policy analysis with respect to the matters referred to in subsection (a).

(d) RELATION TO CERTAIN AUTHORITIES REGARDING SOCIAL SECURITY.—Activities authorized in this section shall be appropriately coordinated with experiments, demonstration projects, and other related activities authorized by the Social Security Act and the Social Security Amendments of 1967. Activities under subsection (a)(2) of this section that affect the programs under titles XVIII, XIX and XXI of the Social Security Act shall be carried out consistent with section 1142 of such Act.

(e) DISCLAIMER.—The Agency shall not mandate national standards of clinical practice or quality health care standards. Recommendations resulting from projects funded and published by the Agency shall include a corresponding disclaimer.

(f) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to imply that the Agency's role is to mandate a national standard or specific approach to quality measurement and reporting. In research and quality improvement activities, the Agency shall consider a wide range of choices, providers, health care delivery systems, and individual preferences.

SEC. 903.[299a–1] RESEARCH ON HEALTH DISPARITIES.

(a) IN GENERAL.—The Director shall—

(1) conduct and support research to identify populations for which there is a significant disparity in the quality, outcomes, cost, or use of health care services or access to and satisfaction with such services, as compared to the general population;

(2) conduct and support research on the causes of and barriers to reducing the health disparities identified in paragraph (1), taking into account such factors as socioeconomic status, attitudes toward health, the language spoken, the extent of formal education, the area or community in which the population

resides, and other factors the Director determines to be appropriate;

(3) conduct and support research and support demonstration projects to identify, test, and evaluate strategies for reducing or eliminating health disparities, including development or identification of effective service delivery models, and disseminate effective strategies and models;

(4) develop measures and tools for the assessment and improvement of the outcomes, quality, and appropriateness of health care services provided to health disparity populations;

(5) in carrying out section 902(c), provide support to increase the number of researchers who are members of health disparity populations, and the health services research capacity of institutions that train such researchers; and

(6) beginning with fiscal year 2003, annually submit to the Congress a report regarding prevailing disparities in health care delivery as it relates to racial factors and socioeconomic factors in priority populations.

(b) RESEARCH AND DEMONSTRATION PROJECTS.—

(1) IN GENERAL.—In carrying out subsection (a), the Director shall conduct and support research and support demonstrations to—

(A) identify the clinical, cultural, socioeconomic, geographic, and organizational factors that contribute to health disparities, including minority health disparity populations, which research shall include behavioral research, such as examination of patterns of clinical decisionmaking, and research on access, outreach, and the availability of related support services (such as cultural and linguistic services);

(B) identify and evaluate clinical and organizational strategies to improve the quality, outcomes, and access to care for health disparity populations, including minority health disparity populations;

(C) test such strategies and widely disseminate those strategies for which there is scientific evidence of effectiveness; and

(D) determine the most effective approaches for disseminating research findings to health disparity populations, including minority populations.

(2) USE OF CERTAIN STRATEGIES.—In carrying out this section, the Director shall implement research strategies and mechanisms that will enhance the involvement of individuals who are members of minority health disparity populations or other health disparity populations, health services researchers who are such individuals, institutions that train such individuals as researchers, members of minority health disparity populations or other health disparity populations for whom the Agency is attempting to improve the quality and outcomes of care, and representatives of appropriate tribal or other community-based organizations with respect to health disparity populations. Such research strategies and mechanisms may include the use of—

(A) centers of excellence that can demonstrate, either individually or through consortia, a combination of multidisciplinary expertise in outcomes or quality improvement research, linkages to relevant sites of care, and a demonstrated capacity to involve members and communities of health disparity populations, including minority health disparity populations, in the planning, conduct, dissemination, and translation of research;

(B) provider-based research networks, including health plans, facilities, or delivery system sites of care (especially primary care), that make extensive use of health care providers who are members of health disparity populations or who serve patients in such populations and have the capacity to evaluate and promote quality improvement;

(C) service delivery models (such as health centers under section 330 and the Indian Health Service) to reduce health disparities; and

(D) innovative mechanisms or strategies that will facilitate the translation of past research investments into clinical practices that can reasonably be expected to benefit these populations.

(c) QUALITY MEASUREMENT DEVELOPMENT.—

(1) IN GENERAL.—To ensure that health disparity populations, including minority health disparity populations, benefit from the progress made in the ability of individuals to measure the quality of health care delivery, the Director shall support the development of quality of health care measures that assess the experience of such populations with health care systems, such as measures that assess the access of such populations to health care, the cultural competence of the care provided, the quality of the care provided, the outcomes of care, or other aspects of health care practice that the Director determines to be important.

(2) EXAMINATION OF CERTAIN PRACTICES.—The Director shall examine the practices of providers that have a record of reducing health disparities or have experience in providing culturally competent health services to minority health disparity populations or other health disparity populations. In examining such practices of providers funded under the authorities of this Act, the Director shall consult with the heads of the relevant agencies of the Public Health Service.

(3) REPORT.—Not later than 36 months after the date of the enactment of this section, the Secretary, acting through the Director, shall prepare and submit to the appropriate committees of Congress a report describing the state-of-the-art of quality measurement for minority and other health disparity populations that will identify critical unmet needs, the current activities of the Department to address those needs, and a description of related activities in the private sector.

(d) DEFINITION.—For purposes of this section:

(1) The term "health disparity population" has the meaning given such term in section 464z–3, except that in addition to the meaning so given, the Director may determine that such term includes populations for which there is a significant dis-

parity in the quality, outcomes, cost, or use of health care services or access to or satisfaction with such services as compared to the general population.

(2) The term "minority", with respect to populations, refers to racial and ethnic minority groups as defined in section 1707.

PART B—HEALTH CARE IMPROVEMENT RESEARCH

SEC. 911.[299b] HEALTH CARE OUTCOME IMPROVEMENT RESEARCH.

(a) EVIDENCE RATING SYSTEMS.—In collaboration with experts from the public and private sector, the Agency shall identify and disseminate methods or systems to assess health care research results, particularly methods or systems to rate the strength of the scientific evidence underlying health care practice, recommendations in the research literature, and technology assessments. The Agency shall make methods or systems for evidence rating widely available. Agency publications containing health care recommendations shall indicate the level of substantiating evidence using such methods or systems.

(b) HEALTH CARE IMPROVEMENT RESEARCH CENTERS AND PROVIDER-BASED RESEARCH NETWORKS.—

(1) IN GENERAL.—In order to address the full continuum of care and outcomes research, to link research to practice improvement, and to speed the dissemination of research findings to community practice settings, the Agency shall employ research strategies and mechanisms that will link research directly with clinical practice in geographically diverse locations throughout the United States, including—

(A) health care improvement research centers that combine demonstrated multidisciplinary expertise in outcomes or quality improvement research with linkages to relevant sites of care;

(B) provider-based research networks, including plan, facility, or delivery system sites of care (especially primary care), that can evaluate outcomes and evaluate and promote quality improvement; and

(C) other innovative mechanisms or strategies to link research with clinical practice.

(2) REQUIREMENTS.—The Director is authorized to establish the requirements for entities applying for grants under this subsection.

SEC. 912.[299b–1] PRIVATE-PUBLIC PARTNERSHIPS TO IMPROVE ORGANIZATION AND DELIVERY.

(a) SUPPORT FOR EFFORTS TO DEVELOP INFORMATION ON QUALITY.—

(1) SCIENTIFIC AND TECHNICAL SUPPORT.—In its role as the principal agency for health care research and quality, the Agency may provide scientific and technical support for private and public efforts to improve health care quality, including the activities of accrediting organizations.

(2) ROLE OF THE AGENCY.—With respect to paragraph (1), the role of the Agency shall include—

(A) the identification and assessment of methods for the evaluation of the health of—

(i) enrollees in health plans by type of plan, provider, and provider arrangements; and

(ii) other populations, including those receiving long-term care services;

(B) the ongoing development, testing, and dissemination of quality measures, including measures of health and functional outcomes;

(C) the compilation and dissemination of health care quality measures developed in the private and public sector;

(D) assistance in the development of improved health care information systems;

(E) the development of survey tools for the purpose of measuring participant and beneficiary assessments of their health care; and

(F) identifying and disseminating information on mechanisms for the integration of information on quality into purchaser and consumer decision-making processes.

(b) CENTERS FOR EDUCATION AND RESEARCH ON THERAPEUTICS.—

(1) IN GENERAL.—The Secretary, acting through the Director and in consultation with the Commissioner of Food and Drugs, shall establish a program for the purpose of making one or more grants for the establishment and operation of one or more centers to carry out the activities specified in paragraph (2).

(2) REQUIRED ACTIVITIES.—The activities referred to in this paragraph are the following:

(A) The conduct of state-of-the-art research for the following purposes:

(i) To increase awareness of—

(I) new uses of drugs, biological products, and devices;

(II) ways to improve the effective use of drugs, biological products, and devices; and

(III) risks of new uses and risks of combinations of drugs and biological products.

(ii) To provide objective clinical information to the following individuals and entities:

(I) Health care practitioners and other providers of health care goods or services.

(II) Pharmacists, pharmacy benefit managers and purchasers.

(III) Health maintenance organizations and other managed health care organizations.

(IV) Health care insurers and governmental agencies.

(V) Patients and consumers.

(iii) To improve the quality of health care while reducing the cost of health care through—

(I) an increase in the appropriate use of drugs, biological products, or devices; and

(II) the prevention of adverse effects of drugs, biological products, and devices and the consequences of such effects, such as unnecessary hospitalizations.

(B) The conduct of research on the comparative effectiveness, cost-effectiveness, and safety of drugs, biological products, and devices.

(C) Such other activities as the Secretary determines to be appropriate, except that a grant may not be expended to assist the Secretary in the review of new drugs, biological products, and devices.

(c) REDUCING ERRORS IN MEDICINE.—The Director shall, in accordance with part C, conduct and support research and build private-public partnerships to—

(1) identify the causes of preventable health care errors and patient injury in health care delivery;

(2) develop, demonstrate, and evaluate strategies for reducing errors and improving patient safety; and

(3) disseminate such effective strategies throughout the health care industry.

SEC. 913.[299b–2] INFORMATION ON QUALITY AND COST OF CARE.

(a) IN GENERAL.—The Director shall—

(1) conduct a survey to collect data on a nationally representative sample of the population on the cost, use and, for fiscal year 2001 and subsequent fiscal years, quality of health care, including the types of health care services Americans use, their access to health care services, frequency of use, how much is paid for the services used, the source of those payments, the types and costs of private health insurance, access, satisfaction, and quality of care for the general population including rural residents and also for populations identified in section 901(c); and

(2) develop databases and tools that provide information to States on the quality, access, and use of health care services provided to their residents.

(b) QUALITY AND OUTCOMES INFORMATION.—

(1) IN GENERAL.—Beginning in fiscal year 2001, the Director shall ensure that the survey conducted under subsection (a)(1) will—

(A) identify determinants of health outcomes and functional status, including the health care needs of populations identified in section 901(c), provide data to study the relationships between health care quality, outcomes, access, use, and cost, measure changes over time, and monitor the overall national impact of Federal and State policy changes on health care;

(B) provide information on the quality of care and patient outcomes for frequently occurring clinical conditions for a nationally representative sample of the population including rural residents; and

(C) provide reliable national estimates for children and persons with special health care needs through the use of supplements or periodic expansions of the survey.

In expanding the Medical Expenditure Panel Survey, as in existence on the date of the enactment of this title in fiscal year 2001 to collect information on the quality of care, the Director shall take into account any outcomes measurements generally collected by private sector accreditation organizations.

(2) ANNUAL REPORT.—Beginning in fiscal year 2003, the Secretary, acting through the Director, shall submit to Congress an annual report on national trends in the quality of health care provided to the American people.

SEC. 914.[299b–3] INFORMATION SYSTEMS FOR HEALTH CARE IMPROVEMENT.

(a) IN GENERAL.—In order to foster a range of innovative approaches to the management and communication of health information, the Agency shall conduct and support research, evaluations, and initiatives to advance—

(1) the use of information systems for the study of health care quality and outcomes, including the generation of both individual provider and plan-level comparative performance data;

(2) training for health care practitioners and researchers in the use of information systems;

(3) the creation of effective linkages between various sources of health information, including the development of information networks;

(4) the delivery and coordination of evidence-based health care services, including the use of real-time health care decision-support programs;

(5) the utility and comparability of health information data and medical vocabularies by addressing issues related to the content, structure, definitions and coding of such information and data in consultation with appropriate Federal, State and private entities;

(6) the use of computer-based health records in all settings for the development of personal health records for individual health assessment and maintenance, and for monitoring public health and outcomes of care within populations; and

(7) the protection of individually identifiable information in health services research and health care quality improvement.

(b) DEMONSTRATION.—The Agency shall support demonstrations into the use of new information tools aimed at improving shared decision-making between patients and their care-givers.

(c) FACILITATING PUBLIC ACCESS TO INFORMATION.—The Director shall work with appropriate public and private sector entities to facilitate public access to information regarding the quality of and consumer satisfaction with health care.

SEC. 915.[299b–4] RESEARCH SUPPORTING PRIMARY CARE AND ACCESS IN UNDERSERVED AREAS.

(a) PREVENTIVE SERVICES TASK FORCE.—

(1) ESTABLISHMENT AND PURPOSE.—The Director shall convene an independent Preventive Services Task Force (referred to in this subsection as the "Task Force") to be composed of individuals with appropriate expertise. Such Task Force shall review the scientific evidence related to the effectiveness, appro-

priateness, and cost-effectiveness of clinical preventive services for the purpose of developing recommendations for the health care community, and updating previous clinical preventive recommendations, to be published in the Guide to Clinical Preventive Services (referred to in this section as the "Guide"), for individuals and organizations delivering clinical services, including primary care professionals, health care systems, professional societies, employers, community organizations, non-profit organizations, Congress and other policy-makers, governmental public health agencies, health care quality organizations, and organizations developing national health objectives. Such recommendations shall consider clinical preventive best practice recommendations from the Agency for Healthcare Research and Quality, the National Institutes of Health, the Centers for Disease Control and Prevention, the Institute of Medicine, specialty medical associations, patient groups, and scientific societies.

(2) DUTIES.—The duties of the Task Force shall include—

(A) the development of additional topic areas for new recommendations and interventions related to those topic areas, including those related to specific sub-populations and age groups;

(B) at least once during every 5-year period, review interventions and update recommendations related to existing topic areas, including new or improved techniques to assess the health effects of interventions;

(C) improved integration with Federal Government health objectives and related target setting for health improvement;

(D) the enhanced dissemination of recommendations;

(E) the provision of technical assistance to those health care professionals, agencies and organizations that request help in implementing the Guide recommendations; and

(F) the submission of yearly reports to Congress and related agencies identifying gaps in research, such as preventive services that receive an insufficient evidence statement, and recommending priority areas that deserve further examination, including areas related to populations and age groups not adequately addressed by current recommendations.

(3) ROLE OF AGENCY.—The Agency shall provide ongoing administrative, research, and technical support for the operations of the Task Force, including coordinating and supporting the dissemination of the recommendations of the Task Force, ensuring adequate staff resources, and assistance to those organizations requesting it for implementation of the Guide's recommendations.

(4) COORDINATION WITH COMMUNITY PREVENTIVE SERVICES TASK FORCE.—The Task Force shall take appropriate steps to coordinate its work with the Community Preventive Services Task Force and the Advisory Committee on Immunization Practices, including the examination of how each task force's

recommendations interact at the nexus of clinic and community.

(5) OPERATION.—Operation. In carrying out the duties under paragraph (2), the Task Force is not subject to the provisions of Appendix 2 of title 5, United States Code.

(6) INDEPENDENCE.—All members of the Task Force convened under this subsection, and any recommendations made by such members, shall be independent and, to the extent practicable, not subject to political pressure.

(7) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary for each fiscal year to carry out the activities of the Task Force.

(b) PRIMARY CARE RESEARCH.—

(1) IN GENERAL.—There is established within the Agency a Center for Primary Care Research (referred to in this subsection as the "Center") that shall serve as the principal source of funding for primary care practice research in the Department of Health and Human Services. For purposes of this paragraph, primary care research focuses on the first contact when illness or health concerns arise, the diagnosis, treatment or referral to specialty care, preventive care, and the relationship between the clinician and the patient in the context of the family and community.

(2) RESEARCH.—In carrying out this section, the Center shall conduct and support research concerning—

(A) the nature and characteristics of primary care practice;

(B) the management of commonly occurring clinical problems;

(C) the management of undifferentiated clinical problems; and

(D) the continuity and coordination of health services.

SEC. 916.[299b–5] HEALTH CARE PRACTICE AND TECHNOLOGY INNOVATION.

(a) IN GENERAL.—The Director shall promote innovation in evidence-based health care practices and technologies by—

(1) conducting and supporting research on the development, diffusion, and use of health care technology;

(2) developing, evaluating, and disseminating methodologies for assessments of health care practices and technologies;

(3) conducting intramural and supporting extramural assessments of existing and new health care practices and technologies;

(4) promoting education and training and providing technical assistance in the use of health care practice and technology assessment methodologies and results; and

(5) working with the National Library of Medicine and the public and private sector to develop an electronic clearinghouse of currently available assessments and those in progress.

(b) SPECIFICATION OF PROCESS.—

(1) IN GENERAL.—Not later than December 31, 2000, the Director shall develop and publish a description of the methods used by the Agency and its contractors for health care practice and technology assessment.

(2) CONSULTATIONS.—In carrying out this subsection, the Director shall cooperate and consult with the Assistant Secretary for Health, the Administrator of the Centers for Medicare & Medicaid Services, the Director of the National Institutes of Health, the Commissioner of Food and Drugs, and the heads of any other interested Federal department or agency, and shall seek input, where appropriate, from professional societies and other private and public entities.

(3) METHODOLOGY.—The Director shall, in developing the methods used under paragraph (1), consider—

(A) safety, efficacy, and effectiveness;

(B) legal, social, and ethical implications;

(C) costs, benefits, and cost-effectiveness;

(D) comparisons to alternate health care practices and technologies; and

(E) requirements of Food and Drug Administration approval to avoid duplication.

(c) SPECIFIC ASSESSMENTS.—

(1) IN GENERAL.—The Director shall conduct or support specific assessments of health care technologies and practices.

(2) REQUESTS FOR ASSESSMENTS.—The Director is authorized to conduct or support assessments, on a reimbursable basis, for the Centers for Medicare & Medicaid Services, the Department of Defense, the Department of Veterans Affairs, the Office of Personnel Management, and other public or private entities.

(3) GRANTS AND CONTRACTS.—In addition to conducting assessments, the Director may make grants to, or enter into cooperative agreements or contracts with, entities described in paragraph (4) for the purpose of conducting assessments of experimental, emerging, existing, or potentially outmoded health care technologies, and for related activities.

(4) ELIGIBLE ENTITIES.—An entity described in this paragraph is an entity that is determined to be appropriate by the Director, including academic medical centers, research institutions and organizations, professional organizations, third party payers, governmental agencies, minority institutions of higher education (such as Historically Black Colleges and Universities, and Hispanic institutions), and consortia of appropriate research entities established for the purpose of conducting technology assessments.

(d) MEDICAL EXAMINATION OF CERTAIN VICTIMS.—

(1) IN GENERAL.—The Director shall develop and disseminate a report on evidence-based clinical practices for—

(A) the examination and treatment by health professionals of individuals who are victims of sexual assault (including child molestation) or attempted sexual assault; and

(B) the training of health professionals, in consultation with the Health Resources and Services Administration, on performing medical evidentiary examinations of individuals who are victims of child abuse or neglect, sexual assault, elder abuse, or domestic violence.

(2) CERTAIN CONSIDERATIONS.—In identifying the issues to be addressed by the report, the Director shall, to the extent

practicable, take into consideration the expertise and experience of Federal and State law enforcement officials regarding the victims referred to in paragraph (1), and of other appropriate public and private entities (including medical societies, victim services organizations, sexual assault prevention organizations, and social services organizations).

SEC. 917.[299b–6] COORDINATION OF FEDERAL GOVERNMENT QUALITY IMPROVEMENT EFFORTS.

(a) REQUIREMENT.—

(1) IN GENERAL.—To avoid duplication and ensure that Federal resources are used efficiently and effectively, the Secretary, acting through the Director, shall coordinate all research, evaluations, and demonstrations related to health services research, quality measurement and quality improvement activities undertaken and supported by the Federal Government.

(2) SPECIFIC ACTIVITIES.—The Director, in collaboration with the appropriate Federal officials representing all concerned executive agencies and departments, shall develop and manage a process to—

(A) improve interagency coordination, priority setting, and the use and sharing of research findings and data pertaining to Federal quality improvement programs, technology assessment, and health services research;

(B) strengthen the research information infrastructure, including databases, pertaining to Federal health services research and health care quality improvement initiatives;

(C) set specific goals for participating agencies and departments to further health services research and health care quality improvement; and

(D) strengthen the management of Federal health care quality improvement programs.

(b) STUDY BY THE INSTITUTE OF MEDICINE.—

(1) IN GENERAL.—To provide Congress, the Department of Health and Human Services, and other relevant departments with an independent, external review of their quality oversight, quality improvement and quality research programs, the Secretary shall enter into a contract with the Institute of Medicine—

(A) to describe and evaluate current quality improvement, quality research and quality monitoring processes through—

(i) an overview of pertinent health services research activities and quality improvement efforts conducted by all Federal programs, with particular attention paid to those under titles XVIII, XIX, and XXI of the Social Security Act; and

(ii) a summary of the partnerships that the Department of Health and Human Services has pursued with private accreditation, quality measurement and improvement organizations; and

(B) to identify options and make recommendations to improve the efficiency and effectiveness of quality improvement programs through—

(i) the improved coordination of activities across the medicare, medicaid and child health insurance programs under titles XVIII, XIX and XXI of the Social Security Act and health services research programs;

(ii) the strengthening of patient choice and participation by incorporating state-of-the-art quality monitoring tools and making information on quality available; and

(iii) the enhancement of the most effective programs, consolidation as appropriate, and elimination of duplicative activities within various Federal agencies.

(2) REQUIREMENTS.—

(A) IN GENERAL.—The Secretary shall enter into a contract with the Institute of Medicine for the preparation—

(i) not later than 12 months after the date of the enactment of this title, of a report providing an overview of the quality improvement programs of the Department of Health and Human Services for the medicare, medicaid, and CHIP programs under titles XVIII, XIX, and XXI of the Social Security Act; and

(ii) not later than 24 months after the date of the enactment of this title, of a final report containing recommendations.

(B) REPORTS.—The Secretary shall submit the reports described in subparagraph (A) to the Committee on Finance and the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Ways and Means and the Committee on Commerce of the House of Representatives.

PART C—PATIENT SAFETY IMPROVEMENT

SEC. 921.[299b–21] DEFINITIONS.

In this part:

(1) HIPAA CONFIDENTIALITY REGULATIONS.—The term "HIPAA confidentiality regulations" means regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191; 110 Stat. 2033).

(2) IDENTIFIABLE PATIENT SAFETY WORK PRODUCT.—The term "identifiable patient safety work product" means patient safety work product that—

(A) is presented in a form and manner that allows the identification of any provider that is a subject of the work product, or any providers that participate in activities that are a subject of the work product;

(B) constitutes individually identifiable health information as that term is defined in the HIPAA confidentiality regulations; or

(C) is presented in a form and manner that allows the identification of an individual who reported information in the manner specified in section 922(e).

(3) NONIDENTIFIABLE PATIENT SAFETY WORK PRODUCT.—The term "nonidentifiable patient safety work product" means patient safety work product that is not identifiable patient safety work product (as defined in paragraph (2)).

(4) PATIENT SAFETY ORGANIZATION.—The term "patient safety organization" means a private or public entity or component thereof that is listed by the Secretary pursuant to section 924(d).

(5) PATIENT SAFETY ACTIVITIES.—The term "patient safety activities" means the following activities:

(A) Efforts to improve patient safety and the quality of health care delivery.

(B) The collection and analysis of patient safety work product.

(C) The development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices.

(D) The utilization of patient safety work product for the purposes of encouraging a culture of safety and of providing feedback and assistance to effectively minimize patient risk.

(E) The maintenance of procedures to preserve confidentiality with respect to patient safety work product.

(F) The provision of appropriate security measures with respect to patient safety work product.

(G) The utilization of qualified staff.

(H) Activities related to the operation of a patient safety evaluation system and to the provision of feedback to participants in a patient safety evaluation system.

(6) PATIENT SAFETY EVALUATION SYSTEM.—The term "patient safety evaluation system" means the collection, management, or analysis of information for reporting to or by a patient safety organization.

(7) PATIENT SAFETY WORK PRODUCT.—

(A) IN GENERAL.—Except as provided in subparagraph (B), the term "patient safety work product" means any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements—

(i) which—

(I) are assembled or developed by a provider for reporting to a patient safety organization and are reported to a patient safety organization; or

(II) are developed by a patient safety organization for the conduct of patient safety activities;

and which could result in improved patient safety, health care quality, or health care outcomes; or

(ii) which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a patient safety evaluation system.

(B) CLARIFICATION.—

(i) Information described in subparagraph (A) does not include a patient's medical record, billing and discharge information, or any other original patient or provider record.

(ii) Information described in subparagraph (A) does not include information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system. Such separate information or a copy thereof reported to a patient safety organization shall not by reason of its reporting be considered patient safety work product.

(iii) Nothing in this part shall be construed to limit—

(I) the discovery of or admissibility of information described in this subparagraph in a criminal, civil, or administrative proceeding;

(II) the reporting of information described in this subparagraph to a Federal, State, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight purposes; or

(III) a provider's recordkeeping obligation with respect to information described in this subparagraph under Federal, State, or local law.

(8) PROVIDER.—The term "provider" means—

(A) an individual or entity licensed or otherwise authorized under State law to provide health care services, including—

(i) a hospital, nursing facility, comprehensive outpatient rehabilitation facility, home health agency, hospice program, renal dialysis facility, ambulatory surgical center, pharmacy, physician or health care practitioner's office, long term care facility, behavior health residential treatment facility, clinical laboratory, or health center; or

(ii) a physician, physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, psychologist, certified social worker, registered dietitian or nutrition professional, physical or occupational therapist, pharmacist, or other individual health care practitioner; or

(B) any other individual or entity specified in regulations promulgated by the Secretary.

SEC. 922.[299b–22] PRIVILEGE AND CONFIDENTIALITY PROTECTIONS.

(a) PRIVILEGE.—Notwithstanding any other provision of Federal, State, or local law, and subject to subsection (c), patient safety work product shall be privileged and shall not be—

(1) subject to a Federal, State, or local civil, criminal, or administrative subpoena or order, including in a Federal, State, or local civil or administrative disciplinary proceeding against a provider;

(2) subject to discovery in connection with a Federal, State, or local civil, criminal, or administrative proceeding, including in a Federal, State, or local civil or administrative disciplinary proceeding against a provider;

(3) subject to disclosure pursuant to section 552 of title 5, United States Code (commonly known as the Freedom of Information Act) or any other similar Federal, State, or local law;

(4) admitted as evidence in any Federal, State, or local governmental civil proceeding, criminal proceeding, administrative rulemaking proceeding, or administrative adjudicatory proceeding, including any such proceeding against a provider; or

(5) admitted in a professional disciplinary proceeding of a professional disciplinary body established or specifically authorized under State law.

(b) CONFIDENTIALITY OF PATIENT SAFETY WORK PRODUCT.—Notwithstanding any other provision of Federal, State, or local law, and subject to subsection (c), patient safety work product shall be confidential and shall not be disclosed.

(c) EXCEPTIONS.—Except as provided in subsection (g)(3)—

(1) EXCEPTIONS FROM PRIVILEGE AND CONFIDENTIALITY.—Subsections (a) and (b) shall not apply to (and shall not be construed to prohibit) one or more of the following disclosures:

(A) Disclosure of relevant patient safety work product for use in a criminal proceeding, but only after a court makes an in camera determination that such patient safety work product contains evidence of a criminal act and that such patient safety work product is material to the proceeding and not reasonably available from any other source.

(B) Disclosure of patient safety work product to the extent required to carry out subsection (f)(4)(A).

(C) Disclosure of identifiable patient safety work product if authorized by each provider identified in such work product.

(2) EXCEPTIONS FROM CONFIDENTIALITY.—Subsection (b) shall not apply to (and shall not be construed to prohibit) one or more of the following disclosures:

(A) Disclosure of patient safety work product to carry out patient safety activities.

(B) Disclosure of nonidentifiable patient safety work product.

(C) Disclosure of patient safety work product to grantees, contractors, or other entities carrying out research, evaluation, or demonstration projects authorized, funded, certified, or otherwise sanctioned by rule or other means by the Secretary, for the purpose of conducting research to the extent that disclosure of protected health information would be allowed for such purpose under the HIPAA confidentiality regulations.

(D) Disclosure by a provider to the Food and Drug Administration with respect to a product or activity regulated by the Food and Drug Administration.

(E) Voluntary disclosure of patient safety work product by a provider to an accrediting body that accredits that provider.

(F) Disclosures that the Secretary may determine, by rule or other means, are necessary for business operations and are consistent with the goals of this part.

(G) Disclosure of patient safety work product to law enforcement authorities relating to the commission of a crime (or to an event reasonably believed to be a crime) if the person making the disclosure believes, reasonably under the circumstances, that the patient safety work product that is disclosed is necessary for criminal law enforcement purposes.

(H) With respect to a person other than a patient safety organization, the disclosure of patient safety work product that does not include materials that—

(i) assess the quality of care of an identifiable provider; or

(ii) describe or pertain to one or more actions or failures to act by an identifiable provider.

(3) EXCEPTION FROM PRIVILEGE.—Subsection (a) shall not apply to (and shall not be construed to prohibit) voluntary disclosure of nonidentifiable patient safety work product.

(d) CONTINUED PROTECTION OF INFORMATION AFTER DISCLOSURE.—

(1) IN GENERAL.—Patient safety work product that is disclosed under subsection (c) shall continue to be privileged and confidential as provided for in subsections (a) and (b), and such disclosure shall not be treated as a waiver of privilege or confidentiality, and the privileged and confidential nature of such work product shall also apply to such work product in the possession or control of a person to whom such work product was disclosed.

(2) EXCEPTION.—Notwithstanding paragraph (1), and subject to paragraph (3)—

(A) if patient safety work product is disclosed in a criminal proceeding, the confidentiality protections provided for in subsection (b) shall no longer apply to the work product so disclosed; and

(B) if patient safety work product is disclosed as provided for in subsection (c)(2)(B) (relating to disclosure of nonidentifiable patient safety work product), the privilege and confidentiality protections provided for in subsections (a) and (b) shall no longer apply to such work product.

(3) CONSTRUCTION.—Paragraph (2) shall not be construed as terminating or limiting the privilege or confidentiality protections provided for in subsection (a) or (b) with respect to patient safety work product other than the specific patient safety work product disclosed as provided for in subsection (c).

(4) LIMITATIONS ON ACTIONS.—

(A) PATIENT SAFETY ORGANIZATIONS.—

(i) IN GENERAL.—A patient safety organization shall not be compelled to disclose information collected or developed under this part whether or not such in-

formation is patient safety work product unless such information is identified, is not patient safety work product, and is not reasonably available from another source.

(ii) NONAPPLICATION.—The limitation contained in clause (i) shall not apply in an action against a patient safety organization or with respect to disclosures pursuant to subsection (c)(1).

(B) PROVIDERS.—An accrediting body shall not take an accrediting action against a provider based on the good faith participation of the provider in the collection, development, reporting, or maintenance of patient safety work product in accordance with this part. An accrediting body may not require a provider to reveal its communications with any patient safety organization established in accordance with this part.

(e) REPORTER PROTECTION.—

(1) IN GENERAL.—A provider may not take an adverse employment action, as described in paragraph (2), against an individual based upon the fact that the individual in good faith reported information—

(A) to the provider with the intention of having the information reported to a patient safety organization; or

(B) directly to a patient safety organization.

(2) ADVERSE EMPLOYMENT ACTION.—For purposes of this subsection, an "adverse employment action" includes—

(A) loss of employment, the failure to promote an individual, or the failure to provide any other employment-related benefit for which the individual would otherwise be eligible; or

(B) an adverse evaluation or decision made in relation to accreditation, certification, credentialing, or licensing of the individual.

(f) ENFORCEMENT.—

(1) CIVIL MONETARY PENALTY.—Subject to paragraphs (2) and (3), a person who discloses identifiable patient safety work product in knowing or reckless violation of subsection (b) shall be subject to a civil monetary penalty of not more than $10,000 for each act constituting such violation.

(2) PROCEDURE.—The provisions of section 1128A of the Social Security Act, other than subsections (a) and (b) and the first sentence of subsection (c)(1), shall apply to civil money penalties under this subsection in the same manner as such provisions apply to a penalty or proceeding under section 1128A of the Social Security Act.

(3) RELATION TO HIPAA.—Penalties shall not be imposed both under this subsection and under the regulations issued pursuant to section 264(c)(1) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d-2 note) for a single act or omission.

(4) EQUITABLE RELIEF.—

(A) IN GENERAL.—Without limiting remedies available to other parties, a civil action may be brought by any aggrieved individual to enjoin any act or practice that violates subsection (e) and to obtain other appropriate equi-

table relief (including reinstatement, back pay, and restoration of benefits) to redress such violation.

(B) AGAINST STATE EMPLOYEES.—An entity that is a State or an agency of a State government may not assert the privilege described in subsection (a) unless before the time of the assertion, the entity or, in the case of and with respect to an agency, the State has consented to be subject to an action described in subparagraph (A), and that consent has remained in effect.

(g) RULE OF CONSTRUCTION.—Nothing in this section shall be construed—

(1) to limit the application of other Federal, State, or local laws that provide greater privilege or confidentiality protections than the privilege and confidentiality protections provided for in this section;

(2) to limit, alter, or affect the requirements of Federal, State, or local law pertaining to information that is not privileged or confidential under this section;

(3) except as provided in subsection (i), to alter or affect the implementation of any provision of the HIPAA confidentiality regulations or section 1176 of the Social Security Act (or regulations promulgated under such section);

(4) to limit the authority of any provider, patient safety organization, or other entity to enter into a contract requiring greater confidentiality or delegating authority to make a disclosure or use in accordance with this section;

(5) as preempting or otherwise affecting any State law requiring a provider to report information that is not patient safety work product; or

(6) to limit, alter, or affect any requirement for reporting to the Food and Drug Administration information regarding the safety of a product or activity regulated by the Food and Drug Administration.

(h) CLARIFICATION.—Nothing in this part prohibits any person from conducting additional analysis for any purpose regardless of whether such additional analysis involves issues identical to or similar to those for which information was reported to or assessed by a patient safety organization or a patient safety evaluation system.

(i) CLARIFICATION OF APPLICATION OF HIPAA CONFIDENTIALITY REGULATIONS TO PATIENT SAFETY ORGANIZATIONS.—For purposes of applying the HIPAA confidentiality regulations—

(1) patient safety organizations shall be treated as business associates; and

(2) patient safety activities of such organizations in relation to a provider are deemed to be health care operations (as defined in such regulations) of the provider.

(j) REPORTS ON STRATEGIES TO IMPROVE PATIENT SAFETY.—

(1) DRAFT REPORT.—Not later than the date that is 18 months after any network of patient safety databases is operational, the Secretary, in consultation with the Director, shall prepare a draft report on effective strategies for reducing medical errors and increasing patient safety. The draft report shall include any measure determined appropriate by the Secretary

to encourage the appropriate use of such strategies, including use in any federally funded programs. The Secretary shall make the draft report available for public comment and submit the draft report to the Institute of Medicine for review.

(2) FINAL REPORT.—Not later than 1 year after the date described in paragraph (1), the Secretary shall submit a final report to the Congress.

SEC. 923.[299b–23] NETWORK OF PATIENT SAFETY DATABASES.

(a) IN GENERAL.—The Secretary shall facilitate the creation of, and maintain, a network of patient safety databases that provides an interactive evidence-based management resource for providers, patient safety organizations, and other entities. The network of databases shall have the capacity to accept, aggregate across the network, and analyze nonidentifiable patient safety work product voluntarily reported by patient safety organizations, providers, or other entities. The Secretary shall assess the feasibility of providing for a single point of access to the network for qualified researchers for information aggregated across the network and, if feasible, provide for implementation.

(b) DATA STANDARDS.—The Secretary may determine common formats for the reporting to and among the network of patient safety databases maintained under subsection (a) of nonidentifiable patient safety work product, including necessary work product elements, common and consistent definitions, and a standardized computer interface for the processing of such work product. To the extent practicable, such standards shall be consistent with the administrative simplification provisions of part C of title XI of the Social Security Act.

(c) USE OF INFORMATION.—Information reported to and among the network of patient safety databases under subsection (a) shall be used to analyze national and regional statistics, including trends and patterns of health care errors. The information resulting from such analyses shall be made available to the public and included in the annual quality reports prepared under section 913(b)(2).

SEC. 924.[299b–24] PATIENT SAFETY ORGANIZATION CERTIFICATION AND LISTING.

(a) CERTIFICATION.—

(1) INITIAL CERTIFICATION.—An entity that seeks to be a patient safety organization shall submit an initial certification to the Secretary that the entity—

(A) has policies and procedures in place to perform each of the patient safety activities described in section 921(5); and

(B) upon being listed under subsection (d), will comply with the criteria described in subsection (b).

(2) SUBSEQUENT CERTIFICATIONS.—An entity that is a patient safety organization shall submit every 3 years after the date of its initial listing under subsection (d) a subsequent certification to the Secretary that the entity—

(A) is performing each of the patient safety activities described in section 921(5); and

(B) is complying with the criteria described in subsection (b).

(b) CRITERIA.—

(1) IN GENERAL.—The following are criteria for the initial and subsequent certification of an entity as a patient safety organization:

(A) The mission and primary activity of the entity are to conduct activities that are to improve patient safety and the quality of health care delivery.

(B) The entity has appropriately qualified staff (whether directly or through contract), including licensed or certified medical professionals.

(C) The entity, within each 24-month period that begins after the date of the initial listing under subsection (d), has bona fide contracts, each of a reasonable period of time, with more than 1 provider for the purpose of receiving and reviewing patient safety work product.

(D) The entity is not, and is not a component of, a health insurance issuer (as defined in section 2791(b)(2)).

(E) The entity shall fully disclose—

(i) any financial, reporting, or contractual relationship between the entity and any provider that contracts with the entity; and

(ii) if applicable, the fact that the entity is not managed, controlled, and operated independently from any provider that contracts with the entity.

(F) To the extent practical and appropriate, the entity collects patient safety work product from providers in a standardized manner that permits valid comparisons of similar cases among similar providers.

(G) The utilization of patient safety work product for the purpose of providing direct feedback and assistance to providers to effectively minimize patient risk.

(2) ADDITIONAL CRITERIA FOR COMPONENT ORGANIZATIONS.—If an entity that seeks to be a patient safety organization is a component of another organization, the following are additional criteria for the initial and subsequent certification of the entity as a patient safety organization:

(A) The entity maintains patient safety work product separately from the rest of the organization, and establishes appropriate security measures to maintain the confidentiality of the patient safety work product.

(B) The entity does not make an unauthorized disclosure under this part of patient safety work product to the rest of the organization in breach of confidentiality.

(C) The mission of the entity does not create a conflict of interest with the rest of the organization.

(c) REVIEW OF CERTIFICATION.—

(1) IN GENERAL.—

(A) INITIAL CERTIFICATION.—Upon the submission by an entity of an initial certification under subsection (a)(1), the Secretary shall determine if the certification meets the requirements of subparagraphs (A) and (B) of such subsection.

(B) SUBSEQUENT CERTIFICATION.—Upon the submission by an entity of a subsequent certification under sub-

section (a)(2), the Secretary shall review the certification with respect to requirements of subparagraphs (A) and (B) of such subsection.

(2) NOTICE OF ACCEPTANCE OR NON-ACCEPTANCE.—If the Secretary determines that—

(A) an entity's initial certification meets requirements referred to in paragraph (1)(A), the Secretary shall notify the entity of the acceptance of such certification; or

(B) an entity's initial certification does not meet such requirements, the Secretary shall notify the entity that such certification is not accepted and the reasons therefor.

(3) DISCLOSURES REGARDING RELATIONSHIP TO PROVIDERS.—The Secretary shall consider any disclosures under subsection (b)(1)(E) by an entity and shall make public findings on whether the entity can fairly and accurately perform the patient safety activities of a patient safety organization. The Secretary shall take those findings into consideration in determining whether to accept the entity's initial certification and any subsequent certification submitted under subsection (a) and, based on those findings, may deny, condition, or revoke acceptance of the entity's certification.

(d) LISTING.—The Secretary shall compile and maintain a listing of entities with respect to which there is an acceptance of a certification pursuant to subsection (c)(2)(A) that has not been revoked under subsection (e) or voluntarily relinquished.

(e) REVOCATION OF ACCEPTANCE OF CERTIFICATION.—

(1) IN GENERAL.—If, after notice of deficiency, an opportunity for a hearing, and a reasonable opportunity for correction, the Secretary determines that a patient safety organization does not meet the certification requirements under subsection (a)(2), including subparagraphs (A) and (B) of such subsection, the Secretary shall revoke the Secretary's acceptance of the certification of such organization.

(2) SUPPLYING CONFIRMATION OF NOTIFICATION TO PROVIDERS.—Within 15 days of a revocation under paragraph (1), a patient safety organization shall submit to the Secretary a confirmation that the organization has taken all reasonable actions to notify each provider whose patient safety work product is collected or analyzed by the organization of such revocation.

(3) PUBLICATION OF DECISION.—If the Secretary revokes the certification of an organization under paragraph (1), the Secretary shall—

(A) remove the organization from the listing maintained under subsection (d); and

(B) publish notice of the revocation in the Federal Register.

(f) STATUS OF DATA AFTER REMOVAL FROM LISTING.—

(1) NEW DATA.—With respect to the privilege and confidentiality protections described in section 922, data submitted to an entity within 30 days after the entity is removed from the listing under subsection (e)(3)(A) shall have the same status as data submitted while the entity was still listed.

(2) PROTECTION TO CONTINUE TO APPLY.—If the privilege and confidentiality protections described in section 922 applied

to patient safety work product while an entity was listed, or to data described in paragraph (1), such protections shall continue to apply to such work product or data after the entity is removed from the listing under subsection (e)(3)(A).

(g) DISPOSITION OF WORK PRODUCT AND DATA.—If the Secretary removes a patient safety organization from the listing as provided for in subsection (e)(3)(A), with respect to the patient safety work product or data described in subsection (f)(1) that the patient safety organization received from another entity, such former patient safety organization shall—

(1) with the approval of the other entity and a patient safety organization, transfer such work product or data to such patient safety organization;

(2) return such work product or data to the entity that submitted the work product or data; or

(3) if returning such work product or data to such entity is not practicable, destroy such work product or data.

SEC. 925.[299b–24a] ACTIVITIES REGARDING WOMEN'S HEALTH.

(a) ESTABLISHMENT.—There is established within the Office of the Director, an Office of Women's Health and Gender-Based Research (referred to in this section as the "Office"). The Office shall be headed by a director who shall be appointed by the Director of Healthcare and Research Quality.

(b) PURPOSE.—The official designated under subsection (a) shall—

(1) report to the Director on the current Agency level of activity regarding women's health, across, where appropriate, age, biological, and sociocultural contexts, in all aspects of Agency work, including the development of evidence reports and clinical practice protocols and the conduct of research into patient outcomes, delivery of health care services, quality of care, and access to health care;

(2) establish short-range and long-range goals and objectives within the Agency for research important to women's health and, as relevant and appropriate, coordinate with other appropriate offices on activities within the Agency that relate to health services and medical effectiveness research, for issues of particular concern to women;

(3) identify projects in women's health that should be conducted or supported by the Agency;

(4) consult with health professionals, nongovernmental organizations, consumer organizations, women's health professionals, and other individuals and groups, as appropriate, on Agency policy with regard to women; and

(5) serve as a member of the Department of Health and Human Services Coordinating Committee on Women's Health (established under section 229(b)(4)).

(c) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2010 through 2014.

SEC. 926.[299b–25] TECHNICAL ASSISTANCE.

The Secretary, acting through the Director, may provide technical assistance to patient safety organizations, including convening annual meetings for patient safety organizations to discuss methodology, communication, data collection, or privacy concerns.

SEC. 927.[299b–26] SEVERABILITY.

If any provision of this part is held to be unconstitutional, the remainder of this part shall not be affected.

PART D—HEALTH CARE QUALITY IMPROVEMENT

Subpart I—Quality Measure Development

SEC. 931.[299b–31] QUALITY MEASURE DEVELOPMENT.

(a) QUALITY MEASURE.—In this subpart, the term "quality measure" means a standard for measuring the performance and improvement of population health or of health plans, providers of services, and other clinicians in the delivery of health care services.

(b) IDENTIFICATION OF QUALITY MEASURES.—

(1) IDENTIFICATION.—The Secretary, in consultation with the Director of the Agency for Healthcare Research and Quality and the Administrator of the Centers for Medicare & Medicaid Services, shall identify, not less often than triennially, gaps where no quality measures exist and existing quality measures that need improvement, updating, or expansion, consistent with the national strategy under section 399HH, to the extent available, for use in Federal health programs. In identifying such gaps and existing quality measures that need improvement, the Secretary shall take into consideration—

(A) the gaps identified by the entity with a contract under section 1890(a) of the Social Security Act and other stakeholders;

(B) quality measures identified by the pediatric quality measures program under section 1139A of the Social Security Act; and

(C) quality measures identified through the Medicaid Quality Measurement Program under section 1139B of the Social Security Act.

(2) PUBLICATION.—The Secretary shall make available to the public on an Internet website a report on any gaps identified under paragraph (1) and the process used to make such identification.

(c) GRANTS OR CONTRACTS FOR QUALITY MEASURE DEVELOPMENT.—

(1) IN GENERAL.—The Secretary shall award grants, contracts, or intergovernmental agreements to eligible entities for purposes of developing, improving, updating, or expanding quality measures identified under subsection (b).

(2) PRIORITIZATION IN THE DEVELOPMENT OF QUALITY MEASURES.—In awarding grants, contracts, or agreements under this subsection, the Secretary shall give priority to the development of quality measures that allow the assessment of—

(A) health outcomes and functional status of patients;

(B) the management and coordination of health care across episodes of care and care transitions for patients across the continuum of providers, health care settings, and health plans;

(C) the experience, quality, and use of information provided to and used by patients, caregivers, and authorized representatives to inform decisionmaking about treatment options, including the use of shared decisionmaking tools and preference sensitive care (as defined in section 936);

(D) the meaningful use of health information technology;

(E) the safety, effectiveness, patient-centeredness, appropriateness, and timeliness of care;

(F) the efficiency of care;

(G) the equity of health services and health disparities across health disparity populations (as defined in section 485E) and geographic areas;

(H) patient experience and satisfaction;

(I) the use of innovative strategies and methodologies identified under section 933; and

(J) other areas determined appropriate by the Secretary.

(3) ELIGIBLE ENTITIES.—To be eligible for a grant or contract under this subsection, an entity shall—

(A) have demonstrated expertise and capacity in the development and evaluation of quality measures;

(B) have adopted procedures to include in the quality measure development process—

(i) the views of those providers or payers whose performance will be assessed by the measure; and

(ii) the views of other parties who also will use the quality measures (such as patients, consumers, and health care purchasers);

(C) collaborate with the entity with a contract under section 1890(a) of the Social Security Act and other stakeholders, as practicable, and the Secretary so that quality measures developed by the eligible entity will meet the requirements to be considered for endorsement by the entity with a contract under such section 1890(a);

(D) have transparent policies regarding governance and conflicts of interest; and

(E) submit an application to the Secretary at such time and in such manner, as the Secretary may require.

(4) USE OF FUNDS.—An entity that receives a grant, contract, or agreement under this subsection shall use such award to develop quality measures that meet the following requirements:

(A) Such measures support measures required to be reported under the Social Security Act, where applicable, and in support of gaps and existing quality measures that need improvement, as described in subsection (b)(1)(A).

(B) Such measures support measures developed under section 1139A of the Social Security Act and the Medicaid

Quality Measurement Program under section 1139B of such Act, where applicable.

(C) To the extent practicable, data on such quality measures is able to be collected using health information technologies.

(D) Each quality measure is free of charge to users of such measure.

(E) Each quality measure is publicly available on an Internet website.

(d) OTHER ACTIVITIES BY THE SECRETARY.—The Secretary may use amounts available under this section to update and test, where applicable, quality measures endorsed by the entity with a contract under section 1890(a) of the Social Security Act or adopted by the Secretary.

(e) COORDINATION OF GRANTS.—The Secretary shall ensure that grants or contracts awarded under this section are coordinated with grants and contracts awarded under sections 1139A(5) and 1139B(4)(A) of the Social Security Act.

(f) DEVELOPMENT OF OUTCOME MEASURES.—

(1) IN GENERAL.—The Secretary shall develop, and periodically update (not less than every 3 years), provider-level outcome measures for hospitals and physicians, as well as other providers as determined appropriate by the Secretary.

(2) CATEGORIES OF MEASURES.—The measures developed under this subsection shall include, to the extent determined appropriate by the Secretary—

(A) outcome measurement for acute and chronic diseases, including, to the extent feasible, the 5 most prevalent and resource-intensive acute and chronic medical conditions; and

(B) outcome measurement for primary and preventative care, including, to the extent feasible, measurements that cover provision of such care for distinct patient populations (such as healthy children, chronically ill adults, or infirm elderly individuals).

(3) GOALS.—In developing such measures, the Secretary shall seek to—

(A) address issues regarding risk adjustment, accountability, and sample size;

(B) include the full scope of services that comprise a cycle of care; and

(C) include multiple dimensions.

(4) TIMEFRAME.—

(A) ACUTE AND CHRONIC DISEASES.—Not later than 24 months after the date of enactment of this Act, the Secretary shall develop not less than 10 measures described in paragraph (2)(A).

(B) PRIMARY AND PREVENTIVE CARE.—Not later than 36 months after the date of enactment of this Act, the Secretary shall develop not less than 10 measures described in paragraph (2)(B).

Subpart II—Health Care Quality Improvement Programs

SEC. 933.[299b–33] HEALTH CARE DELIVERY SYSTEM RESEARCH.

(a) PURPOSE.—The purposes of this section are to—

(1) enable the Director to identify, develop, evaluate, disseminate, and provide training in innovative methodologies and strategies for quality improvement practices in the delivery of health care services that represent best practices (referred to as "best practices") in health care quality, safety, and value; and

(2) ensure that the Director is accountable for implementing a model to pursue such research in a collaborative manner with other related Federal agencies.

(b) GENERAL FUNCTIONS OF THE CENTER.—The Center for Quality Improvement and Patient Safety of the Agency for Healthcare Research and Quality (referred to in this section as the "Center"), or any other relevant agency or department designated by the Director, shall—

(1) carry out its functions using research from a variety of disciplines, which may include epidemiology, health services, sociology, psychology, human factors engineering, biostatistics, health economics, clinical research, and health informatics;

(2) conduct or support activities consistent with the purposes described in subsection (a), and for—

(A) best practices for quality improvement practices in the delivery of health care services; and

(B) that include changes in processes of care and the redesign of systems used by providers that will reliably result in intended health outcomes, improve patient safety, and reduce medical errors (such as skill development for health care providers in team-based health care delivery and rapid cycle process improvement) and facilitate adoption of improved workflow;

(3) identify health care providers, including health care systems, single institutions, and individual providers, that—

(A) deliver consistently high-quality, efficient health care services (as determined by the Secretary); and

(B) employ best practices that are adaptable and scalable to diverse health care settings or effective in improving care across diverse settings;

(4) assess research, evidence, and knowledge about what strategies and methodologies are most effective in improving health care delivery;

(5) find ways to translate such information rapidly and effectively into practice, and document the sustainability of those improvements;

(6) create strategies for quality improvement through the development of tools, methodologies, and interventions that can successfully reduce variations in the delivery of health care;

(7) identify, measure, and improve organizational, human, or other causative factors, including those related to the cul-

ture and system design of a health care organization, that contribute to the success and sustainability of specific quality improvement and patient safety strategies;

(8) provide for the development of best practices in the delivery of health care services that—

(A) have a high likelihood of success, based on structured review of empirical evidence;

(B) are specified with sufficient detail of the individual processes, steps, training, skills, and knowledge required for implementation and incorporation into workflow of health care practitioners in a variety of settings;

(C) are designed to be readily adapted by health care providers in a variety of settings; and

(D) where applicable, assist health care providers in working with other health care providers across the continuum of care and in engaging patients and their families in improving the care and patient health outcomes;

(9) provide for the funding of the activities of organizations with recognized expertise and excellence in improving the delivery of health care services, including children's health care, by involving multiple disciplines, managers of health care entities, broad development and training, patients, caregivers and families, and frontline health care workers, including activities for the examination of strategies to share best quality improvement practices and to promote excellence in the delivery of health care services; and

(10) build capacity at the State and community level to lead quality and safety efforts through education, training, and mentoring programs to carry out the activities under paragraphs (1) through (9).

(c) RESEARCH FUNCTIONS OF CENTER.—

(1) IN GENERAL.—The Center shall support, such as through a contract or other mechanism, research on health care delivery system improvement and the development of tools to facilitate adoption of best practices that improve the quality, safety, and efficiency of health care delivery services. Such support may include establishing a Quality Improvement Network Research Program for the purpose of testing, scaling, and disseminating of interventions to improve quality and efficiency in health care. Recipients of funding under the Program may include national, State, multi-State, or multi-site quality improvement networks.

(2) RESEARCH REQUIREMENTS.—The research conducted pursuant to paragraph (1) shall—

(A) address the priorities identified by the Secretary in the national strategic plan established under section 399HH;

(B) identify areas in which evidence is insufficient to identify strategies and methodologies, taking into consideration areas of insufficient evidence identified by the entity with a contract under section 1890(a) of the Social Security Act in the report required under section 399JJ;

(C) address concerns identified by health care institutions and providers and communicated through the Center pursuant to subsection (d);

(D) reduce preventable morbidity, mortality, and associated costs of morbidity and mortality by building capacity for patient safety research;

(E) support the discovery of processes for the reliable, safe, efficient, and responsive delivery of health care, taking into account discoveries from clinical research and comparative effectiveness research;

(F) allow communication of research findings and translate evidence into practice recommendations that are adaptable to a variety of settings, and which, as soon as practicable after the establishment of the Center, shall include—

(i) the implementation of a national application of Intensive Care Unit improvement projects relating to the adult (including geriatric), pediatric, and neonatal patient populations;

(ii) practical methods for addressing health care associated infections, including Methicillin-Resistant Staphylococcus Aureus and Vancomycin-Resistant Entercoccus infections and other emerging infections; and

(iii) practical methods for reducing preventable hospital admissions and readmissions;

(G) expand demonstration projects for improving the quality of children's health care and the use of health information technology, such as through Pediatric Quality Improvement Collaboratives and Learning Networks, consistent with provisions of section 1139A of the Social Security Act for assessing and improving quality, where applicable;

(H) identify and mitigate hazards by—

(i) analyzing events reported to patient safety reporting systems and patient safety organizations; and

(ii) using the results of such analyses to develop scientific methods of response to such events;

(I) include the conduct of systematic reviews of existing practices that improve the quality, safety, and efficiency of health care delivery, as well as new research on improving such practices; and

(J) include the examination of how to measure and evaluate the progress of quality and patient safety activities.

(d) DISSEMINATION OF RESEARCH FINDINGS.—

(1) PUBLIC AVAILABILITY.—The Director shall make the research findings of the Center available to the public through multiple media and appropriate formats to reflect the varying needs of health care providers and consumers and diverse levels of health literacy.

(2) LINKAGE TO HEALTH INFORMATION TECHNOLOGY.—The Secretary shall ensure that research findings and results generated by the Center are shared with the Office of the National

Coordinator of Health Information Technology and used to inform the activities of the health information technology extension program under section 3012, as well as any relevant standards, certification criteria, or implementation specifications.

(e) PRIORITIZATION.—The Director shall identify and regularly update a list of processes or systems on which to focus research and dissemination activities of the Center, taking into account—

(1) the cost to Federal health programs;

(2) consumer assessment of health care experience;

(3) provider assessment of such processes or systems and opportunities to minimize distress and injury to the health care workforce;

(4) the potential impact of such processes or systems on health status and function of patients, including vulnerable populations including children;

(5) the areas of insufficient evidence identified under subsection (c)(2)(B); and

(6) the evolution of meaningful use of health information technology, as defined in section 3000.

(f) COORDINATION.—The Center shall coordinate its activities with activities conducted by the Center for Medicare and Medicaid Innovation established under section 1115A of the Social Security Act.

(g) FUNDING.—There is authorized to be appropriated to carry out this section $20,000,000 for fiscal years 2010 through 2014.

SEC. 934.[299b–34] QUALITY IMPROVEMENT TECHNICAL ASSISTANCE AND IMPLEMENTATION.

(a) IN GENERAL.—The Director, through the Center for Quality Improvement and Patient Safety of the Agency for Healthcare Research and Quality (referred to in this section as the "Center"), shall award—

(1) technical assistance grants or contracts to eligible entities to provide technical support to institutions that deliver health care and health care providers (including rural and urban providers of services and suppliers with limited infrastructure and financial resources to implement and support quality improvement activities, providers of services and suppliers with poor performance scores, and providers of services and suppliers for which there are disparities in care among subgroups of patients) so that such institutions and providers understand, adapt, and implement the models and practices identified in the research conducted by the Center, including the Quality Improvement Networks Research Program; and

(2) implementation grants or contracts to eligible entities to implement the models and practices described under paragraph (1).

(b) ELIGIBLE ENTITIES.—

(1) TECHNICAL ASSISTANCE AWARD.—To be eligible to receive a technical assistance grant or contract under subsection (a)(1), an entity—

(A) may be a health care provider, health care provider association, professional society, health care worker organization, Indian health organization, quality improve-

ment organization, patient safety organization, local quality improvement collaborative, the Joint Commission, academic health center, university, physician-based research network, primary care extension program established under section 399V–1, a Federal Indian Health Service program or a health program operated by an Indian tribe (as defined in section 4 of the Indian Health Care Improvement Act), or any other entity identified by the Secretary; and

(B) shall have demonstrated expertise in providing information and technical support and assistance to health care providers regarding quality improvement.

(2) IMPLEMENTATION AWARD.—To be eligible to receive an implementation grant or contract under subsection (a)(2), an entity—

(A) may be a hospital or other health care provider or consortium or providers, as determined by the Secretary; and

(B) shall have demonstrated expertise in providing information and technical support and assistance to health care providers regarding quality improvement.

(c) APPLICATION.—

(1) TECHNICAL ASSISTANCE AWARD.—To receive a technical assistance grant or contract under subsection (a)(1), an eligible entity shall submit an application to the Secretary at such time, in such manner, and containing—

(A) a plan for a sustainable business model that may include a system of—

(i) charging fees to institutions and providers that receive technical support from the entity; and

(ii) reducing or eliminating such fees for such institutions and providers that serve low-income populations; and

(B) such other information as the Director may require.

(2) IMPLEMENTATION AWARD.—To receive a grant or contract under subsection (a)(2), an eligible entity shall submit an application to the Secretary at such time, in such manner, and containing—

(A) a plan for implementation of a model or practice identified in the research conducted by the Center including—

(i) financial cost, staffing requirements, and timeline for implementation; and

(ii) pre- and projected post-implementation quality measure performance data in targeted improvement areas identified by the Secretary; and

(B) such other information as the Director may require.

(d) MATCHING FUNDS.—The Director may not award a grant or contract under this section to an entity unless the entity agrees that it will make available (directly or through contributions from other public or private entities) non-Federal contributions toward the activities to be carried out under the grant or contract in an

amount equal to $1 for each $5 of Federal funds provided under the grant or contract. Such non-Federal matching funds may be provided directly or through donations from public or private entities and may be in cash or in-kind, fairly evaluated, including plant, equipment, or services.

(e) EVALUATION.—

(1) IN GENERAL.—The Director shall evaluate the performance of each entity that receives a grant or contract under this section. The evaluation of an entity shall include a study of—

(A) the success of such entity in achieving the implementation, by the health care institutions and providers assisted by such entity, of the models and practices identified in the research conducted by the Center under section 933;

(B) the perception of the health care institutions and providers assisted by such entity regarding the value of the entity; and

(C) where practicable, better patient health outcomes and lower cost resulting from the assistance provided by such entity.

(2) EFFECT OF EVALUATION.—Based on the outcome of the evaluation of the entity under paragraph (1), the Director shall determine whether to renew a grant or contract with such entity under this section.

(f) COORDINATION.—The entities that receive a grant or contract under this section shall coordinate with health information technology regional extension centers under section 3012(c) and the primary care extension program established under section 399V–1 regarding the dissemination of quality improvement, system delivery reform, and best practices information.

SEC. 935.[299b–35] GRANTS OR CONTRACTS TO IMPLEMENT MEDICATION MANAGEMENT SERVICES IN TREATMENT OF CHRONIC DISEASES.

(a) IN GENERAL.—The Secretary, acting through the Patient Safety Research Center established in section 933 (referred to in this section as the "Center"), shall establish a program to provide grants or contracts to eligible entities to implement medication management (referred to in this section as "MTM") services provided by licensed pharmacists, as a collaborative, multidisciplinary, inter-professional approach to the treatment of chronic diseases for targeted individuals, to improve the quality of care and reduce overall cost in the treatment of such diseases. The Secretary shall commence the program under this section not later than May 1, 2010.

(b) ELIGIBLE ENTITIES.—To be eligible to receive a grant or contract under subsection (a), an entity shall—

(1) provide a setting appropriate for MTM services, as recommended by the experts described in subsection (e);

(2) submit to the Secretary a plan for achieving long-term financial sustainability;

(3) where applicable, submit a plan for coordinating MTM services through local community health teams established in section 3502 of the Patient Protection and Affordable Care Act

or in collaboration with primary care extension programs established in section 399V–1;

(4) submit a plan for meeting the requirements under subsection (c); and

(5) submit to the Secretary such other information as the Secretary may require.

(c) MTM SERVICES TO TARGETED INDIVIDUALS.—The MTM services provided with the assistance of a grant or contract awarded under subsection (a) shall, as allowed by State law including applicable collaborative pharmacy practice agreements, include—

(1) performing or obtaining necessary assessments of the health and functional status of each patient receiving such MTM services;

(2) formulating a medication treatment plan according to therapeutic goals agreed upon by the prescriber and the patient or caregiver or authorized representative of the patient;

(3) selecting, initiating, modifying, recommending changes to, or administering medication therapy;

(4) monitoring, which may include access to, ordering, or performing laboratory assessments, and evaluating the response of the patient to therapy, including safety and effectiveness;

(5) performing an initial comprehensive medication review to identify, resolve, and prevent medication-related problems, including adverse drug events, quarterly targeted medication reviews for ongoing monitoring, and additional followup interventions on a schedule developed collaboratively with the prescriber;

(6) documenting the care delivered and communicating essential information about such care, including a summary of the medication review, and the recommendations of the pharmacist to other appropriate health care providers of the patient in a timely fashion;

(7) providing education and training designed to enhance the understanding and appropriate use of the medications by the patient, caregiver, and other authorized representative;

(8) providing information, support services, and resources and strategies designed to enhance patient adherence with therapeutic regimens;

(9) coordinating and integrating MTM services within the broader health care management services provided to the patient; and

(10) such other patient care services allowed under pharmacist scopes of practice in use in other Federal programs that have implemented MTM services.

(d) TARGETED INDIVIDUALS.—MTM services provided by licensed pharmacists under a grant or contract awarded under subsection (a) shall be offered to targeted individuals who—

(1) take 4 or more prescribed medications (including over-the-counter medications and dietary supplements);

(2) take any "high risk" medications;

(3) have 2 or more chronic diseases, as identified by the Secretary; or

(4) have undergone a transition of care, or other factors, as determined by the Secretary, that are likely to create a high risk of medication-related problems.

(e) CONSULTATION WITH EXPERTS.—In designing and implementing MTM services provided under grants or contracts awarded under subsection (a), the Secretary shall consult with Federal, State, private, public-private, and academic entities, pharmacy and pharmacist organizations, health care organizations, consumer advocates, chronic disease groups, and other stakeholders involved with the research, dissemination, and implementation of pharmacist-delivered MTM services, as the Secretary determines appropriate. The Secretary, in collaboration with this group, shall determine whether it is possible to incorporate rapid cycle process improvement concepts in use in other Federal programs that have implemented MTM services.

(f) REPORTING TO THE SECRETARY.—An entity that receives a grant or contract under subsection (a) shall submit to the Secretary a report that describes and evaluates, as requested by the Secretary, the activities carried out under subsection (c), including quality measures endorsed by the entity with a contract under section 1890 of the Social Security Act, as determined by the Secretary.

(g) EVALUATION AND REPORT.—The Secretary shall submit to the relevant committees of Congress a report which shall—

(1) assess the clinical effectiveness of pharmacist-provided services under the MTM services program, as compared to usual care, including an evaluation of whether enrollees maintained better health with fewer hospitalizations and emergency room visits than similar patients not enrolled in the program;

(2) assess changes in overall health care resource use by targeted individuals;

(3) assess patient and prescriber satisfaction with MTM services;

(4) assess the impact of patient-cost sharing requirements on medication adherence and recommendations for modifications;

(5) identify and evaluate other factors that may impact clinical and economic outcomes, including demographic characteristics, clinical characteristics, and health services use of the patient, as well as characteristics of the regimen, pharmacy benefit, and MTM services provided; and

(6) evaluate the extent to which participating pharmacists who maintain a dispensing role have a conflict of interest in the provision of MTM services, and if such conflict is found, provide recommendations on how such a conflict might be appropriately addressed.

(h) GRANTS OR CONTRACTS TO FUND DEVELOPMENT OF PERFORMANCE MEASURES.—The Secretary may, through the quality measure development program under section 931 of the Public Health Service Act, award grants or contracts to eligible entities for the purpose of funding the development of performance measures that assess the use and effectiveness of medication therapy management services.

SEC. 936.[299b–36] PROGRAM TO FACILITATE SHARED DECISION-MAKING.

(a) PURPOSE.—The purpose of this section is to facilitate collaborative processes between patients, caregivers or authorized representatives, and clinicians that engages the patient, caregiver or authorized representative in decisionmaking, provides patients, caregivers or authorized representatives with information about trade-offs among treatment options, and facilitates the incorporation of patient preferences and values into the medical plan.

(b) DEFINITIONS.—In this section:

(1) PATIENT DECISION AID.—The term "patient decision aid" means an educational tool that helps patients, caregivers or authorized representatives understand and communicate their beliefs and preferences related to their treatment options, and to decide with their health care provider what treatments are best for them based on their treatment options, scientific evidence, circumstances, beliefs, and preferences.

(2) PREFERENCE SENSITIVE CARE.—The term "preference sensitive care" means medical care for which the clinical evidence does not clearly support one treatment option such that the appropriate course of treatment depends on the values of the patient or the preferences of the patient, caregivers or authorized representatives regarding the benefits, harms and scientific evidence for each treatment option, the use of such care should depend on the informed patient choice among clinically appropriate treatment options.

(c) ESTABLISHMENT OF INDEPENDENT STANDARDS FOR PATIENT DECISION AIDS FOR PREFERENCE SENSITIVE CARE.—

(1) CONTRACT WITH ENTITY TO ESTABLISH STANDARDS AND CERTIFY PATIENT DECISION AIDS.—

(A) IN GENERAL.—For purposes of supporting consensus-based standards for patient decision aids for preference sensitive care and a certification process for patient decision aids for use in the Federal health programs and by other interested parties, the Secretary shall have in effect a contract with the entity with a contract under section 1890 of the Social Security Act. Such contract shall provide that the entity perform the duties described in paragraph (2).

(B) TIMING FOR FIRST CONTRACT.—As soon as practicable after the date of the enactment of this section, the Secretary shall enter into the first contract under subparagraph (A).

(C) PERIOD OF CONTRACT.—A contract under subparagraph (A) shall be for a period of 18 months (except such contract may be renewed after a subsequent bidding process).

(2) DUTIES.—The following duties are described in this paragraph:

(A) DEVELOP AND IDENTIFY STANDARDS FOR PATIENT DECISION AIDS.—The entity shall synthesize evidence and convene a broad range of experts and key stakeholders to develop and identify consensus-based standards to evaluate patient decision aids for preference sensitive care.

(B) ENDORSE PATIENT DECISION AIDS.—The entity shall review patient decision aids and develop a certification process whether patient decision aids meet the standards developed and identified under subparagraph (A). The entity shall give priority to the review and certification of patient decision aids for preference sensitive care.

(d) PROGRAM TO DEVELOP, UPDATE AND PATIENT DECISION AIDS TO ASSIST HEALTH CARE PROVIDERS AND PATIENTS.—

(1) IN GENERAL.—The Secretary, acting through the Director, and in coordination with heads of other relevant agencies, such as the Director of the Centers for Disease Control and Prevention and the Director of the National Institutes of Health, shall establish a program to award grants or contracts—

(A) to develop, update, and produce patient decision aids for preference sensitive care to assist health care providers in educating patients, caregivers, and authorized representatives concerning the relative safety, relative effectiveness (including possible health outcomes and impact on functional status), and relative cost of treatment or, where appropriate, palliative care options;

(B) to test such materials to ensure such materials are balanced and evidence based in aiding health care providers and patients, caregivers, and authorized representatives to make informed decisions about patient care and can be easily incorporated into a broad array of practice settings; and

(C) to educate providers on the use of such materials, including through academic curricula.

(2) REQUIREMENTS FOR PATIENT DECISION AIDS.—Patient decision aids developed and produced pursuant to a grant or contract under paragraph (1)—

(A) shall be designed to engage patients, caregivers, and authorized representatives in informed decision-making with health care providers;

(B) shall present up-to-date clinical evidence about the risks and benefits of treatment options in a form and manner that is age-appropriate and can be adapted for patients, caregivers, and authorized representatives from a variety of cultural and educational backgrounds to reflect the varying needs of consumers and diverse levels of health literacy;

(C) shall, where appropriate, explain why there is a lack of evidence to support one treatment option over another; and

(D) shall address health care decisions across the age span, including those affecting vulnerable populations including children.

(3) DISTRIBUTION.—The Director shall ensure that patient decision aids produced with grants or contracts under this section are available to the public.

(4) NONDUPLICATION OF EFFORTS.—The Director shall ensure that the activities under this section of the Agency and other agencies, including the Centers for Disease Control and

Prevention and the National Institutes of Health, are free of unnecessary duplication of effort.

(e) GRANTS TO SUPPORT SHARED DECISIONMAKING IMPLEMENTATION.—

(1) IN GENERAL.—The Secretary shall establish a program to provide for the phased-in development, implementation, and evaluation of shared decisionmaking using patient decision aids to meet the objective of improving the understanding of patients of their medical treatment options.

(2) SHARED DECISIONMAKING RESOURCE CENTERS.—

(A) IN GENERAL.—The Secretary shall provide grants for the establishment and support of Shared Decisionmaking Resource Centers (referred to in this subsection as "Centers") to provide technical assistance to providers and to develop and disseminate best practices and other information to support and accelerate adoption, implementation, and effective use of patient decision aids and shared decisionmaking by providers.

(B) OBJECTIVES.—The objective of a Center is to enhance and promote the adoption of patient decision aids and shared decisionmaking through—

(i) providing assistance to eligible providers with the implementation and effective use of, and training on, patient decision aids; and

(ii) the dissemination of best practices and research on the implementation and effective use of patient decision aids.

(3) SHARED DECISIONMAKING PARTICIPATION GRANTS.—

(A) IN GENERAL.—The Secretary shall provide grants to health care providers for the development and implementation of shared decisionmaking techniques and to assess the use of such techniques.

(B) PREFERENCE.—In order to facilitate the use of best practices, the Secretary shall provide a preference in making grants under this subsection to health care providers who participate in training by Shared Decisionmaking Resource Centers or comparable training.

(C) LIMITATION.—Funds under this paragraph shall not be used to purchase or implement use of patient decision aids other than those certified under the process identified in subsection (c).

(4) GUIDANCE.—The Secretary may issue guidance to eligible grantees under this subsection on the use of patient decision aids.

(f) FUNDING.—For purposes of carrying out this section there are authorized to be appropriated such sums as may be necessary for fiscal year 2010 and each subsequent fiscal year.

SEC. 937.[299b–37] DISSEMINATION AND BUILDING CAPACITY FOR RESEARCH.

(a) IN GENERAL.—

(1) DISSEMINATION.—The Office of Communication and Knowledge Transfer (referred to in this section as the "Office") at the Agency for Healthcare Research and Quality (or any other relevant office designated by Agency for Healthcare Re-

search and Quality), in consultation with the National Institutes of Health, shall broadly disseminate the research findings that are published by the Patient Centered Outcomes Research Institute established under section 1181(b) of the Social Security Act (referred to in this section as the "Institute") and other government-funded research relevant to comparative clinical effectiveness research. The Office shall create informational tools that organize and disseminate research findings for physicians, health care providers, patients, payers, and policy makers. The Office shall also develop a publicly available resource database that collects and contains government-funded evidence and research from public, private, not-for profit, and academic sources.

(2) REQUIREMENTS.—The Office shall provide for the dissemination of the Institute's research findings and government-funded research relevant to comparative clinical effectiveness research to physicians, health care providers, patients, vendors of health information technology focused on clinical decision support, appropriate professional associations, and Federal and private health plans. Materials, forums, and media used to disseminate the findings, informational tools, and resource databases shall—

(A) include a description of considerations for specific subpopulations, the research methodology, and the limitations of the research, and the names of the entities, agencies, instrumentalities, and individuals who conducted any research which was published by the Institute; and

(B) not be construed as mandates, guidelines, or recommendations for payment, coverage, or treatment.

(b) INCORPORATION OF RESEARCH FINDINGS.—The Office, in consultation with relevant medical and clinical associations, shall assist users of health information technology focused on clinical decision support to promote the timely incorporation of research findings disseminated under subsection (a) into clinical practices and to promote the ease of use of such incorporation.

(c) FEEDBACK.—The Office shall establish a process to receive feedback from physicians, health care providers, patients, and vendors of health information technology focused on clinical decision support, appropriate professional associations, and Federal and private health plans about the value of the information disseminated and the assistance provided under this section.

(d) RULE OF CONSTRUCTION.—Nothing in this section shall preclude the Institute from making its research findings publicly available as required under section 1181(d)(8) of the Social Security Act.

(e) TRAINING OF RESEARCHERS.—The Agency for Health Care Research and Quality, in consultation with the National Institutes of Health, shall build capacity for comparative clinical effectiveness research by establishing a grant program that provides for the training of researchers in the methods used to conduct such research, including systematic reviews of existing research and primary research such as clinical trials. At a minimum, such training shall be in methods that meet the methodological standards adopted under section 1181(d)(9) of the Social Security Act.

(f) BUILDING DATA FOR RESEARCH.—The Secretary shall provide for the coordination of relevant Federal health programs to build data capacity for comparative clinical effectiveness research, including the development and use of clinical registries and health outcomes research data networks, in order to develop and maintain a comprehensive, interoperable data network to collect, link, and analyze data on outcomes and effectiveness from multiple sources, including electronic health records.

(g) AUTHORITY TO CONTRACT WITH THE INSTITUTE.—Agencies and instrumentalities of the Federal Government may enter into agreements with the Institute, and accept and retain funds, for the conduct and support of research described in this part, provided that the research to be conducted or supported under such agreements is authorized under the governing statutes of such agencies and instrumentalities.

PART E—GENERAL PROVISIONS

SEC. 941.[299c] ADVISORY COUNCIL FOR HEALTHCARE RESEARCH AND QUALITY.

(a) ESTABLISHMENT.—There is established an advisory council to be known as the National Advisory Council for Healthcare Research and Quality.

(b) DUTIES.—

(1) IN GENERAL.—The Advisory Council shall advise the Secretary and the Director with respect to activities proposed or undertaken to carry out the mission of the Agency under section 901(b).

(2) CERTAIN RECOMMENDATIONS.—Activities of the Advisory Council under paragraph (1) shall include making recommendations to the Director regarding—

(A) priorities regarding health care research, especially studies related to quality, outcomes, cost and the utilization of, and access to, health care services;

(B) the field of health care research and related disciplines, especially issues related to training needs, and dissemination of information pertaining to health care quality; and

(C) the appropriate role of the Agency in each of these areas in light of private sector activity and identification of opportunities for public-private sector partnerships.

(c) MEMBERSHIP.—

(1) IN GENERAL.—The Advisory Council shall, in accordance with this subsection, be composed of appointed members and ex officio members. All members of the Advisory Council shall be voting members other than the individuals designated under paragraph (3)(B) as ex officio members.

(2) APPOINTED MEMBERS.—The Secretary shall appoint to the Advisory Council 21 appropriately qualified individuals. At least 17 members of the Advisory Council shall be representatives of the public who are not officers or employees of the United States and at least 1 member who shall be a specialist in the rural aspects of 1 or more of the professions or fields described in subparagraphs (A) through (G). The Secretary shall

ensure that the appointed members of the Council, as a group, are representative of professions and entities concerned with, or affected by, activities under this title and under section 1142 of the Social Security Act. Of such members—

(A) three shall be individuals distinguished in the conduct of research, demonstration projects, and evaluations with respect to health care;

(B) three shall be individuals distinguished in the fields of health care quality research or health care improvement;

(C) three shall be individuals distinguished in the practice of medicine of which at least one shall be a primary care practitioner;

(D) three shall be individuals distinguished in the other health professions;

(E) three shall be individuals either representing the private health care sector, including health plans, providers, and purchasers or individuals distinguished as administrators of health care delivery systems;

(F) three shall be individuals distinguished in the fields of health care economics, information systems, law, ethics, business, or public policy; and

(G) three shall be individuals representing the interests of patients and consumers of health care.

(3) EX OFFICIO MEMBERS.—The Secretary shall designate as ex officio members of the Advisory Council—

(A) the Assistant Secretary for Health, the Director of the National Institutes of Health, the Director of the Centers for Disease Control and Prevention, the Administrator of the Centers for Medicare & Medicaid Services, the Commissioner of the Food and Drug Administration, the Director of the Office of Personnel Management, the Assistant Secretary of Defense (Health Affairs), and the Under Secretary for Health of the Department of Veterans Affairs; and

(B) such other Federal officials as the Secretary may consider appropriate.

(d) TERMS.—

(1) IN GENERAL.—Members of the Advisory Council appointed under subsection (c)(2) shall serve for a term of 3 years.

(2) STAGGERED TERMS.—To ensure the staggered rotation of one-third of the members of the Advisory Council each year, the Secretary is authorized to appoint the initial members of the Advisory Council for terms of 1, 2, or 3 years.

(3) SERVICE BEYOND TERM.—A member of the Council appointed under subsection (c)(2) may continue to serve after the expiration of the term of the members until a successor is appointed.

(e) VACANCIES.—If a member of the Advisory Council appointed under subsection (c)(2) does not serve the full term applicable under subsection (d), the individual appointed to fill the resulting vacancy shall be appointed for the remainder of the term of the predecessor of the individual.

(f) CHAIR.—The Director shall, from among the members of the Advisory Council appointed under subsection (c)(2), designate an individual to serve as the chair of the Advisory Council.

(g) MEETINGS.—The Advisory Council shall meet not less than once during each discrete 4-month period and shall otherwise meet at the call of the Director or the chair.

(h) COMPENSATION AND REIMBURSEMENT OF EXPENSES.—

(1) APPOINTED MEMBERS.—Members of the Advisory Council appointed under subsection (c)(2) shall receive compensation for each day (including travel time) engaged in carrying out the duties of the Advisory Council unless declined by the member. Such compensation may not be in an amount in excess of the daily equivalent of the annual rate of basic pay prescribed for level IV of the Executive Schedule under section 5315 of title 5, United States Code, for each day during which such member is engaged in the performance of the duties of the Advisory Council.

(2) EX OFFICIO MEMBERS.—Officials designated under subsection (c)(3) as ex officio members of the Advisory Council may not receive compensation for service on the Advisory Council in addition to the compensation otherwise received for duties carried out as officers of the United States.

(i) STAFF.—The Director shall provide to the Advisory Council such staff, information, and other assistance as may be necessary to carry out the duties of the Council.

(j) DURATION.—Notwithstanding section 14(a) of the Federal Advisory Committee Act, the Advisory Council shall continue in existence until otherwise provided by law.

SEC. 942.[299c–1] PEER REVIEW WITH RESPECT TO GRANTS AND CONTRACTS.

(a) REQUIREMENT OF REVIEW.—

(1) IN GENERAL.—Appropriate technical and scientific peer review shall be conducted with respect to each application for a grant, cooperative agreement, or contract under this title.

(2) REPORTS TO DIRECTOR.—Each peer review group to which an application is submitted pursuant to paragraph (1) shall report its finding and recommendations respecting the application to the Director in such form and in such manner as the Director shall require.

(b) APPROVAL AS PRECONDITION OF AWARDS.—The Director may not approve an application described in subsection (a)(1) unless the application is recommended for approval by a peer review group established under subsection (c).

(c) ESTABLISHMENT OF PEER REVIEW GROUPS.—

(1) IN GENERAL.—The Director shall establish such technical and scientific peer review groups as may be necessary to carry out this section. Such groups shall be established without regard to the provisions of title 5, United States Code, that govern appointments in the competitive service, and without regard to the provisions of chapter 51, and subchapter III of chapter 53, of such title that relate to classification and pay rates under the General Schedule.

(2) MEMBERSHIP.—The members of any peer review group established under this section shall be appointed from among

individuals who by virtue of their training or experience are eminently qualified to carry out the duties of such peer review group. Officers and employees of the United States may not constitute more than 25 percent of the membership of any such group. Such officers and employees may not receive compensation for service on such groups in addition to the compensation otherwise received for these duties carried out as such officers and employees.

(3) DURATION.—Notwithstanding section 14(a) of the Federal Advisory Committee Act, peer review groups established under this section may continue in existence until otherwise provided by law.

(4) QUALIFICATIONS.—Members of any peer review group shall, at a minimum, meet the following requirements:

(A) Such members shall agree in writing to treat information received, pursuant to their work for the group, as confidential information, except that this subparagraph shall not apply to public records and public information.

(B) Such members shall agree in writing to recuse themselves from participation in the peer review of specific applications which present a potential personal conflict of interest or appearance of such conflict, including employment in a directly affected organization, stock ownership, or any financial or other arrangement that might introduce bias in the process of peer review.

(d) AUTHORITY FOR PROCEDURAL ADJUSTMENTS IN CERTAIN CASES.—In the case of applications for financial assistance whose direct costs will not exceed $100,000, the Director may make appropriate adjustments in the procedures otherwise established by the Director for the conduct of peer review under this section. Such adjustments may be made for the purpose of encouraging the entry of individuals into the field of research, for the purpose of encouraging clinical practice-oriented or provider-based research, and for such other purposes as the Director may determine to be appropriate.

(e) REGULATIONS.—The Director shall issue regulations for the conduct of peer review under this section.

SEC. 943.[299c–2] CERTAIN PROVISIONS WITH RESPECT TO DEVELOPMENT, COLLECTION, AND DISSEMINATION OF DATA.

(a) STANDARDS WITH RESPECT TO UTILITY OF DATA.—

(1) IN GENERAL.—To ensure the utility, accuracy, and sufficiency of data collected by or for the Agency for the purpose described in section 901(b), the Director shall establish standard methods for developing and collecting such data, taking into consideration—

(A) other Federal health data collection standards; and

(B) the differences between types of health care plans, delivery systems, health care providers, and provider arrangements.

(2) RELATIONSHIP WITH OTHER DEPARTMENT PROGRAMS.—In any case where standards under paragraph (1) may affect the administration of other programs carried out by the Department of Health and Human Services, including the programs under title XVIII, XIX or XXI of the Social Security Act, or

may affect health information that is subject to a standard developed under part C of title XI of the Social Security Act, they shall be in the form of recommendations to the Secretary for such program.

(b) STATISTICS AND ANALYSES.—The Director shall—

(1) take appropriate action to ensure that statistics and analyses developed under this title are of high quality, timely, and duly comprehensive, and that the statistics are specific, standardized, and adequately analyzed and indexed; and

(2) publish, make available, and disseminate such statistics and analyses on as wide a basis as is practicable.

(c) AUTHORITY REGARDING CERTAIN REQUESTS.—Upon request of a public or private entity, the Director may conduct or support research or analyses otherwise authorized by this title pursuant to arrangements under which such entity will pay the cost of the services provided. Amounts received by the Director under such arrangements shall be available to the Director for obligation until expended.

SEC. 944.[299c–3] DISSEMINATION OF INFORMATION.

(a) IN GENERAL.—The Director shall—

(1) without regard to section 501 of title 44, United States Code, promptly publish, make available, and otherwise disseminate, in a form understandable and on as broad a basis as practicable so as to maximize its use, the results of research, demonstration projects, and evaluations conducted or supported under this title;

(2) ensure that information disseminated by the Agency is science-based and objective and undertakes consultation as necessary to assess the appropriateness and usefulness of the presentation of information that is targeted to specific audiences;

(3) promptly make available to the public data developed in such research, demonstration projects, and evaluations;

(4) provide, in collaboration with the National Library of Medicine where appropriate, indexing, abstracting, translating, publishing, and other services leading to a more effective and timely dissemination of information on research, demonstration projects, and evaluations with respect to health care to public and private entities and individuals engaged in the improvement of health care delivery and the general public, and undertake programs to develop new or improved methods for making such information available; and

(5) as appropriate, provide technical assistance to State and local government and health agencies and conduct liaison activities to such agencies to foster dissemination.

(b) PROHIBITION AGAINST RESTRICTIONS.—Except as provided in subsection (c), the Director may not restrict the publication or dissemination of data from, or the results of, projects conducted or supported under this title.

(c) LIMITATION ON USE OF CERTAIN INFORMATION.—No information, if an establishment or person supplying the information or described in it is identifiable, obtained in the course of activities undertaken or supported under this title may be used for any pur-

pose other than the purpose for which it was supplied unless such establishment or person has consented (as determined under regulations of the Director) to its use for such other purpose. Such information may not be published or released in other form if the person who supplied the information or who is described in it is identifiable unless such person has consented (as determined under regulations of the Director) to its publication or release in other form.

(d) PENALTY.—Any person who violates subsection (c) shall be subject to a civil monetary penalty of not more than $10,000 for each such violation involved. Such penalty shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1128A of the Social Security Act are imposed and collected.

SEC. 945.[299c–4] ADDITIONAL PROVISIONS WITH RESPECT TO GRANTS AND CONTRACTS.

(a) FINANCIAL CONFLICTS OF INTEREST.—With respect to projects for which awards of grants, cooperative agreements, or contracts are authorized to be made under this title, the Director shall by regulation define—

(1) the specific circumstances that constitute financial interests in such projects that will, or may be reasonably expected to, create a bias in favor of obtaining results in the projects that are consistent with such interests; and

(2) the actions that will be taken by the Director in response to any such interests identified by the Director.

(b) REQUIREMENT OF APPLICATION.—The Director may not, with respect to any program under this title authorizing the provision of grants, cooperative agreements, or contracts, provide any such financial assistance unless an application for the assistance is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Director determines to be necessary to carry out the program involved.

(c) PROVISION OF SUPPLIES AND SERVICES IN LIEU OF FUNDS.—

(1) IN GENERAL.—Upon the request of an entity receiving a grant, cooperative agreement, or contract under this title, the Secretary may, subject to paragraph (2), provide supplies, equipment, and services for the purpose of aiding the entity in carrying out the project involved and, for such purpose, may detail to the entity any officer or employee of the Department of Health and Human Services.

(2) CORRESPONDING REDUCTION IN FUNDS.—With respect to a request described in paragraph (1), the Secretary shall reduce the amount of the financial assistance involved by an amount equal to the costs of detailing personnel and the fair market value of any supplies, equipment, or services provided by the Director. The Secretary shall, for the payment of expenses incurred in complying with such request, expend the amounts withheld.

(d) APPLICABILITY OF CERTAIN PROVISIONS WITH RESPECT TO CONTRACTS.—Contracts may be entered into under this part without regard to sections 3648 and 3709 of the Revised Statutes (31 U.S.C. 529 and 41 U.S.C. 5).

SEC. 946.[299c–5] CERTAIN ADMINISTRATIVE AUTHORITIES.

(a) DEPUTY DIRECTOR AND OTHER OFFICERS AND EMPLOYEES.—

(1) DEPUTY DIRECTOR.—The Director may appoint a deputy director for the Agency.

(2) OTHER OFFICERS AND EMPLOYEES.—The Director may appoint and fix the compensation of such officers and employees as may be necessary to carry out this title. Except as otherwise provided by law, such officers and employees shall be appointed in accordance with the civil service laws and their compensation fixed in accordance with title 5, United States Code.

(b) FACILITIES.—The Secretary, in carrying out this title—

(1) may acquire, without regard to the Act of March 3, 1877 (40 U.S.C. 34), by lease or otherwise through the Administrator of General Services, buildings or portions of buildings in the District of Columbia or communities located adjacent to the District of Columbia for use for a period not to exceed 10 years; and

(2) may acquire, construct, improve, repair, operate, and maintain laboratory, research, and other necessary facilities and equipment, and such other real or personal property (including patents) as the Secretary deems necessary.

(c) PROVISION OF FINANCIAL ASSISTANCE.—The Director, in carrying out this title, may make grants to public and nonprofit entities and individuals, and may enter into cooperative agreements or contracts with public and private entities and individuals.

(d) UTILIZATION OF CERTAIN PERSONNEL AND RESOURCES.—

(1) DEPARTMENT OF HEALTH AND HUMAN SERVICES.—The Director, in carrying out this title, may utilize personnel and equipment, facilities, and other physical resources of the Department of Health and Human Services, permit appropriate (as determined by the Secretary) entities and individuals to utilize the physical resources of such Department, and provide technical assistance and advice.

(2) OTHER AGENCIES.—The Director, in carrying out this title, may use, with their consent, the services, equipment, personnel, information, and facilities of other Federal, State, or local public agencies, or of any foreign government, with or without reimbursement of such agencies.

(e) CONSULTANTS.—The Secretary, in carrying out this title, may secure, from time to time and for such periods as the Director deems advisable but in accordance with section 3109 of title 5, United States Code, the assistance and advice of consultants from the United States or abroad.

(f) EXPERTS.—

(1) IN GENERAL.—The Secretary may, in carrying out this title, obtain the services of not more than 50 experts or consultants who have appropriate scientific or professional qualifications. Such experts or consultants shall be obtained in accordance with section 3109 of title 5, United States Code, except that the limitation in such section on the duration of service shall not apply.

(2) TRAVEL EXPENSES.—

(A) IN GENERAL.—Experts and consultants whose services are obtained under paragraph (1) shall be paid or re-

imbursed for their expenses associated with traveling to and from their assignment location in accordance with sections 5724, 5724a(a), 5724a(c), and 5726(c) of title 5, United States Code.

(B) LIMITATION.—Expenses specified in subparagraph (A) may not be allowed in connection with the assignment of an expert or consultant whose services are obtained under paragraph (1) unless and until the expert agrees in writing to complete the entire period of assignment, or 1 year, whichever is shorter, unless separated or reassigned for reasons that are beyond the control of the expert or consultant and that are acceptable to the Secretary. If the expert or consultant violates the agreement, the money spent by the United States for the expenses specified in subparagraph (A) is recoverable from the expert or consultant as a statutory obligation owed to the United States. The Secretary may waive in whole or in part a right of recovery under this subparagraph.

(g) VOLUNTARY AND UNCOMPENSATED SERVICES.—The Director, in carrying out this title, may accept voluntary and uncompensated services.

SEC. 947.[299c–6] FUNDING.

(a) INTENT.—To ensure that the United States investment in biomedical research is rapidly translated into improvements in the quality of patient care, there must be a corresponding investment in research on the most effective clinical and organizational strategies for use of these findings in daily practice. The authorization levels in subsections (b) and (c) provide for a proportionate increase in health care research as the United States investment in biomedical research increases.

(b) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this title, there are authorized to be appropriated $250,000,000 for fiscal year 2000, and such sums as may be necessary for each of the fiscal years 2001 through 2005.

(c) EVALUATIONS.—In addition to amounts available pursuant to subsection (b) for carrying out this title, there shall be made available for such purpose, from the amounts made available pursuant to section 241 (relating to evaluations), an amount equal to 40 percent of the maximum amount authorized in such section 241 to be made available for a fiscal year.

(d) HEALTH DISPARITIES RESEARCH.—For the purpose of carrying out the activities under section 903, there are authorized to be appropriated $50,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 through 2005.

(e) PATIENT SAFETY AND QUALITY IMPROVEMENT.—For the purpose of carrying out part C, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2006 through 2010.

SEC. 948.[299c–7] DEFINITIONS.

In this title:

(1) ADVISORY COUNCIL.—The term "Advisory Council" means the National Advisory Council on Healthcare Research and Quality established under section 941.

(2) AGENCY.—The term "Agency" means the Agency for Healthcare Research and Quality.

(3) DIRECTOR.—The term "Director" means the Director of the Agency for Healthcare Research and Quality.

PUBLIC HEALTH SERVICE ACT

As Amended Through P.L. 112–240, Enacted January 2, 2013

TITLE X—POPULATION RESEARCH AND VOLUNTARY FAMILY PLANNING PROGRAMS

PROJECT GRANTS AND CONTRACTS FOR FAMILY PLANNING SERVICES.

SEC. 1001.[300] (a) The Secretary is authorized to make grants to and enter into contracts with public or nonprofit private entities to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services (including natural family planning methods, infertility services, and services for adolescents). To the extent practicable, entities which receive grants or contracts under this subsection shall encourage familiy[1] participation in projects assisted under this subsection.

(b) In making grants and contracts under this section the Secretary shall take into account the number of patients to be served, the extent to which family planning services are needed locally, the relative need of the applicant, and its capacity to make rapid and effective use of such assistance. Local and regional entities shall be assured the right to apply for direct grants and contracts under this section, and the Secretary shall by regulation fully provide for and protect such right.

(c) The Secretary, at the request of a recipient of a grant under subsection (a), may reduce the amount of such grant by the fair market value of any supplies or equipment furnished the grant recipient by the Secretary. The amount by which any such grant is so reduced shall be available for payment by the Secretary of the costs incurred in furnishing the supplies or equipment on which the reduction of such grant is based. Such amount shall be deemed as part of the grant and shall be deemed to have been paid to the grant recipient.

(d) For the purpose of making grants and contracts under this section, there are authorized to be appropriated $30,000,000 for the fiscal year ending June 30, 1971; $60,000,000 for the fiscal year ending June 30, 1972; $111,500,000 for the fiscal year ending June 30, 1973; $111,500,000 each for the fiscal years ending June 30, 1974, and June 30, 1975; $115,000,000 for fiscal year 1976; $115,000,000 for the fiscal year ending September 30, 1977; $136,400,000 for the fiscal year ending September 30, 1978; $200,000,000 for the fiscal year ending September 30, 1979; $230,000,000 for the fiscal year ending September 30, 1980; $264,500,000 for the fiscal year ending September 30, 1981;

[1] So in law. See section 931(b)(1) of Public Law 97–35 (95 Stat. 570). Probably should be "family".

$126,510,000 for the fiscal year ending September 30, 1982; $139,200,000 for the fiscal year ending September 30, 1983; $150,030,000 for the fiscal year ending September 30, 1984; and $158,400,000 for the fiscal year ending September 30, 1985.

FORMULA GRANTS TO STATES FOR FAMILY PLANNING SERVICES.

SEC. 1002.[300a] (a) The Secretary is authorized to make grants, from allotments made under subsection (b), to State health authorities to assist in planning, establishing, maintaining, coordinating, and evaluating family planning services. No grant may be made to a State health authority under this section unless such authority has submitted, and had approved by the Secretary, a State plan for a coordinated and comprehensive program of family planning services.

(b) The sums appropriated to carry out the provisions of this section shall be allotted to the States by the Secretary on the basis of the population and the financial need of the respective States.

(c) For the purposes of this section, the term "State" includes the Commonwealth of Puerto Rico, the Northern Mariana Islands, Guam, American Samoa, the Virgin Islands, the District of Columbia, and the Trust Territory of the Pacific Islands.

(d) For the purpose of making grants under this section, there are authorized to be appropriated $10,000,000 for the fiscal year ending June 30, 1971; $15,000,000 for the fiscal year ending June 30, 1972; and $20,000,000 for the fiscal year ending June 30, 1973.

TRAINING GRANTS AND CONTRACTS.

SEC. 1003.[300a–1] (a) The Secretary is authorized to make grants to public or nonprofit private entities and to enter into contracts with public or private entities and individuals to provide the training for personnel to carry out family planning service programs described in section 1001 or 1002.

(b) For the purpose of making payments pursuant to grants and contracts under this section, there are authorized to be appropriated $2,000,000 for the fiscal year ending June 30, 1971; $3,000,000 for the fiscal year ending June 30, 1972; $4,000,000 for the fiscal year ending June 30, 1973; and $3,000,000 each for the fiscal years ending June 30, 1974, and June 30, 1975; $4,000,000 for fiscal year 1976; $5,000,000 for the fiscal year ending September 30, 1977; $3,000,000 for the fiscal year ending September 30, 1978; $3,100,000 for the fiscal year ending September 30, 1979; $3,600,000 for the fiscal year ending September 30, 1980; $4,100,000 for the fiscal year ending September 30, 1981; $2,920,000 for the fiscal year ending September 30, 1982; $3,200,000 for the fiscal year ending September 30, 1983; $3,500,000 for the fiscal year ending September 30, 1984; and $3,500,000 for the fiscal year ending September 30, 1985.

RESEARCH.

SEC. 1004.[300a–2] The Secretary may—

(1) conduct, and

(2) make grants to public or nonprofit private entities and enter into contracts with public or private entities and individuals for projects for,

research in the biomedical, contraceptive development, behavioral, and program implementation fields related to family planning and population.

INFORMATIONAL AND EDUCATIONAL MATERIALS.

SEC. 1005.[300a–3] (a) The Secretary is authorized to make grants to public or nonprofit private entities and to enter into contracts with public or private entities and individuals to assist in developing and making available family planning and population growth information (including educational materials) to all persons desiring such information (or materials).

(b) For the purpose of making payments pursuant to grants and contracts under this section, there are authorized to be appropriated $750,000 for the fiscal year ending June 30, 1971; $1,000,000 for the fiscal year ending June 30, 1972; $1,250,000 for the fiscal year ending June 30, 1973; $909,000 each for the fiscal years ending June 30, 1974, and June 30, 1975; $2,000,000 for fiscal year 1976; $2,500,000 for the fiscal year ending September 30, 1977; $600,000 for the fiscal year ending September 30, 1978; $700,000 for the fiscal year ending September 30, 1979; $805,000 for the fiscal year ending September 30, 1980; $926,000 for the fiscal year ending September 30, 1981; $570,000 for the fiscal year ending September 30, 1982; $600,000 for the fiscal year ending September 30, 1983; $670,000 for the fiscal year ending September 30, 1984; and $700,000 for the fiscal year ending September 30, 1985.

REGULATIONS AND PAYMENTS.

SEC. 1006.[300a–4] (a) Grants and contracts made under this title shall be made in accordance with such regulations as the Secretary may promulgate. The amount of any grant under any section of this title shall be determined by the Secretary; except that no grant under any such section for any program or project for a fiscal year beginning after June 30, 1975, may be made for less than 90 per centum of its costs (as determined under regulations of the Secretary) unless the grant is to be made for a program or project for which a grant was made (under the same section) for the fiscal year ending June 30, 1975, for less than 90 per centum of its costs (as so determined), in which case a grant under such section for that program or project for a fiscal year beginning after that date may be made for a percentage which shall not be less than the percentage of its costs for which the fiscal year 1975 grant was made.

(b) Grants under this title shall be payable in such installments and subject to such conditions as the Secretary may determine to be appropriate to assure that such grants will be effectively utilized for the purposes for which made.

(c) A grant may be made or contract entered into under section 1001 or 1002 for a family planning service project or program only upon assurances satisfactory to the Secretary that—

(1) priority will be given in such project or program to the furnishing of such services to persons from low-income families; and

(2) no charge will be made in such project or program for services provided to any person from a low-income family except to the extent that payment will be made by a third party (including a government agency) which is authorized or is under legal obligation to pay such charge.

For purposes of this subsection, the term "low-income family" shall be defined by the Secretary in accordance with such criteria as he may prescribe so as to insure that economic status shall not be a deterrent to participation in the programs assisted under this title.

(d)(1) A grant may be made or a contract entered into under section 1001 or 1005 only upon assurances satisfactory to the Secretary that informational or educational materials developed or made available under the grant or contract will be suitable for the purposes of this title and for the population or community to which they are to be made available, taking into account the educational and cultural background of the individuals to whom such materials are addressed and the standards of such population or community with respect to such materials.

(2) In the case of any grant or contract under section 1001, such assurances shall provide for the review and approval of the suitability of such materials, prior to their distribution, by an advisory committee established by the grantee or contractor in accordance with the Secretary's regulations. Such a committee shall include individuals broadly representative of the population or community to which the materials are to be made available.

VOLUNTARY PARTICIPATION.

SEC. 1007.[300a–5] The acceptance by any individual of family planning services or family planning or population growth information (including educational materials) provided through financial assistance under this title (whether by grant or contract) shall be voluntary and shall not be a prerequisite to eligibility for or receipt of any other service or assistance from, or to participation in, any other program of the entity or individual that provided such service or information.

PROHIBITION OF ABORTION.

SEC. 1008.[2][300a–6] None of the funds appropriated under this title shall be used in programs where abortion is a method of family planning.

[2] Section 1009 was repealed by section 601(a)(1)(G) of Public Law 105–362 (112 Stat. 3285).

PUBLIC HEALTH SERVICE ACT

As Amended Through P.L. 112–240, Enacted January 2, 2013

TITLE XI—GENETIC DISEASES, HEMOPHILIA PROGRAMS, AND SUDDEN INFANT DEATH SYNDROME

PART A—GENETIC DISEASES

RESEARCH PROJECT GRANTS AND CONTRACTS.

SEC. 1102.[300b–1] In carrying out section 301, the Secretary, may make grants to public and nonprofit private entities, and may enter into contracts with public and private entities and individuals, for projects for (1) basic or applied research leading to the understanding, diagnosis, treatment, and control of genetic diseases, (2) planning, establishing, demonstrating, and developing special programs for the training of genetic counselors, social and behavioral scientists, and other health professionals, (3) the development of programs to educate practicing physicians, other health professionals and the public regarding the nature of genetic processes, the inheritance patterns of genetic diseases, and the means, methods, and facilities available to diagnose, control, counsel, and treat genetic diseases, and (4) the development of counseling and testing programs and other programs for the diagnosis, control, and treatment of genetic diseases. In making grants and entering into contracts for projects described in clause (1) of the preceding sentence, the Secretary shall give priority to applications for such grants or contracts which are submitted for research on sickle cell anemia and for research on Cooley's anemia.

VOLUNTARY PARTICIPATION.

SEC. 1103.[300b–2] The participation by any individual in any program or portion thereof under this part shall be wholly voluntary and shall not be a prerequisite to eligibility for or receipt of any other service or assistance from, or to participation in, any other program.

APPLICATION; ADMINISTRATION OF GRANTS AND CONTRACT PROGRAMS.

SEC. 1104.[300b–3] (a) A grant or contract under this part may be made upon application submitted to the Secretary at such time, in such manner, and containing and accompanied by such information, as the Secretary may require including assurances for an evaluation whether performed by the applicant or by the Secretary. Such grant or contract may be made available on less than a state-wide or regional basis. Each applicant shall—

(1) provide that the programs and activities for which assistance under this part is sought will be administered by or under the supervision of the applicant;

(2) provide for strict confidentiality of all test results, medical records, and other information regarding testing, diagnosis, counseling, or treatment of any person treated, except for (A) such information as the patient (or his guardian) gives informed consent to be released, or (B) statistical data compiled without reference to the identity of any such patient;

(3) provide for community representation where appropriate in the development and operation of voluntary genetic testing or counseling programs funded by a grant or contract under this part; and

(4) establish fiscal control and fund accounting procedures as may be necessary to assure proper disbursement of and accounting of Federal funds paid to the applicant under this part.

(b) In making grants and entering into contracts for any fiscal year under section 301 for projects described in section 1102 the Secretary shall give special consideration to applications from entities that received grants from, or entered into contracts with, the Secretary for the preceding fiscal year for the conduct of comprehensive sickle cell centers or sickle cell screening and education clinics.

PUBLIC HEALTH SERVICE FACILITIES.

SEC. 1105.[300b–4] The Secretary shall establish a program within the Service to provide voluntary testing, diagnosis, counseling, and treatment of individuals respecting genetic diseases. Services under such program shall be made available through facilities of the Service to persons requesting such services, and the program shall provide appropriate publicity of the availability and voluntary nature of such services.

SEC. 1106.

APPLIED TECHNOLOGY.

SEC. 1107.[300b–6] The Secretary, acting through an identifiable administrative unit, shall—

(1) conduct epidemiological assessments and surveillance of genetic diseases to define the scope and extent of such diseases and the need for programs for the diagnosis, treatment, and control of such diseases, screening for such diseases, and the counseling of persons with such diseases;

(2) on the basis of the assessments and surveillance described in paragraph (1), develop for use by the States programs which combine in an effective manner diagnosis, treatment, and control of such diseases, screening for such diseases, and counseling of persons with such diseases; and

(3) on the basis of the assessments and surveillance described in paragraph (1), provide technical assistance to States to implement the programs developed under paragraph (2) and train appropriate personnel for such programs.

In carrying out this section, the Secretary may, from funds allotted for use under section 502(a) of the Social Security Act, make grants

to or contracts with public or nonprofit private entities (including grants and contracts for demonstration projects).

TOURETTE SYNDROME.

SEC. 1108.[300b–7] (a) IN GENERAL.—The Secretary shall develop and implement outreach programs to educate the public, health care providers, educators and community based organizations about the etiology, symptoms, diagnosis and treatment of Tourette Syndrome, with a particular emphasis on children with Tourette Syndrome. Such programs may be carried out by the Secretary directly and through awards of grants or contracts to public or nonprofit private entities.

(b) CERTAIN ACTIVITIES.—Activities under subsection (a) shall include—

(1) the production and translation of educational materials, including public service announcements;

(2) the development of training material for health care providers, educators and community based organizations; and

(3) outreach efforts directed at the misdiagnosis and underdiagnosis of Tourette Syndrome in children and in minority groups.

(c) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005.

SEC. 1109.[300b–8] IMPROVED NEWBORN AND CHILD SCREENING FOR HERITABLE DISORDERS.

(a) AUTHORIZATION OF GRANT PROGRAM.—From amounts appropriated under subsection (j), the Secretary, acting through the Administrator of the Health Resources and Services Administration (referred to in this section as the "Administrator") and in consultation with the Advisory Committee on Heritable Disorders in Newborns and Children (referred to in this section as the "Advisory Committee"), shall award grants to eligible entities to enable such entities—

(1) to enhance, improve or expand the ability of State and local public health agencies to provide screening, counseling, or health care services to newborns and children having or at risk for heritable disorders;

(2) to assist in providing health care professionals and newborn screening laboratory personnel with education in newborn screening and training in relevant and new technologies in newborn screening and congenital, genetic, and metabolic disorders;

(3) to develop and deliver educational programs (at appropriate literacy levels) about newborn screening counseling, testing, follow-up, treatment, and specialty services to parents, families, and patient advocacy and support groups; and

(4) to establish, maintain, and operate a system to assess and coordinate treatment relating to congenital, genetic, and metabolic disorders.

(b) ELIGIBLE ENTITY.—In this section, the term "eligible entity" means—

(1) a State or a political subdivision of a State;

(2) a consortium of 2 or more States or political subdivisions of States;

(3) a territory;

(4) a health facility or program operated by or pursuant to a contract with or grant from the Indian Health Service; or

(5) any other entity with appropriate expertise in newborn screening, as determined by the Secretary.

(c) APPROVAL FACTORS.—An application submitted for a grant under subsection (a)(1) shall not be approved by the Secretary unless the application contains assurances that the eligible entity has adopted and implemented, is in the process of adopting and implementing, or will use amounts received under such grant to adopt and implement the guidelines and recommendations of the Advisory Committee that are adopted by the Secretary and in effect at the time the grant is awarded or renewed under this section, which shall include the screening of each newborn for the heritable disorders recommended by the Advisory Committee and adopted by the Secretary.

(d) COORDINATION.—The Secretary shall take all necessary steps to coordinate programs funded with grants received under this section and to coordinate with existing newborn screening activities.

(e) LIMITATION.—An eligible entity may not use amounts received under this section to—

(1) provide cash payments to or on behalf of affected individuals;

(2) provide inpatient services;

(3) purchase land or make capital improvements to property; or

(4) provide for proprietary research or training.

(f) VOLUNTARY PARTICIPATION.—The participation by any individual in any program or portion thereof established or operated with funds received under this section shall be wholly voluntary and shall not be a prerequisite to eligibility for or receipt of any other service or assistance from, or to participation in, another Federal or State program.

(g) SUPPLEMENT NOT SUPPLANT.—Funds appropriated under this section shall be used to supplement and not supplant other Federal, State, and local public funds provided for activities of the type described in this section.

(h) PUBLICATION.—

(1) IN GENERAL.—An application submitted under subsection (c)(2)[1] shall be made public by the State in such a manner as to facilitate comment from any person, including through hearings and other methods used to facilitate comments from the public.

(2) COMMENTS.—Comments received by the State after the publication described in paragraph (1) shall be addressed in the application submitted under subsection (c)(2).

[1] Subsection (c)(2) was stricken by section 2(1) of the Newborn Screening Saves Lives Act of 2007 (Public Law 110–204).

(i) TECHNICAL ASSISTANCE.—The Secretary shall provide to entities receiving grants under subsection (a) such technical assistance as may be necessary to ensure the quality of programs conducted under this section.

(j) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated—

(1) to provide grants for the purpose of carrying out activities under subsection (a)(1), $15,000,000 for fiscal year 2009;[2] $15,187,500 for fiscal year 2010, $15,375,000 for fiscal year 2011, $15,562,500 for fiscal year 2012, and $15,750,000 for fiscal year 2013; and

(2) to provide grants for the purpose of carrying out activities under paragraphs (2), (3), and (4) of subsection (a), $15,000,000 for fiscal year 2009, $15,187,500 for fiscal year 2010, $15,375,000 for fiscal year 2011, $15,562,500 for fiscal year 2012, and $15,750,000 for fiscal year 2013.

SEC. 1110.[300b–9] EVALUATING THE EFFECTIVENESS OF NEWBORN AND CHILD SCREENING PROGRAMS.

(a) IN GENERAL.—The Secretary shall award grants to eligible entities to provide for the conduct of demonstration programs to evaluate the effectiveness of screening, counseling or health care services in reducing the morbidity and mortality caused by heritable disorders in newborns and children.

(b) DEMONSTRATION PROGRAMS.—A demonstration program conducted under a grant under this section shall be designed to evaluate and assess, within the jurisdiction of the entity receiving such grant—

(1) the effectiveness of screening, counseling, testing or specialty services for newborns and children at risk for heritable disorders in reducing the morbidity and mortality associated with such disorders;

(2) the effectiveness of screening, counseling, testing or specialty services in accurately and reliably diagnosing heritable disorders in newborns and children; or

(3) the availability of screening, counseling, testing or specialty services for newborns and children at risk for heritable disorders.

(c) ELIGIBLE ENTITIES.—To be eligible to receive a grant under subsection (a) an entity shall be a State or political subdivision of a State, or a consortium of two or more States or political subdivisions of States.

(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $5,000,000 for fiscal year 2009, $5,062,500 for fiscal year 2010, $5,125,000 for fiscal year 2011, $5,187,500 for fiscal year 2012, and $5,250,000 for fiscal year 2013.

SEC. 1111.[300b–10] ADVISORY COMMITTEE ON HERITABLE DISORDERS IN NEWBORNS AND CHILDREN.

(a) ESTABLISHMENT.—The Secretary shall establish an advisory committee to be known as the "Advisory Committee on Heritable Disorders in Newborns and Children" (referred to in this section as the "Advisory Committee").

[2] So in law. The semicolon after the dollar amount for fiscal year 2009 should be a comma.

(b) DUTIES.—The Advisory Committee shall—

(1) provide advice and recommendations to the Secretary concerning grants and projects awarded or funded under section 1109;

(2) provide technical information to the Secretary for the development of policies and priorities for the administration of grants under section 1109;

(3) make systematic evidence-based and peer-reviewed recommendations that include the heritable disorders that have the potential to significantly impact public health for which all newborns should be screened, including secondary conditions that may be identified as a result of the laboratory methods used for screening;

(4) develop a model decision-matrix for newborn screening expansion, including an evaluation of the potential public health impact of such expansion, and periodically update the recommended uniform screening panel, as appropriate, based on such decision-matrix;

(5) consider ways to ensure that all States attain the capacity to screen for the conditions described in paragraph (3), and include in such consideration the results of grant funding under section 1109; and

(6) provide such recommendations, advice or information as may be necessary to enhance, expand or improve the ability of the Secretary to reduce the mortality or morbidity from heritable disorders, which may include recommendations, advice, or information dealing with—

(A) follow-up activities, including those necessary to achieve rapid diagnosis in the short-term, and those that ascertain long-term case management outcomes and appropriate access to related services;

(B) implementation, monitoring, and evaluation of newborn screening activities, including diagnosis, screening, follow-up, and treatment activities;

(C) diagnostic and other technology used in screening;

(D) the availability and reporting of testing for conditions for which there is no existing treatment;

(E) conditions not included in the recommended uniform screening panel that are treatable with Food and Drug Administration-approved products or other safe and effective treatments, as determined by scientific evidence and peer review;

(F) minimum standards and related policies and procedures used by State newborn screening programs, such as language and terminology used by State newborn screening programs to include standardization of case definitions and names of disorders for which newborn screening tests are performed;

(G) quality assurance, oversight, and evaluation of State newborn screening programs, including ensuring that tests and technologies used by each State meet established standards for detecting and reporting positive screening results;

(H) public and provider awareness and education;

(I) the cost and effectiveness of newborn screening and medical evaluation systems and intervention programs conducted by State-based programs;

(J) identification of the causes of, public health impacts of, and risk factors for heritable disorders; and

(K) coordination of surveillance activities, including standardized data collection and reporting, harmonization of laboratory definitions for heritable disorders and testing results, and confirmatory testing and verification of positive results, in order to assess and enhance monitoring of newborn diseases.

(c) MEMBERSHIP.—

(1) IN GENERAL.—The Secretary shall appoint not to exceed 15 members to the Advisory Committee. In appointing such members, the Secretary shall ensure that the total membership of the Advisory Committee is an odd number.

(2) REQUIRED MEMBERS.—The Secretary shall appoint to the Advisory Committee under paragraph (1)—

(A) the Administrator of the Health Resources and Services Administration;

(B) the Director of the Centers for Disease Control and Prevention;

(C) the Director of the National Institutes of Health;

(D) the Director of the Agency for Healthcare Research and Quality;

(E) the Commissioner of the Food and Drug Administration;

(F) medical, technical, or scientific professionals with special expertise in heritable disorders, or in providing screening, counseling, testing or specialty services for newborns and children at risk for heritable disorders;

(G) individuals with expertise in ethics and infectious diseases who have worked and published material in the area of newborn screening;

(H) members of the public having special expertise about or concern with heritable disorders; and

(I) representatives from such Federal agencies, public health constituencies, and medical professional societies as determined to be necessary by the Secretary, to fulfill the duties of the Advisory Committee, as established under subsection (b).

(d) DECISION ON RECOMMENDATIONS.—

(1) IN GENERAL.—Not later than 180 days after the Advisory Committee issues a recommendation pursuant to this section, the Secretary shall adopt or reject such recommendation.

(2) PENDING RECOMMENDATIONS.—The Secretary shall adopt or reject any recommendation issued by the Advisory Committee that is pending on the date of enactment of the Newborn Screening Saves Lives Act of 2008 by not later than 180 days after the date of enactment of such Act.

(3) DETERMINATIONS TO BE MADE PUBLIC.—The Secretary shall publicize any determination on adopting or rejecting a recommendation of the Advisory Committee pursuant to this subsection, including the justification for the determination.

(e) ANNUAL REPORT.—Not later than 3 years after the date of enactment of the Newborn Screening Saves Lives Act of 2008, and each fiscal year thereafter, the Advisory Committee shall—

(1) publish a report on peer-reviewed newborn screening guidelines, including follow-up and treatment, in the United States;

(2) submit such report to the appropriate committees of Congress, the Secretary, the Interagency Coordinating Committee established under Section 1114, and the State departments of health; and

(3) disseminate such report on as wide a basis as practicable, including through posting on the internet clearinghouse established under section 1112.

(f) CONTINUATION OF OPERATION OF COMMITTEE.—Notwithstanding section 14 of the Federal Advisory Committee Act (5 U.S.C. App.), the Advisory Committee shall continue to operate during the 5-year period beginning on the date of enactment of the Newborn Screening Saves Lives Act of 2008.

(g) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, $1,000,000 for fiscal year 2009, $1,012,500 for fiscal year 2010, $1,025,000 for fiscal year 2011, $1,037,500 for fiscal year 2012, and $1,050,000 for fiscal year 2013.

SEC. 1112.[300b–11] CLEARINGHOUSE OF NEWBORN SCREENING INFORMATION.

(a) IN GENERAL.—The Secretary, acting through the Administrator of the Health Resources and Services Administration (referred to in this part as the "Administrator"), in consultation with the Director of the Centers for Disease Control and Prevention and the Director of the National Institutes of Health, shall establish and maintain a central clearinghouse of current educational and family support and services information, materials, resources, research, and data on newborn screening to—

(1) enable parents and family members of newborns, health professionals, industry representatives, and other members of the public to increase their awareness, knowledge, and understanding of newborn screening;

(2) increase awareness, knowledge, and understanding of newborn diseases and screening services for expectant individuals and families; and

(3) maintain current data on quality indicators to measure performance of newborn screening, such as false-positive rates and other quality indicators as determined by the Advisory Committee under section 1111.

(b) INTERNET AVAILABILITY.—The Secretary, acting through the Administrator, shall ensure that the clearinghouse described under subsection (a)—

(1) is available on the Internet;

(2) includes an interactive forum;

(3) is updated on a regular basis, but not less than quarterly; and

(4) provides—

(A) links to Government-sponsored, non-profit, and other Internet websites of laboratories that have dem-

onstrated expertise in newborn screening that supply research-based information on newborn screening tests currently available throughout the United States;

(B) information about newborn conditions and screening services available in each State from laboratories certified under subpart 2 of part F of title III, including information about supplemental screening that is available but not required, in the State where the infant is born;

(C) current research on both treatable and not-yet treatable conditions for which newborn screening tests are available;

(D) the availability of Federal funding for newborn and child screening for heritable disorders including grants authorized under the Newborn Screening Saves Lives Act of 2008; and

(E) other relevant information as determined appropriate by the Secretary.

(c) NONDUPLICATION.—In developing the clearinghouse under this section, the Secretary shall ensure that such clearinghouse minimizes duplication and supplements, not supplants, existing information sharing efforts.

(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, $2,500,000 for fiscal year 2009, $2,531,250 for fiscal year 2010, $2,562,500 for fiscal year 2011, $2,593,750 for fiscal year 2012, and $2,625,000 for fiscal year 2013.

SEC. 1113.[300b–12] LABORATORY QUALITY.

(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention and in consultation with the Advisory Committee on Heritable Disorders in Newborns and Children established under section 1111, shall provide for—

(1) quality assurance for laboratories involved in screening newborns and children for heritable disorders, including quality assurance for newborn-screening tests, performance evaluation services, and technical assistance and technology transfer to newborn screening laboratories to ensure analytic validity and utility of screening tests; and

(2) appropriate quality control and other performance test materials to evaluate the performance of new screening tools.

(b) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $5,000,000 for fiscal year 2009, $5,062,500 for fiscal year 2010, $5,125,000 for fiscal year 2011, $5,187,500 for fiscal year 2012, and $5,250,000 for fiscal year 2013.

SEC. 1114.[300b–13] INTERAGENCY COORDINATING COMMITTEE ON NEWBORN AND CHILD SCREENING.

(a) PURPOSE.—It is the purpose of this section to—

(1) assess existing activities and infrastructure, including activities on birth defects and developmental disabilities authorized under section 317C, in order to make recommendations for programs to collect, analyze, and make available data on the heritable disorders recommended by the Advisory Committee on Heritable Disorders in Newborns and Children under

section 1111, including data on the incidence and prevalence of, as well as poor health outcomes resulting from, such disorders; and

(2) make recommendations for the establishment of regional centers for the conduct of applied epidemiological research on effective interventions to promote the prevention of poor health outcomes resulting from such disorders as well as providing information and education to the public on such effective interventions.

(b) ESTABLISHMENT.—The Secretary shall establish an Interagency Coordinating Committee on Newborn and Child Screening (referred to in this section as the "Interagency Coordinating Committee") to carry out the purpose of this section.

(c) COMPOSITION.—The Interagency Coordinating Committee shall be composed of the Director of the Centers for Disease Control and Prevention, the Administrator, the Director of the Agency for Healthcare Research and Quality, and the Director of the National Institutes of Health, or their designees.

(d) ACTIVITIES.—The Interagency Coordinating Committee shall—

(1) report to the Secretary and the appropriate committees of Congress on its recommendations related to the purpose described in subsection (a); and

(2) carry out other activities determined appropriate by the Secretary.

(e) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $1,000,000 for fiscal year 2009, $1,012,500 for fiscal year 2010, $1,025,000 for fiscal year 2011, $1,037,500 for fiscal year 2012, and $1,050,000 for fiscal year 2013.

SEC. 1115.[300b–14] NATIONAL CONTINGENCY PLAN FOR NEWBORN SCREENING.

(a) IN GENERAL.—Not later than 180 days after the date of enactment of this section, the Secretary, acting through the Director of the Centers for Disease Control and Prevention and in consultation with the Administrator and State departments of health (or related agencies), shall develop a national contingency plan for newborn screening for use by a State, region, or consortia[3] of States in the event of a public health emergency.

(b) CONTENTS.—The contingency plan developed under subsection (a) shall include a plan for—

(1) the collection and transport of specimens;

(2) the shipment of specimens to State newborn screening laboratories;

(3) the processing of specimens;

(4) the reporting of screening results to physicians and families;

(5) the diagnostic confirmation of positive screening results;

(6) ensuring the availability of treatment and management resources;

[3] The reference to "consortia of States" in subsection (a) probably should refer to the "consortium of States".

(7) educating families about newborn screening; and

(8) carrying out other activities determined appropriate by the Secretary.

SEC. 1116.[300b–15] HUNTER KELLY RESEARCH PROGRAM.

(a) NEWBORN SCREENING ACTIVITIES.—

(1) IN GENERAL.—The Secretary, in conjunction with the Director of the National Institutes of Health and taking into consideration the recommendations of the Advisory Committee, may continue carrying out, coordinating, and expanding research in newborn screening (to be known as "Hunter Kelly Newborn Screening Research Program") including—

(A) identifying, developing, and testing the most promising new screening technologies, in order to improve already existing screening tests, increase the specificity of newborn screening, and expand the number of conditions for which screening tests are available;

(B) experimental treatments and disease management strategies for additional newborn conditions, and other genetic, metabolic, hormonal, or functional conditions that can be detected through newborn screening for which treatment is not yet available; and

(C) other activities that would improve newborn screening, as identified by the Director.

(2) ADDITIONAL NEWBORN CONDITION.—For purposes of this subsection, the term "additional newborn condition" means any condition that is not one of the core conditions recommended by the Advisory Committee and adopted by the Secretary.

(b) FUNDING.—In carrying out the research program under this section, the Secretary and the Director shall ensure that entities receiving funding through the program will provide assurances, as practicable, that such entities will work in consultation with the appropriate State departments of health, and, as practicable, focus their research on screening technology not currently performed in the States in which the entities are located, and the conditions on the uniform screening panel (or the standard test existing on the uniform screening panel).

(c) REPORTS.—The Director is encouraged to include information about the activities carried out under this section in the biennial report required under section 403 of the National Institutes of Health Reform Act of 2006. If such information is included, the Director shall make such information available to be included on the Internet Clearinghouse established under section 1112.

(d) NONDUPLICATION.—In carrying out programs under this section, the Secretary shall minimize duplication and supplement, not supplant, existing efforts of the type carried out under this section.

(e) PEER REVIEW.—Nothing in this section shall be construed to interfere with the scientific peer-review process at the National Institutes of Health.

PART B—SUDDEN INFANT DEATH SYNDROME

SUDDEN INFANT DEATH SYNDROME RESEARCH AND RESEARCH REPORTS.

SEC. 1122.[300c–12] From the sums appropriated to the Eunice Kennedy Shriver National Institute of Child Health and Human Development, the Secretary shall assure that there are applied to research of the type described in subparagraphs (A) and (B) of subsection (b)(1) of this section such amounts each year as will be adequate, given the leads and findings then available from such research, in order to make maximum feasible progress toward identification of infants at risk of sudden infant death syndrome and prevention of sudden infant death syndrome.

PART C—HEMOPHILIA PROGRAMS

BLOOD SEPARATION CENTERS.

SEC. 1132.[300c–22] (a) The Secretary may make grants to and enter into contracts with public and nonprofit private entities for projects to develop and expand, within existing facilities, blood-separation centers to separate and make available for distribution blood components to providers of blood services and manufacturers of blood fractions. For purposes of this section—

(1) the term "blood components" means those constituents of whole blood which are used for therapy and which are obtained by physical separation processes which result in licensed products such as red blood cells, platelets, white blood cells, AHF-rich plasma, fresh-frozen plasma, cryoprecipitate, and single unit plasma for infusion; and

(2) the term "blood fractions" means those constituents of plasma which are used for therapy and which are obtained by licensed fractionation processes presently used in manufacturing which result in licensed products such as normal serum albumin, plasma, protein fraction, prothrombin complex, fibrinogen, AHF concentrate, immune serum globulin, and hyperimmune globulins.

(b) In the event the Secretary finds that there is an insufficient supply of blood fractions available to meet the needs for treatment of persons suffering from hemophilia, and that public and other nonprofit private centers already engaged in the production of blood fractions could alleviate such insufficiency with assistance under this subsection, he may make grants not to exceed $500,000 to such centers for the purposes of alleviating the insufficiency.

(c) No grant or contract may be made under subsection (a) or (b) unless an application therefor has been submitted to and approved by the Secretary. Such an application shall be in such form, submitted in such manner, and contain such information as the Secretary shall by regulation prescribe.

(d) Contracts may be entered into under subsection (a) without regard to section 3648 and 3709 of the Revised Statutes (31 U.S.C. 529; 41 U.S.C. 5).

(e) For the purpose of making payments under grants and contracts under subsections (a) and (b), there are authorized to be ap-

propriated $4,000,000 for fiscal year 1976, $5,000,000 for the fiscal year ending September 30, 1977, $3,450,000 for the fiscal year ending September 30, 1978, $2,500,000 for the fiscal year ending September 30, 1979, $3,000,000 for the fiscal year ending September 30, 1980, $3,500,000 for the fiscal year ending September 30, 1981.

December 13, 2013

PUBLIC HEALTH SERVICE ACT

As Amended Through P.L. 112–240, Enacted January 2, 2013

TITLE XII—TRAUMA CARE

PART A—GENERAL AUTHORITY AND DUTIES OF SECRETARY

SEC. 1201.[300d] ESTABLISHMENT.

(a) IN GENERAL.—The Secretary shall, with respect to trauma care—

(1) conduct and support research, training, evaluations, and demonstration projects;

(2) foster the development of appropriate, modern systems of such care through the sharing of information among agencies and individuals involved in the study and provision of such care;

(3) collect, compile, and disseminate information on the achievements of, and problems experienced by, State and local agencies and private entities in providing trauma care and emergency medical services and, in so doing, give special consideration to the unique needs of rural areas;

(4) provide to State and local agencies technical assistance to enhance each State's capability to develop, implement, and sustain the trauma care component of each State's plan for the provision of emergency medical services;

(5) sponsor workshops and conferences; and

(6) promote the collection and categorization of trauma data in a consistent and standardized manner.

(b) GRANTS, COOPERATIVE AGREEMENTS, AND CONTRACTS.—The Secretary may make grants, and enter into cooperative agreements and contracts, for the purpose of carrying out subsection (a).

SEC. 1202.[300d–3] ESTABLISHMENT OF PROGRAMS FOR IMPROVING TRAUMA CARE IN RURAL AREAS.

(a) IN GENERAL.—The Secretary may make grants to public and nonprofit private entities for the purpose of carrying out research and demonstration projects with respect to improving the availability and quality of emergency medical services in rural areas—

(1) by developing innovative uses of communications technologies and the use of new communications technology;

(2) by developing model curricula, such as advanced trauma life support, for training emergency medical services personnel, including first responders, emergency medical technicians, emergency nurses and physicians, and paramedics—

(A) in the assessment, stabilization, treatment, preparation for transport, and resuscitation of seriously injured patients, with special attention to problems that arise dur-

ing long transports and to methods of minimizing delays in transport to the appropriate facility; and

(B) in the management of the operation of the emergency medical services system;

(3) by making training for original certification, and continuing education, in the provision and management of emergency medical services more accessible to emergency medical personnel in rural areas through telecommunications, home studies, providing teachers and training at locations accessible to such personnel, and other methods;

(4) by developing innovative protocols and agreements to increase access to prehospital care and equipment necessary for the transportation of seriously injured patients to the appropriate facilities;

(5) by evaluating the effectiveness of protocols with respect to emergency medical services and systems; and

(6) by increasing communication and coordination with State trauma systems.

(b) SPECIAL CONSIDERATION FOR CERTAIN RURAL AREAS.—In making grants under subsection (a), the Secretary shall give special consideration to any applicant for the grant that will provide services under the grant in any rural area identified by a State under section 1214(d)(1).

(c) REQUIREMENT OF APPLICATION.—The Secretary may not make a grant under subsection (a) unless an application for the grant is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

SEC. 1203.[300d–5] COMPETITIVE GRANTS FOR TRAUMA SYSTEMS FOR THE IMPROVEMENT OF TRAUMA CARE.

(a) IN GENERAL.—The Secretary, acting through the Assistant Secretary for Preparedness and Response, may make grants to States, political subdivisions, or consortia of States or political subdivisions for the purpose of improving access to and enhancing the development of trauma care systems.

(b) USE OF FUNDS.—The Secretary may make a grant under this section only if the applicant agrees to use the grant—

(1) to integrate and broaden the reach of a trauma care system, such as by developing innovative protocols to increase access to prehospital care;

(2) to strengthen, develop, and improve an existing trauma care system;

(3) to expand communications between the trauma care system and emergency medical services through improved equipment or a telemedicine system;

(4) to improve data collection and retention; or

(5) to increase education, training, and technical assistance opportunities, such as training and continuing education in the management of emergency medical services accessible to emergency medical personnel in rural areas through telehealth, home studies, and other methods.

(c) PREFERENCE.—In selecting among States, political subdivisions, and consortia of States or political subdivisions for purposes

of making grants under this section, the Secretary shall give preference to applicants that—

(1) have developed a process, using national standards, for designating trauma centers;

(2) recognize protocols for the delivery of seriously injured patients to trauma centers;

(3) implement a process for evaluating the performance of the trauma system; and

(4) agree to participate in information systems described in section 1202 by collecting, providing, and sharing information.

(d) PRIORITY.—In making grants under this section, the Secretary shall give priority to applicants that will use the grants to focus on improving access to trauma care systems.

(e) SPECIAL CONSIDERATION.—In awarding grants under this section, the Secretary shall give special consideration to projects that demonstrate strong State or local support, including availability of non-Federal contributions.

SEC. 1204.[300d–6] COMPETITIVE GRANTS FOR REGIONALIZED SYSTEMS FOR EMERGENCY CARE RESPONSE.

(a) IN GENERAL.—The Secretary, acting through the Assistant Secretary for Preparedness and Response, shall award not fewer than 4 multiyear contracts or competitive grants to eligible entities to support pilot projects that design, implement, and evaluate innovative models of regionalized, comprehensive, and accountable emergency care and trauma systems.

(b) ELIGIBLE ENTITY; REGION.—In this section:

(1) ELIGIBLE ENTITY.—The term "eligible entity" means—

(A) a State or a partnership of 1 or more States and 1 or more local governments; or

(B) an Indian tribe (as defined in section 4 of the Indian Health Care Improvement Act) or a partnership of 1 or more Indian tribes.

(2) REGION.—The term "region" means an area within a State, an area that lies within multiple States, or a similar area (such as a multicounty area), as determined by the Secretary.

(3) EMERGENCY SERVICES.—The term "emergency services" includes acute, prehospital, and trauma care.

(c) PILOT PROJECTS.—The Secretary shall award a contract or grant under subsection (a) to an eligible entity that proposes a pilot project to design, implement, and evaluate an emergency medical and trauma system that—

(1) coordinates with public health and safety services, emergency medical services, medical facilities, trauma centers, and other entities in a region to develop an approach to emergency medical and trauma system access throughout the region, including 9–1–1 Public Safety Answering Points and emergency medical dispatch;

(2) includes a mechanism, such as a regional medical direction or transport communications system, that operates throughout the region to ensure that the patient is taken to the medically appropriate facility (whether an initial facility or a higher-level facility) in a timely fashion;

(3) allows for the tracking of prehospital and hospital resources, including inpatient bed capacity, emergency department capacity, trauma center capacity, on-call specialist coverage, ambulance diversion status, and the coordination of such tracking with regional communications and hospital destination decisions; and

(4) includes a consistent region-wide prehospital, hospital, and interfacility data management system that—

(A) submits data to the National EMS Information System, the National Trauma Data Bank, and others;

(B) reports data to appropriate Federal and State databanks and registries; and

(C) contains information sufficient to evaluate key elements of prehospital care, hospital destination decisions, including initial hospital and interfacility decisions, and relevant health outcomes of hospital care.

(d) APPLICATION.—

(1) IN GENERAL.—An eligible entity that seeks a contract or grant described in subsection (a) shall submit to the Secretary an application at such time and in such manner as the Secretary may require.

(2) APPLICATION INFORMATION.—Each application shall include—

(A) an assurance from the eligible entity that the proposed system—

(i) has been coordinated with the applicable State Office of Emergency Medical Services (or equivalent State office);

(ii) includes consistent indirect and direct medical oversight of prehospital, hospital, and interfacility transport throughout the region;

(iii) coordinates prehospital treatment and triage, hospital destination, and interfacility transport throughout the region;

(iv) includes a categorization or designation system for special medical facilities throughout the region that is integrated with transport and destination protocols;

(v) includes a regional medical direction, patient tracking, and resource allocation system that supports day-to-day emergency care and surge capacity and is integrated with other components of the national and State emergency preparedness system; and

(vi) addresses pediatric concerns related to integration, planning, preparedness, and coordination of emergency medical services for infants, children and adolescents; and

(B) such other information as the Secretary may require.

(e) REQUIREMENT OF MATCHING FUNDS.—

(1) IN GENERAL.—The Secretary may not make a grant under this section unless the State (or consortia of States) involved agrees, with respect to the costs to be incurred by the State (or consortia) in carrying out the purpose for which such

grant was made, to make available non-Federal contributions (in cash or in kind under paragraph (2)) toward such costs in an amount equal to not less than $1 for each $3 of Federal funds provided in the grant. Such contributions may be made directly or through donations from public or private entities.

(2) NON-FEDERAL CONTRIBUTIONS.—Non-Federal contributions required in paragraph (1) may be in cash or in kind, fairly evaluated, including equipment or services (and excluding indirect or overhead costs). Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

(f) PRIORITY.—The Secretary shall give priority for the award of the contracts or grants described in subsection (a) to any eligible entity that serves a population in a medically underserved area (as defined in section 330(b)(3)).

(g) REPORT.—Not later than 90 days after the completion of a pilot project under subsection (a), the recipient of such contract or grant described in shall submit to the Secretary a report containing the results of an evaluation of the program, including an identification of—

(1) the impact of the regional, accountable emergency care and trauma system on patient health outcomes for various critical care categories, such as trauma, stroke, cardiac emergencies, neurological emergencies, and pediatric emergencies;

(2) the system characteristics that contribute to the effectiveness and efficiency of the program (or lack thereof);

(3) methods of assuring the long-term financial sustainability of the emergency care and trauma system;

(4) the State and local legislation necessary to implement and to maintain the system;

(5) the barriers to developing regionalized, accountable emergency care and trauma systems, as well as the methods to overcome such barriers; and

(6) recommendations on the utilization of available funding for future regionalization efforts.

(h) DISSEMINATION OF FINDINGS.—The Secretary shall, as appropriate, disseminate to the public and to the appropriate Committees of the Congress, the information contained in a report made under subsection (g).

PART B—FORMULA GRANTS WITH RESPECT TO MODIFICATIONS OF STATE PLANS

SEC. 1211.[300d–11] ESTABLISHMENT OF PROGRAM.

(a) REQUIREMENT OF ALLOTMENTS FOR STATES.—The Secretary shall for each fiscal year make an allotment for each State in an amount determined in accordance with section 1218. The Secretary shall make payments, as grants, each fiscal year to each State from the allotment for the State if the Secretary approves for the fiscal year involved an application submitted by the State pursuant to section 1217.

(b) PURPOSE.—Except as provided in section 1233, the Secretary may not make payments under this part for a fiscal year un-

less the State involved agrees that, with respect to the trauma care component of the State plan for the provision of emergency medical services, the payments will be expended only for the purpose of developing, implementing, and monitoring the modifications to such component described in section 1213.

SEC. 1212.[300d–12] REQUIREMENT OF MATCHING FUNDS FOR FISCAL YEARS SUBSEQUENT TO FIRST FISCAL YEAR OF PAYMENTS.

(a) NON-FEDERAL CONTRIBUTIONS.—

(1) IN GENERAL.—The Secretary may not make payments under section 1211(a) unless the State involved agrees, with respect to the costs described in paragraph (2), to make available non-Federal contributions (in cash or in kind under subsection (b)(1)) toward such costs in an amount that—

(A) for the second and third fiscal years of such payments to the State, is not less than $1 for each $1 of Federal funds provided in such payments for such fiscal years; and

(B) for the fourth and subsequent fiscal years of such payments to the State, is not less than $2 for each $1 of Federal funds provided in such payments for such fiscal years.

(2) PROGRAM COSTS.—The costs referred to in paragraph (1) are—

(A) the costs to be incurred by the State in carrying out the purpose described in section 1211(b); or

(B) the costs of improving the quality and availability of emergency medical services in rural areas of the State.

(3) INITIAL YEAR OF PAYMENTS.—The Secretary may not require a State to make non-Federal contributions as a condition of receiving payments under section 1211(a) for the first fiscal year of such payments to the State.

(b) DETERMINATION OF AMOUNT OF NON-FEDERAL CONTRIBUTION.—With respect to compliance with subsection (a) as a condition of receiving payments under section 1211(a)—

(1) a State may make the non-Federal contributions required in such subsection in cash or in kind, fairly evaluated, including plant, equipment, or services; and

(2) the Secretary may not, in making a determination of the amount of non-Federal contributions, include amounts provided by the Federal Government or services assisted or subsidized to any significant extent by the Federal Government.

SEC. 1213.[300d–13] REQUIREMENTS WITH RESPECT TO CARRYING OUT PURPOSE OF ALLOTMENTS.

(a) TRAUMA CARE MODIFICATIONS TO STATE PLAN FOR EMERGENCY MEDICAL SERVICES.—With respect to the trauma care component of a State plan for the provision of emergency medical services, the modifications referred to in section 1211(b) are such modifications to the State plan as may be necessary for the State involved to ensure that the plan provides for access to the highest possible quality of trauma care, and that the plan—

(1) specifies that the modifications required pursuant to paragraphs (2) through (11) will be implemented by the prin-

cipal State agency with respect to emergency medical services or by the designee of such agency;

(2) specifies a public or private entity that will designate trauma care regions and trauma centers in the State;

(3) subject to subsection (b), contains national standards and requirements of the American College of Surgeons or another appropriate entity for the designation of level I and level II trauma centers, and in the case of rural areas level III trauma centers (including trauma centers with specified capabilities and expertise in the care of pediatric trauma patients), by such entity, including standards and requirements for—

(A) the number and types of trauma patients for whom such centers must provide care in order to ensure that such centers will have sufficient experience and expertise to be able to provide quality care for victims of injury;

(B) the resources and equipment needed by such centers; and

(C) the availability of rehabilitation services for trauma patients;

(4) contains standards and requirements for the implementation of regional trauma care systems, including standards and guidelines (consistent with the provisions of section 1867 of the Social Security Act) for medically directed triage and transportation of trauma patients (including patients injured in rural areas) prior to care in designated trauma centers;

(5) subject to subsection (b), contains national standards and requirements, including those of the American Academy of Pediatrics and the American College of Emergency Physicians, for medically directed triage and transport of severely injured children to designated trauma centers with specified capabilities and expertise in the care of pediatric trauma patients;

(6) utilizes a program with procedures for the evaluation of designated trauma centers (including trauma centers described in paragraph (5)) and trauma care systems;

(7) provides for the establishment and collection of data in accordance with data collection requirements developed in consultation with surgical, medical, and nursing specialty groups, State and local emergency medical services directors, and other trained professionals in trauma care, from each designated trauma center in the State of a central data reporting and analysis system—

(A) to identify the number of severely injured trauma patients and the number of deaths from trauma within trauma care systems in the State;

(B) to identify the cause of the injury and any factors contributing to the injury;

(C) to identify the nature and severity of the injury;

(D) to monitor trauma patient care (including prehospital care) in each designated trauma center within regional trauma care systems in the State (including relevant emergency-department discharges and rehabilitation information) for the purpose of evaluating the diagnosis, treatment, and treatment outcome of such trauma patients;

(E) to identify the total amount of uncompensated trauma care expenditures for each fiscal year by each designated trauma center in the State; and

(F) to identify patients transferred within a regional trauma system, including reasons for such transfer and the outcomes of such patients;

(8) provides for the use of procedures by paramedics and emergency medical technicians to assess the severity of the injuries incurred by trauma patients;

(9) provides for appropriate transportation and transfer policies to ensure the delivery of patients to designated trauma centers and other facilities within and outside of the jurisdiction of such system, including policies to ensure that only individuals appropriately identified as trauma patients are transferred to designated trauma centers, and to provide periodic reviews of the transfers and the auditing of such transfers that are determined to be appropriate;

(10) conducts public education activities concerning injury prevention and obtaining access to trauma care;

(11) coordinates planning for trauma systems with State disaster emergency planning and bioterrorism hospital preparedness planning; and

(12) with respect to the requirements established in this subsection, provides for coordination and cooperation between the State and any other State with which the State shares any standard metropolitan statistical area.

(b) CERTAIN STANDARDS WITH RESPECT TO TRAUMA CARE CENTERS AND SYSTEMS.—

(1) IN GENERAL.—The Secretary may not make payments under section 1211(a) for a fiscal year unless the State involved agrees that, in carrying out paragraphs (3) through (5) of subsection (a), the State will adopt standards for the designation of trauma centers, and for triage, transfer, and transportation policies, and that the State will, in adopting such standards—

(A) take into account national standards that outline resources for optimal care of injured patients;

(B) consult with medical, surgical, and nursing speciality groups, hospital associations, emergency medical services State and local directors, concerned advocates, and other interested parties;

(C) conduct hearings on the proposed standards after providing adequate notice to the public concerning such hearing; and

(D) beginning in fiscal year 2008, take into account the model plan described in subsection (c).

(2) QUALITY OF TRAUMA CARE.—The highest quality of trauma care shall be the primary goal of State standards adopted under this subsection.

(3) APPROVAL BY THE SECRETARY.—The Secretary may not make payments under section 1211(a) to a State if the Secretary determines that—

(A) in the case of payments for fiscal year 2008 and subsequent fiscal years, the State has not taken into ac-

count national standards, including those of the American College of Surgeons, the American College of Emergency Physicians, and the American Academy of Pediatrics, in adopting standards under this subsection; or

(B) in the case of payments for fiscal year 2008 and subsequent fiscal years, the State has not, in adopting such standards, taken into account the model plan developed under subsection (c).

(c) MODEL TRAUMA CARE PLAN.—

(1) IN GENERAL.—Not later than 1 year after the date of the enactment of the Trauma Care Systems Planning and Development Act of 2007, the Secretary shall update the model plan for the designation of trauma centers and for triage, transfer, and transportation policies that may be adopted for guidance by the State. Such plan shall—

(A) take into account national standards, including those of the American College of Surgeons, American College of Emergency Physicians, and the American Academy of Pediatrics;

(B) take into account existing State plans;

(C) be developed in consultation with medical, surgical, and nursing speciality groups, hospital associations, emergency medical services State directors and associations, and other interested parties; and

(D) include standards for the designation of rural health facilities and hospitals best able to receive, stabilize, and transfer trauma patients to the nearest appropriate designated trauma center, and for triage, transfer, and transportation policies as they relate to rural areas.

(2) APPLICABILITY.—Standards described in paragraph (1)(D) shall be applicable to all rural areas in the State, including both non-metropolitan areas and frontier areas that have populations of less than 6,000 per square mile.

(d) RULE OF CONSTRUCTION WITH RESPECT TO NUMBER OF DESIGNATED TRAUMA CENTERS.—With respect to compliance with subsection (a) as a condition of the receipt of a grant under section 1211(a), such subsection may not be construed to specify the number of trauma care centers designated pursuant to such subsection.

SEC. 1214.[300d–14] REQUIREMENT OF SUBMISSION TO SECRETARY OF TRAUMA PLAN AND CERTAIN INFORMATION.

(a) IN GENERAL.—For each fiscal year, the Secretary may not make payments to a State under section 1211(a) unless, subject to subsection (b), the State submits to the Secretary the trauma care component of the State plan for the provision of emergency medical services, including any changes to the trauma care component and any plans to address deficiencies in the trauma care component.

(b) INTERIM PLAN OR DESCRIPTION OF EFFORTS.—For each fiscal year, if a State has not completed the trauma care component of the State plan described in subsection (a), the State may provide, in lieu of such completed component, an interim component or a description of efforts made toward the completion of the component.

(c) INFORMATION RECEIVED BY STATE REPORTING AND ANALYSIS SYSTEM.—The Secretary may not make payments to a State under section 1211(a) unless the State agrees that the State will, not less

than once each year, provide to the Secretary the information received by the State pursuant to section 1213(a)(7).

(d) AVAILABILITY OF EMERGENCY MEDICAL SERVICES IN RURAL AREAS.—The Secretary may not make payments to a State under section 1211(a) unless—

(1) the State identifies any rural area in the State for which—

(A) there is no system of access to emergency medical services through the telephone number 911;

(B) there is no basic life-support system; or

(C) there is no advanced life-support system; and

(2) the State submits to the Secretary a list of rural areas identified pursuant to paragraph (1) or, if there are no such areas, a statement that there are no such areas.

SEC. 1215.[300d–15] RESTRICTIONS ON USE OF PAYMENTS.

(a) IN GENERAL.—The Secretary may not, except as provided in subsection (b), make payments under section 1211(a) for a fiscal year unless the State involved agrees that the payments will not be expended—

(1) for any purpose other than developing, implementing, and monitoring the modifications required by section 1211(b) to be made to the State plan for the provision of emergency medical services;

(2) to make cash payments to intended recipients of services provided pursuant to this section;

(3) to purchase or improve real property (other than minor remodeling of existing improvements to real property);

(4) to satisfy any requirement for the expenditure of non-Federal funds as a condition for the receipt of Federal funds; or

(5) to provide financial assistance to any entity other than a public or nonprofit private entity.

(b) WAIVER.—The Secretary may waive a restriction under subsection (a) only if the Secretary determines that the activities outlined by the State plan submitted under section 1214(a) by the State involved cannot otherwise be carried out.

SEC. 1217.[300d–17] REQUIREMENT OF SUBMISSION OF APPLICATION CONTAINING CERTAIN AGREEMENTS AND ASSURANCES.

The Secretary may not make payments under section 1211(a) to a State for a fiscal year unless—

(1) the State submits to the Secretary an application for the payments containing agreements in accordance with this part;

(2) the agreements are made through certification from the chief executive officer of the State;

(3) with respect to such agreements, the application provides assurances of compliance satisfactory to the Secretary;

(4) the application contains the plan provisions and the information required to be submitted to the Secretary pursuant to section 1214; and

(5) the application otherwise is in such form, is made in such manner, and contains such agreements, assurances, and

information as the Secretary determines to be necessary to carry out this part.

SEC. 1218.[300d–18] DETERMINATION OF AMOUNT OF ALLOTMENT.

(a) MINIMUM ALLOTMENT.—Subject to the extent of amounts made available in appropriations Acts, the amount of an allotment under section 1211(a) for a State for a fiscal year shall be the greater of—

(1) the amount determined under subsection (b)(1); and

(2) $250,000 in the case of each of the several States, the District of Columbia, and the Commonwealth of Puerto Rico, and $50,000 in the case of each of the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

(b) DETERMINATION UNDER FORMULA.—

(1) IN GENERAL.—The amount referred to in subsection (a)(1) for a State for a fiscal year is the sum of—

(A) an amount determined under paragraph (2); and

(B) an amount determined under paragraph (3).

(2) AMOUNT RELATING TO POPULATION.—The amount referred to in subparagraph (A) of paragraph (1) for a State for a fiscal year is the product of—

(A) an amount equal to 80 percent of the amounts appropriated under section 1232(a) for the fiscal year and available for allotment under section 1211(a); and

(B) a percentage equal to the quotient of—

(i) an amount equal to the population of the State; divided by

(ii) an amount equal to the population of all States.

(3) AMOUNT RELATING TO SQUARE MILEAGE.—The amount referred to in subparagraph (B) of paragraph (1) for a State for a fiscal year is the product of—

(A) an amount equal to 20 percent of the amounts appropriated under section 1232(a) for the fiscal year and available for allotment under section 1211(a); and

(B) a percentage equal to the quotient of—

(i) an amount equal to the lesser of 266,807 and the amount of the square mileage of the State; divided by

(ii) an amount equal to the sum of the respective amounts determined for the States under clause (i).

(c) DISPOSITION OF CERTAIN FUNDS APPROPRIATED FOR ALLOTMENTS.—

(1) IN GENERAL.—Amounts described in paragraph (2) shall, in accordance with paragraph (3), be allotted by the Secretary to States receiving payments under section 1211(a) for the fiscal year (other than any State referred to in paragraph (2)(C)).

(2) TYPE OF AMOUNTS.—The amounts referred to in paragraph (1) are any amounts made available pursuant to 1232(b)(3) that are not paid under section 1211(a) to a State as a result of—

(A) the failure of the State to submit an application under section 1217;

(B) the failure, in the determination of the Secretary, of the State to prepare within a reasonable period of time such application in compliance with such section; or

(C) the State informing the Secretary that the State does not intend to expend the full amount of the allotment made for the State.

(3) AMOUNT.—The amount of an allotment under paragraph (1) for a State for a fiscal year shall be an amount equal to the product of—

(A) an amount equal to the amount described in paragraph (2) for the fiscal year involved; and

(B) the percentage determined under subsection (b)(2) for the State.

SEC. 1219.[300d–19] FAILURE TO COMPLY WITH AGREEMENTS.

(a) REPAYMENT OF PAYMENTS.—

(1) REQUIREMENT.—The Secretary may, in accordance with subsection (b), require a State to repay any payments received by the State pursuant to section 1211(a) that the Secretary determines were not expended by the State in accordance with the agreements required to be made by the State as a condition of the receipt of payments under such section.

(2) OFFSET OF AMOUNTS.—If a State fails to make a repayment required in paragraph (1), the Secretary may offset the amount of the repayment against any amount due to be paid to the State under section 1211(a).

(b) OPPORTUNITY FOR A HEARING.—Before requiring repayment of payments under subsection (a)(1), the Secretary shall provide to the State an opportunity for a hearing.

SEC. 1220.[300d–20] PROHIBITION AGAINST CERTAIN FALSE STATEMENTS.

(a) IN GENERAL.—

(1) FALSE STATEMENTS OR REPRESENTATIONS.—A person may not knowingly and willfully make or cause to be made any false statement or representation of a material fact in connection with the furnishing of items or services for which payments may be made by a State from amounts paid to the State under section 1211(a).

(2) CONCEALING OR FAILING TO DISCLOSE INFORMATION.—A person with knowledge of the occurrence of any event affecting the right of the person to receive any payments from amounts paid to the State under section 1211(a) may not conceal or fail to disclose any such event with the intent of fraudulently securing such amount.

(b) CRIMINAL PENALTY FOR VIOLATION OF PROHIBITION.—Any person who violates a prohibition established in subsection (a) may for each violation be fined in accordance with title 18, United States Code, or imprisoned for not more than 5 years, or both.

SEC. 1221.[300d–21] TECHNICAL ASSISTANCE AND PROVISION BY SECRETARY OF SUPPLIES AND SERVICES IN LIEU OF GRANT FUNDS.

(a) TECHNICAL ASSISTANCE.—The Secretary shall, without charge to a State receiving payments under section 1211(a), provide to the State (or to any public or nonprofit private entity designated by the State) technical assistance with respect to the planning, development, and operation of any program carried out pursuant to section 1211(b). The Secretary may provide such technical assistance directly, through contract, or through grants.

(b) PROVISION BY SECRETARY OF SUPPLIES AND SERVICES IN LIEU OF GRANT FUNDS.—

(1) IN GENERAL.—Upon the request of a State receiving payments under section 1211(a), the Secretary may, subject to paragraph (2), provide supplies, equipment, and services for the purpose of aiding the State in carrying out section 1211(b) and, for such purpose, may detail to the State any officer or employee of the Department of Health and Human Services.

(2) REDUCTION IN PAYMENTS.—With respect to a request described in paragraph (1), the Secretary shall reduce the amount of payments to the State under section 1211(a) by an amount equal to the costs of detailing personnel and the fair market value of any supplies, equipment, or services provided by the Secretary. The Secretary shall, for the payment of expenses incurred in complying with such request, expend the amounts withheld.

SEC. 1222.[300d–22] REPORT BY SECRETARY.

Not later than October 1, 2008, the Secretary shall report to the appropriate committees of Congress on the activities of the States carried out pursuant to section 1211. Such report shall include an assessment of the extent to which Federal and State efforts to develop systems of trauma care and to designate trauma centers have reduced the incidence of mortality, and the incidence of permanent disability, resulting from trauma. Such report may include any recommendations of the Secretary for appropriate administrative and legislative initiatives with respect to trauma care.

PART C—GENERAL PROVISIONS REGARDING PARTS A AND B

SEC. 1231.[300d–31] DEFINITIONS.

For purposes of this part and parts A and B:

(1) DESIGNATED TRAUMA CENTER.—The term "designated trauma center" means a trauma center designated in accordance with the modifications to the State plan described in section 1213.

(2) STATE PLAN REGARDING EMERGENCY MEDICAL SERVICES.—The term "State plan", with respect to the provision of emergency medical services, means a plan for a comprehensive, organized system to provide for the access, response, triage, field stabilization, transport, hospital stabilization, definitive care, and rehabilitation of patients of all ages with respect to emergency medical services.

(3) STATE.—The term "State" means each of the several States, the District of Columbia, the Commonwealth of Puerto

Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

(4) TRAUMA.—The term "trauma" means an injury resulting from exposure to a mechanical force.

(5) TRAUMA CARE COMPONENT OF STATE PLAN.—The term "trauma care component", with respect to components of the State plan for the provision of emergency medical services, means a plan for a comprehensive health care system, within rural and urban areas of the State, for the prompt recognition, prehospital care, emergency medical care, acute surgical and medical care, rehabilitation, and outcome evaluation of seriously injured patients.

SEC. 1232.[300d–32] FUNDING.

(a) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out parts A and B, subject to subsections (b) and (c), there are authorized to be appropriated $24,000,000 for each of fiscal years 2010 through 2014.

(b) RESERVATION OF FUNDS.—If the amount appropriated under subsection (a) for a fiscal year is equal to or less than $1,000,000, such appropriation is available only for the purpose of carrying out part A. If the amount so appropriated is greater than $1,000,000, 50 percent of such appropriation shall be made available for the purpose of carrying out part A and 50 percent shall be made available for the purpose of carrying out part B.

(c) ALLOCATION OF PART A FUNDS.—Of the amounts appropriated under subsection (a) for a fiscal year to carry out part A—

(1) 10 percent of such amounts for such year shall be allocated for administrative purposes; and

(2) 10 percent of such amounts for such year shall be allocated for the purpose of carrying out section 1202.

(d) AUTHORITY.—For the purpose of carrying out parts A through C, beginning on the date of enactment of the Patient Protection and Affordable Care Act, the Secretary shall transfer authority in administering grants and related authorities under such parts from the Administrator of the Health Resources and Services Administration to the Assistant Secretary for Preparedness and Response.

PART D—TRAUMA CENTERS OPERATING IN AREAS SEVERELY AFFECTED BY DRUG-RELATED VIOLENCE

SEC. 1241.[300d–41] GRANTS FOR CERTAIN TRAUMA CENTERS.

(a) IN GENERAL.—The Secretary shall establish 3 programs to award grants to qualified public, nonprofit Indian Health Service, Indian tribal, and urban Indian trauma centers—

(1) to assist in defraying substantial uncompensated care costs;

(2) to further the core missions of such trauma centers, including by addressing costs associated with patient stabilization and transfer, trauma education and outreach, coordination with local and regional trauma systems, essential personnel and other fixed costs, and expenses associated with employee and non-employee physician services; and

(3) to provide emergency relief to ensure the continued and future availability of trauma services.

(b) MINIMUM QUALIFICATIONS OF TRAUMA CENTERS.—

(1) PARTICIPATION IN TRAUMA CARE SYSTEM OPERATING UNDER CERTAIN PROFESSIONAL GUIDELINES.—Except as provided in paragraph (2), the Secretary may not award a grant to a trauma center under subsection (a) unless the trauma center is a participant in a trauma system that substantially complies with section 1213.

(2) EXEMPTION.—Paragraph (1) shall not apply to trauma centers that are located in States with no existing trauma care system.

(3) QUALIFICATION FOR SUBSTANTIAL UNCOMPENSATED CARE COSTS.—The Secretary shall award substantial uncompensated care grants under subsection (a)(1) only to trauma centers meeting at least 1 of the criteria in 1 of the following 3 categories:

(A) CATEGORY A.—The criteria for category A are as follows:

(i) At least 40 percent of the visits in the emergency department of the hospital in which the trauma center is located were charity or self-pay patients.

(ii) At least 50 percent of the visits in such emergency department were Medicaid (under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.)) and charity and self-pay patients combined.

(B) CATEGORY B.—The criteria for category B are as follows:

(i) At least 35 percent of the visits in the emergency department were charity or self-pay patients.

(ii) At least 50 percent of the visits in the emergency department were Medicaid and charity and self-pay patients combined.

(C) CATEGORY C.—The criteria for category C are as follows:

(i) At least 20 percent of the visits in the emergency department were charity or self-pay patients.

(ii) At least 30 percent of the visits in the emergency department were Medicaid and charity and self-pay patients combined.

(4) TRAUMA CENTERS IN 1115 WAIVER STATES.—Notwithstanding paragraph (3), the Secretary may award a substantial uncompensated care grant to a trauma center under subsection (a)(1) if the trauma center qualifies for funds under a Low Income Pool or Safety Net Care Pool established through a waiver approved under section 1115 of the Social Security Act (42 U.S.C. 1315).

(5) DESIGNATION.—The Secretary may not award a grant to a trauma center unless such trauma center is verified by the American College of Surgeons or designated by an equivalent State or local agency.

(c) ADDITIONAL REQUIREMENTS.—The Secretary may not award a grant to a trauma center under subsection (a)(1) unless such trauma center—

(1) submits to the Secretary a plan satisfactory to the Secretary that demonstrates a continued commitment to serving trauma patients regardless of their ability to pay; and

(2) has policies in place to assist patients who cannot pay for part or all of the care they receive, including a sliding fee scale, and to ensure fair billing and collection practices.

SEC. 1242.[300d–42] PREFERENCES IN MAKING GRANTS.

(a) SUBSTANTIAL UNCOMPENSATED CARE AWARDS.—

(1) IN GENERAL.—The Secretary shall establish an award basis for each eligible trauma center for grants under section 1241(a)(1) according to the percentage described in paragraph (2), subject to the requirements of section 1241(b)(3).

(2) PERCENTAGES.—The applicable percentages are as follows:

(A) With respect to a category A trauma center, 100 percent of the uncompensated care costs.

(B) With respect to a category B trauma center, not more than 75 percent of the uncompensated care costs.

(C) With respect to a category C trauma center, not more than 50 percent of the uncompensated care costs.

(b)[1] CORE MISSION AWARDS.—

(1) IN GENERAL.—In awarding grants under section 1241(a)(2), the Secretary shall—

(A) reserve 25 percent of the amount allocated for core mission awards for Level III and Level IV trauma centers; and

(B) reserve 25 percent of the amount allocated for core mission awards for large urban Level I and II trauma centers—

(i) that have at least 1 graduate medical education fellowship in trauma or trauma related specialties for which demand is exceeding supply;

(ii) for which—

(I) annual uncompensated care costs exceed $10,000,000; or

(II) at least 20 percent of emergency department visits are charity or self-pay or Medicaid patients; and

(iii) that are not eligible for substantial uncompensated care awards under section 1241(a)(1).

(c) EMERGENCY AWARDS.—In awarding grants under section 1241(a)(3), the Secretary shall—

(1) give preference to any application submitted by a trauma center that provides trauma care in a geographic area in which the availability of trauma care has significantly decreased or will significantly decrease if the center is forced to close or downgrade service or growth in demand for trauma services exceeds capacity; and

(2) reallocate any emergency awards funds not obligated due to insufficient, or a lack of qualified, applications to the significant uncompensated care award program.

[1] So in law. Subsection (b) includes a paragraph (1) but does not include subsequent paragaraphs.

SEC. 1243.[300d–43] CERTAIN AGREEMENTS.

(a) MAINTENANCE OF FINANCIAL SUPPORT.—The Secretary may require a trauma center receiving a grant under section 1241(a) to maintain access to trauma services at comparable levels to the prior year during the grant period.

(b) TRAUMA CARE REGISTRY.—The Secretary may require the trauma center receiving a grant under section 1241(a) to provide data to a national and centralized registry of trauma cases, in accordance with guidelines developed by the American College of Surgeons, and as the Secretary may otherwise require.

SEC. 1244.[300d–44] GENERAL PROVISIONS.

(a) APPLICATION.—The Secretary may not award a grant to a trauma center under section 1241(a) unless such center submits an application for the grant to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this part.

(b) LIMITATION ON DURATION OF SUPPORT.—The period during which a trauma center receives payments under a grant under section 1241(a)(3) shall be for 3 fiscal years, except that the Secretary may waive such requirement for a center and authorize such center to receive such payments for 1 additional fiscal year.

(c) LIMITATION ON AMOUNT OF GRANT.—Notwithstanding section 1242(a), a grant under section 1241 may not be made in an amount exceeding $2,000,000 for each fiscal year.

(d) ELIGIBILITY.—Except as provided in section 1242(b)(1)(B)(iii), acquisition of, or eligibility for, a grant under section 1241(a) shall not preclude a trauma center from being eligible for other grants described in such section.

(e) FUNDING DISTRIBUTION.—Of the total amount appropriated for a fiscal year under section 1245, 70 percent shall be used for substantial uncompensated care awards under section 1241(a)(1), 20 percent shall be used for core mission awards under section 1241(a)(2), and 10 percent shall be used for emergency awards under section 1241(a)(3).

(f) MINIMUM ALLOWANCE.—Notwithstanding subsection (e), if the amount appropriated for a fiscal year under section 1245 is less than $25,000,000, all available funding for such fiscal year shall be used for substantial uncompensated care awards under section 1241(a)(1).

(g) SUBSTANTIAL UNCOMPENSATED CARE AWARD DISTRIBUTION AND PROPORTIONAL SHARE.—Notwithstanding section 1242(a), of the amount appropriated for substantial uncompensated care grants for a fiscal year, the Secretary shall—

(1) make available—

(A) 50 percent of such funds for category A trauma center grantees;

(B) 35 percent of such funds for category B trauma center grantees; and

(C) 15 percent of such funds for category C trauma center grantees; and

(2) provide available funds within each category in a manner proportional to the award basis specified in section 1242(a)(2) to each eligible trauma center.

(h) REPORT.—Beginning 2 years after the date of enactment of the Patient Protection and Affordable Care Act, and every 2 years thereafter, the Secretary shall biennially report to Congress regarding the status of the grants made under section 1241 and on the overall financial stability of trauma centers.

SEC. 1245.[300d–45] AUTHORIZATION OF APPROPRIATIONS.

For the purpose of carrying out this part, there are authorized to be appropriated $100,000,000 for fiscal year 2009, and such sums as may be necessary for each of fiscal years 2010 through 2015. Such authorization of appropriations is in addition to any other authorization of appropriations or amounts that are available for such purpose.

SEC. 1246.[300d–46] DEFINITION.

In this part, the term "uncompensated care costs" means unreimbursed costs from serving self-pay, charity, or Medicaid patients, without regard to payment under section 1923 of the Social Security Act, all of which are attributable to emergency care and trauma care, including costs related to subsequent inpatient admissions to the hospital.

Part E—Miscellaneous Programs

SEC. 1251.[300d–51] RESIDENCY TRAINING PROGRAMS IN EMERGENCY MEDICINE.

(a) IN GENERAL.—The Secretary may make grants to public and nonprofit private entities for the purpose of planning and developing approved residency training programs in emergency medicine.

(b) IDENTIFICATION AND REFERRAL OF DOMESTIC VIOLENCE.—The Secretary may make a grant under subsection (a) only if the applicant involved agrees that the training programs under subsection (a) will provide education and training in identifying and referring cases of domestic violence.

(c) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there is authorized to be appropriated $400,000 for each of the fiscal years 2008 though 2012.

SEC. 1252.[300d–52] STATE GRANTS FOR PROJECTS REGARDING TRAUMATIC BRAIN INJURY.

(a) IN GENERAL.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, may make grants to States and American Indian consortia for the purpose of carrying out projects to improve access to rehabilitation and other services regarding traumatic brain injury.

(b) STATE ADVISORY BOARD.—

(1) IN GENERAL.—The Secretary may make a grant under subsection (a) only if the State or American Indian consortium involved agrees to establish an advisory board within the appropriate health department of the State or American Indian consortium or within another department as designated by the chief executive officer of the State or American Indian consortium.

(2) FUNCTIONS.—An advisory board established under paragraph (1) shall advise and make recommendations to the

State or American Indian consortium on ways to improve services coordination regarding traumatic brain injury. Such advisory boards shall encourage citizen participation through the establishment of public hearings and other types of community outreach programs. In developing recommendations under this paragraph, such boards shall consult with Federal, State, and local governmental agencies and with citizens groups and other private entities.

(3) COMPOSITION.—An advisory board established under paragraph (1) shall be composed of—

(A) representatives of—

(i) the corresponding State or American Indian consortium agencies involved;

(ii) public and nonprofit private health related organizations;

(iii) other disability advisory or planning groups within the State or American Indian consortium;

(iv) members of an organization or foundation representing individuals with traumatic brain injury in that State or American Indian consortium; and

(v) injury control programs at the State or local level if such programs exist; and

(B) a substantial number of individuals with traumatic brain injury, or the family members of such individuals.

(c) MATCHING FUNDS.—

(1) IN GENERAL.—With respect to the costs to be incurred by a State or American Indian consortium in carrying out the purpose described in subsection (a), the Secretary may make a grant under such subsection only if the State or American Indian consortium agrees to make available non-Federal contributions toward such costs in an amount that is not less than $1 for each $2 of Federal funds provided under the grant.

(2) DETERMINATION OF AMOUNT CONTRIBUTED.—Non-Federal contributions under paragraph (1) may be in cash or in kind, fairly evaluated, including plant, equipment, or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such contributions.

(d) APPLICATION FOR GRANT.—The Secretary may make a grant under subsection (a) only if an application for the grant is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(e) CONTINUATION OF PREVIOUSLY AWARDED DEMONSTRATION PROJECTS.—A State or American Indian consortium that received a grant under this section prior to the date of the enactment of the Traumatic Brain Injury Act of 2008 may complete the activities funded by the grant.

(f) USE OF STATE AND AMERICAN INDIAN CONSORTIUM GRANTS.—

(1) COMMUNITY SERVICES AND SUPPORTS.—A State or American Indian consortium shall (directly or through awards

of contracts to nonprofit private entities) use amounts received under a grant under this section for the following:

(A) To develop, change, or enhance community-based service delivery systems that include timely access to comprehensive appropriate services and supports. Such service and supports—

(i) shall promote full participation by individuals with brain injury and their families in decision making regarding the services and supports; and

(ii) shall be designed for children, youth, and adults with traumatic brain injury.

(B) To focus on outreach to underserved and inappropriately served individuals, such as individuals in institutional settings, individuals with low socioeconomic resources, individuals in rural communities, and individuals in culturally and linguistically diverse communities.

(C) To award contracts to nonprofit entities for consumer or family service access training, consumer support, peer mentoring, and parent to parent programs.

(D) To develop individual and family service coordination or case management systems.

(E) To support other needs identified by the advisory board under subsection (b) for the State or American Indian consortium involved.

(2) BEST PRACTICES.—

(A) IN GENERAL.—State or American Indian consortium services and supports provided under a grant under this section shall reflect the best practices in the field of traumatic brain injury, shall be in compliance with title II of the Americans with Disabilities Act of 1990, and shall be supported by quality assurance measures as well as state-of-the-art health care and integrated community supports, regardless of the severity of injury.

(B) DEMONSTRATION BY STATE AGENCY.—The State or American Indian consortium agency responsible for administering amounts received under a grant under this section shall demonstrate that it has obtained knowledge and expertise of traumatic brain injury and the unique needs associated with traumatic brain injury.

(3) STATE CAPACITY BUILDING.—A State or American Indian consortium may use amounts received under a grant under this section to—

(A) educate consumers and families;

(B) train professionals in public and private sector financing (such as third party payers, State agencies, community-based providers, schools, and educators);

(C) develop or improve case management or service coordination systems;

(D) develop best practices in areas such as family or consumer support, return to work, housing or supportive living personal assistance services, assistive technology and devices, behavioral health services, substance abuse services, and traumatic brain injury treatment and rehabilitation;

(E) tailor existing State or American Indian consortium systems to provide accommodations to the needs of individuals with brain injury (including systems administered by the State or American Indian consortium departments responsible for health, mental health, labor/employment, education, intellectual disabilities or developmental disorders, transportation, and correctional systems);

(F) improve data sets coordinated across systems and other needs identified by a State or American Indian consortium plan supported by its advisory council; and

(G) develop capacity within targeted communities.

(g) COORDINATION OF ACTIVITIES.—The Secretary shall ensure that activities under this section are coordinated as appropriate with other Federal agencies that carry out activities regarding traumatic brain injury.

(h) REPORT.—Not less than biennially, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Health, Education, Labor, and Pensions of the Senate, a report describing the findings and results of the programs established under this section,[2] and section 1253 including measures of outcomes and consumer and surrogate satisfaction.

(i) DEFINITIONS.—For purposes of this section:

(1) The terms "American Indian consortium" and "State" have the meanings given to those terms in section 1253.

(2) The term "traumatic brain injury" means an acquired injury to the brain. Such term does not include brain dysfunction caused by congenital or degenerative disorders, nor birth trauma, but may include brain injuries caused by anoxia due to trauma. The Secretary may revise the definition of such term as the Secretary determines necessary, after consultation with States and other appropriate public or nonprofit private entities.

(j) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005, and such sums as may be necessary for each of the fiscal years 2009 through 2012.

SEC. 1253.[300d–53] STATE GRANTS FOR PROTECTION AND ADVOCACY SERVICES.

(a) IN GENERAL.—The Secretary, acting through the Administrator of the Health Resources and Services Administration (referred to in this section as the "Administrator"), shall make grants to protection and advocacy systems for the purpose of enabling such systems to provide services to individuals with traumatic brain injury.

(b) SERVICES PROVIDED.—Services provided under this section may include the provision of—

(1) information, referrals, and advice;

(2) individual and family advocacy;

(3) legal representation; and

[2] The comma after "this section" probably should be moved to follow the reference to "section 1253".

(4) specific assistance in self-advocacy.

(c) APPLICATION.—To be eligible to receive a grant under this section, a protection and advocacy system shall submit an application to the Administrator at such time, in such form and manner, and accompanied by such information and assurances as the Administrator may require.

(d) APPROPRIATIONS LESS THAN $2,700,000.—

(1) IN GENERAL.—With respect to any fiscal year in which the amount appropriated under subsection (l) to carry out this section is less than $2,700,000, the Administrator shall make grants from such amount to individual protection and advocacy systems within States to enable such systems to plan for, develop outreach strategies for, and carry out services authorized under this section for individuals with traumatic brain injury.

(2) AMOUNT.—The amount of each grant provided under paragraph (1) shall be determined as set forth in paragraphs (2) and (3) of subsection (e).

(e) APPROPRIATIONS OF $2,700,000 OR MORE.—

(1) POPULATION BASIS.—Except as provided in paragraph (2), with respect to each fiscal year in which the amount appropriated under subsection (l) to carry out this section is $2,700,000 or more, the Administrator shall make a grant to a protection and advocacy system within each State.

(2) AMOUNT.—The amount of a grant provided to a system under paragraph (1) shall be equal to an amount bearing the same ratio to the total amount appropriated for the fiscal year involved under subsection (l) as the population of the State in which the grantee is located bears to the population of all States.

(3) MINIMUMS.—Subject to the availability of appropriations, the amount of a grant a protection and advocacy system under paragraph (1) for a fiscal year shall—

(A) in the case of a protection and advocacy system located in American Samoa, Guam, the United States Virgin Islands, or the Commonwealth of the Northern Mariana Islands, and the protection and advocacy system serving the American Indian consortium, not be less than $20,000; and

(B) in the case of a protection and advocacy system in a State not described in subparagraph (A), not be less than $50,000.

(4) INFLATION ADJUSTMENT.—For each fiscal year in which the total amount appropriated under subsection (l) to carry out this section is $5,000,000 or more, and such appropriated amount exceeds the total amount appropriated to carry out this section in the preceding fiscal year, the Administrator shall increase each of the minimum grants amount described in subparagraphs (A) and (B) of paragraph (3) by a percentage equal to the percentage increase in the total amount appropriated under subsection (l) to carry out this section between the preceding fiscal year and the fiscal year involved.

(f) CARRYOVER.—Any amount paid to a protection and advocacy system that serves a State or the American Indian consortium for a fiscal year under this section that remains unobligated at the end

of such fiscal year shall remain available to such system for obligation during the next fiscal year for the purposes for which such amount was originally provided.

(g) DIRECT PAYMENT.—Notwithstanding any other provision of law, each fiscal year not later than October 1, the Administrator shall pay directly to any protection and advocacy system that complies with the provisions of this section, the total amount of the grant for such system, unless the system provides otherwise for such payment.

(h) ANNUAL REPORT.—Each protection and advocacy system that receives a payment under this section shall submit an annual report to the Administrator concerning the services provided to individuals with traumatic brain injury by such system.

(i) DATA COLLECTION.—The Administrator of the Health Resources and Services Administration and the Commissioner of the Administration on Developmental Disabilities shall enter into an agreement to coordinate the collection of data by the Administrator and the Commissioner regarding protection and advocacy services.

(j) TRAINING AND TECHNICAL ASSISTANCE.—

(1) GRANTS.—For any fiscal year for which the amount appropriated to carry out this section is $6,000,000 or greater, the Administrator shall use 2 percent of such amount to make a grant to an eligible national association for providing for training and technical assistance to protection and advocacy systems.

(2) DEFINITION.—In this subsection, the term "eligible national association" means a national association with demonstrated experience in providing training and technical assistance to protection and advocacy systems.

(k) SYSTEM AUTHORITY.—In providing services under this section, a protection and advocacy system shall have the same authorities, including access to records, as such system would have for purposes of providing services under subtitle C of the Developmental Disabilities Assistance and Bill of Rights Act of 2000[3].

(l) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $5,000,000 for fiscal year 2001, and such sums as may be necessary for each the fiscal years 2009 through 2012.

(m) DEFINITIONS.—In this section:

(1) AMERICAN INDIAN CONSORTIUM.—The term "American Indian consortium" means a consortium established under part C of the Developmental Disabilities Assistance Bill of Rights Act (42 U.S.C. 6042 et seq.).

(2) PROTECTION AND ADVOCACY SYSTEM.—The term "protection and advocacy system" means a protection and advocacy system established under part C of the Developmental Disabilities Assistance and Bill of Rights Act (42 U.S.C. 6042 et seq.).

(3) STATE.—The term "State", unless otherwise specified, means the several States of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the United

[3] The reference to subtitle C of the Developmental Disabilities Assistance and Bill of Rights Act of 2000 should refer to subtitle C of "title I" of such Act.

States Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

PART F—INTERAGENCY PROGRAM FOR TRAUMA RESEARCH

SEC. 1261.[300d–61] ESTABLISHMENT OF PROGRAM.

(a) IN GENERAL.—The Secretary, acting through the Director of the National Institutes of Health (in this section referred to as the "Director"), shall establish a comprehensive program of conducting basic and clinical research on trauma (in this section referred to as the "Program"). The Program shall include research regarding the diagnosis, treatment, rehabilitation, and general management of trauma.

(b) PLAN FOR PROGRAM.—

(1) IN GENERAL.—The Director, in consultation with the Trauma Research Interagency Coordinating Committee established under subsection (g), shall establish and implement a plan for carrying out the activities of the Program, including the activities described in subsection (d). All such activities shall be carried out in accordance with the plan. The plan shall be periodically reviewed, and revised as appropriate.

(2) SUBMISSION TO CONGRESS.—Not later than December 1, 1993, the Director shall submit the plan required in paragraph (1) to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Health, Education, Labor, and Pensions of the Senate, together with an estimate of the funds needed for each of the fiscal years 1994 through 1996 to implement the plan.

(c) PARTICIPATING AGENCIES; COORDINATION AND COLLABORATION.—The Director—

(1) shall provide for the conduct of activities under the Program by the Directors of the agencies of the National Institutes of Health involved in research with respect to trauma;

(2) shall ensure that the activities of the Program are coordinated among such agencies; and

(3) shall, as appropriate, provide for collaboration among such agencies in carrying out such activities.

(d) CERTAIN ACTIVITIES OF PROGRAM.—The Program shall include—

(1) studies with respect to all phases of trauma care, including prehospital, resuscitation, surgical intervention, critical care, infection control, wound healing, nutritional care and support, and medical rehabilitation care;

(2) basic and clinical research regarding the response of the body to trauma and the acute treatment and medical rehabilitation of individuals who are the victims of trauma;

(3) basic and clinical research regarding trauma care for pediatric and geriatric patients; and

(4) the authority to make awards of grants or contracts to public or nonprofit private entities for the conduct of basic and applied research regarding traumatic brain injury, which research may include—

(A) the development of new methods and modalities for the more effective diagnosis, measurement of degree of

brain injury, post-injury monitoring and prognostic assessment of head injury for acute, subacute and later phases of care;

(B) the development, modification and evaluation of therapies that retard, prevent or reverse brain damage after acute head injury[4], that arrest further deterioration following injury and that provide the restitution of function for individuals with long-term injuries;

(C) the development of research on a continuum of care from acute care through rehabilitation, designed, to the extent practicable, to integrate rehabilitation and long-term outcome evaluation with acute care research;

(D) the development of programs that increase the participation of academic centers of excellence in brain injury treatment and rehabilitation research and training; and

(E) carrying out subparagraphs (A) through (D) with respect to cognitive disorders and neurobehavioral consequences arising from traumatic brain injury, including the development, modification, and evaluation of therapies and programs of rehabilitation toward reaching or restoring normal capabilities in areas such as reading, comprehension, speech, reasoning, and deduction.

(e) MECHANISMS OF SUPPORT.—In carrying out the Program, the Director, acting through the Directors of the agencies referred to in subsection (c)(1), may make grants to public and nonprofit entities, including designated trauma centers.

(f) RESOURCES.—The Director shall assure the availability of appropriate resources to carry out the Program, including the plan established under subsection (b) (including the activities described in subsection (d)).

(g) COORDINATING COMMITTEE.—

(1) IN GENERAL.—There shall be established a Trauma Research Interagency Coordinating Committee (in this section referred to as the "Coordinating Committee").

(2) DUTIES.—The Coordinating Committee shall make recommendations regarding—

(A) the activities of the Program to be carried out by each of the agencies represented on the Committee and the amount of funds needed by each of the agencies for such activities; and

(B) effective collaboration among the agencies in carrying out the activities.

(3) COMPOSITION.—The Coordinating Committee shall be composed of the Directors of each of the agencies that, under subsection (c), have responsibilities under the Program, and any other individuals who are practitioners in the trauma field as designated by the Director of the National Institutes of Health.

(h) DEFINITIONS.—For purposes of this section:

[4] Section 1303(a)(2) of Public Law 106–310 (114 Stat. 1138) provides that subparagraph (B) is amended by striking "acute injury" and inserting "acute brain injury". The amendment cannot be executed because the term to be struck does not appear in subparagraph (B). (Compare "acute injury" and "acute head injury".)

(1) The term "designated trauma center" has the meaning given such term in section 1231(1).

(2) The term "Director" means the Director of the National Institutes of Health.

(3) The term "trauma" means any serious injury that could result in loss of life or in significant disability and that would meet pre-hospital triage criteria for transport to a designated trauma center.

(4) The term "traumatic brain injury" means an acquired injury to the brain. Such term does not include brain dysfunction caused by congenital or degenerative disorders, nor birth trauma, but may include brain injuries caused by anoxia due to trauma. The Secretary may revise the definition of such term as the Secretary determines necessary, after consultation with States and other appropriate public or nonprofit private entities.

(i) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005, and such sums as may be necessary for each of the fiscal years 2009 through 2012.

PART G—POISON CONTROL

SEC. 1271.[300d–71] MAINTENANCE OF THE NATIONAL TOLL-FREE NUMBER.

(a) IN GENERAL.—The Secretary shall provide coordination and assistance to poison control centers for the establishment of a nationwide toll-free phone number, and the maintenance of such number, to be used to access such centers.

(b) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated $2,000,000 for fiscal year 2009 to carry out this section, and $700,000 for each of fiscal years 2010 through 2014 for the maintenance of the nationwide toll free phone number under subsection (a).

SEC. 1272.[300d–72] NATIONWIDE MEDIA CAMPAIGN TO PROMOTE POISON CONTROL CENTER UTILIZATION.

(a) IN GENERAL.—The Secretary shall carry out, and expand upon, a national media campaign to educate the public and health care providers about poison prevention and the availability of poison control center resources in local communities and to conduct advertising campaigns concerning the nationwide toll-free number established under section 1271(a).

(b) CONTRACT WITH ENTITY.—The Secretary may carry out subsection (a) by entering into contracts with one or more public or private entities, including nationally recognized organizations in the field of poison control and national media firms, for the development and implementation of a nationwide poison prevention and poison control center awareness campaign, which may include—

(1) the development and distribution of poison prevention and poison control center awareness materials;

(2) television, radio, Internet, and newspaper public service announcements; and

(3) other activities to provide for public and professional awareness and education.

(c) EVALUATION.—The Secretary shall—

(1) establish baseline measures and benchmarks to quantitatively evaluate the impact of the nationwide media campaign carried out under this section; and

(2) on an annual basis, prepare and submit to the appropriate committees of Congress,[5] an evaluation of the nationwide media campaign.

(d) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, such sums as may be necessary for fiscal year 2009, and $800,000 for each of fiscal years 2010 through 2014.

SEC. 1273.[300d–73] MAINTENANCE OF THE POISON CONTROL CENTER GRANT PROGRAM.

(a) AUTHORIZATION OF PROGRAM.—The Secretary shall award grants to poison control centers certified under subsection (c) (or granted a waiver under subsection (d)) and professional organizations in the field of poison control for the purposes of preventing, and providing treatment recommendations for, poisonings and complying with the operational requirements needed to sustain the certification of the center under subsection (c).

(b) ADDITIONAL USES OF FUNDS.—In addition to the purposes described in subsection (a), a poison center or professional organization awarded a grant, contract, or cooperative agreement under such subsection may also use amounts received under such grant, contract, or cooperative agreement—

(1) to establish and evaluate best practices in the United States for poison prevention, poison control center outreach, and emergency and preparedness programs;

(2) to research, develop, implement, revise, and communicate standard patient management guidelines for commonly encountered toxic exposures;

(3) to improve national toxic exposure surveillance by enhancing cooperative activities between poison control centers in the United States and the Centers for Disease Control and Prevention;

(4) to develop, support, and enhance technology and capabilities of professional organizations in the field of poison control to collect national poisoning, toxic occurrence, and related public health data;

(5) to develop initiatives to foster the enhanced public health utilization of national poison data collected by organizations described in paragraph (4);

(6) to support and expand the toxicologic expertise within poison control centers; and

(7) to improve the capacity of poison control centers to answer high volumes of calls and respond during times of national crisis or other public health emergencies.

(c) CERTIFICATION.—Except as provided in subsection (d), the Secretary may award a grant to a poison control center under subsection (a) only if—

[5] The comma after "Congress" probably should not appear.

(1) the center has been certified by a professional organization in the field of poison control, and the Secretary has approved the organization as having in effect standards for certification that reasonably provide for the protection of the public health with respect to poisoning; or

(2) the center has been certified by a State government, and the Secretary has approved the State government as having in effect standards for certification that reasonably provide for the protection of the public health with respect to poisoning.

(d) WAIVER OF CERTIFICATION REQUIREMENTS.—

(1) IN GENERAL.—The Secretary may grant a waiver of the certification requirements of subsection (c) with respect to a noncertified poison control center that applies for a grant under this section if such center can reasonably demonstrate that the center will obtain such a certification within a reasonable period of time as determined appropriate by the Secretary.

(2) RENEWAL.—The Secretary may renew a waiver under paragraph (1).

(3) LIMITATION.—In no case may the sum of the number of years for a waiver under paragraph (1) and a renewal under paragraph (2) exceed 5 years. The preceding sentence shall take effect as of the date of the enactment of the Poison Center Support, Enhancement, and Awareness Act of 2008.

(e) SUPPLEMENT NOT SUPPLANT.—Amounts made available to a poison control center under this section shall be used to supplement and not supplant other Federal, State or local funds provided for such center.

(f) MAINTENANCE OF EFFORT.—A poison control center, in utilizing the proceeds of a grant under this section, shall maintain the expenditures of the center for activities of the center at a level that is not less than the level of expenditures maintained by the center for the fiscal year preceding the fiscal year for which the grant is received.

(g) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $27,500,000 for fiscal year 2009, and $28,600,000 for each of fiscal years 2010 through 2014. The Secretary may utilize not to exceed 8 percent of the amount appropriated under this preceding sentence in each fiscal year for coordination, dissemination, technical assistance, program evaluation, data activities, and other program administration functions that do not include grants, contracts, or cooperative agreements under subsections (a) and (b), which are determined by the Secretary to be appropriate for carrying out the program under this section.

SEC. 1274.[300d–74] RULE OF CONSTRUCTION.

Nothing in this part may be construed to ease any restriction in Federal law applicable to the amount or percentage of funds appropriated to carry out this part that may be used to prepare or submit a report.

PART H—TRAUMA SERVICE AVAILABILITY

SEC. 1281.[300d–81] GRANTS TO STATES.

(a) ESTABLISHMENT.—To promote universal access to trauma care services provided by trauma centers and trauma-related physician specialties, the Secretary shall provide funding to States to enable such States to award grants to eligible entities for the purposes described in this section.

(b) AWARDING OF GRANTS BY STATES.—Each State may award grants to eligible entities within the State for the purposes described in subparagraph (d).

(c) ELIGIBILITY.—

(1) IN GENERAL.—To be eligible to receive a grant under subsection (b) an entity shall—

(A) be—

(i) a public or nonprofit trauma center or consortium thereof that meets that requirements of paragraphs (1), (2), and (5) of section 1241(b);

(ii) a safety net public or nonprofit trauma center that meets the requirements of paragraphs (1) through (5) of section 1241(b); or

(iii) a hospital in an underserved area (as defined by the State) that seeks to establish new trauma services; and

(B) submit to the State an application at such time, in such manner, and containing such information as the State may require.

(2) LIMITATION.—A State shall use at least 40 percent of the amount available to the State under this part for a fiscal year to award grants to safety net trauma centers described in paragraph (1)(A)(ii).

(d) USE OF FUNDS.—The recipient of a grant under subsection (b) shall carry out 1 or more of the following activities consistent with subsection (b):

(1) Providing trauma centers with funding to support physician compensation in trauma-related physician specialties where shortages exist in the region involved, with priority provided to safety net trauma centers described in subsection (c)(1)(A)(ii).

(2) Providing for individual safety net trauma center fiscal stability and costs related to having service that is available 24 hours a day, 7 days a week, with priority provided to safety net trauma centers described in subsection (c)(1)(A)(ii) located in urban, border, and rural areas.

(3) Reducing trauma center overcrowding at specific trauma centers related to throughput of trauma patients.

(4) Establishing new trauma services in underserved areas as defined by the State.

(5) Enhancing collaboration between trauma centers and other hospitals and emergency medical services personnel related to trauma service availability.

(6) Making capital improvements to enhance access and expedite trauma care, including providing helipads and associated safety infrastructure.

(7) Enhancing trauma surge capacity at specific trauma centers.

(8) Ensuring expedient receipt of trauma patients transported by ground or air to the appropriate trauma center.

(9) Enhancing interstate trauma center collaboration.

(e) LIMITATION.—

(1) IN GENERAL.—A State may use not more than 20 percent of the amount available to the State under this part for a fiscal year for administrative costs associated with awarding grants and related costs.

(2) MAINTENANCE OF EFFORT.—The Secretary may not provide funding to a State under this part unless the State agrees that such funds will be used to supplement and not supplant State funding otherwise available for the activities and costs described in this part.

(f) DISTRIBUTION OF FUNDS.—The following shall apply with respect to grants provided in this part:

(1) LESS THAN $10,000,000.—If the amount of appropriations for this part in a fiscal year is less than $10,000,000, the Secretary shall divide such funding evenly among only those States that have 1 or more trauma centers eligible for funding under section 1241(b)(3)(A).

(2) LESS THAN $20,000,000.—If the amount of appropriations in a fiscal year is less than $20,000,000, the Secretary shall divide such funding evenly among only those States that have 1 or more trauma centers eligible for funding under subparagraphs (A) and (B) of section 1241(b)(3).

(3) LESS THAN $30,000,000.—If the amount of appropriations for this part in a fiscal year is less than $30,000,000, the Secretary shall divide such funding evenly among only those States that have 1 or more trauma centers eligible for funding under section 1241(b)(3).

(4) $30,000,000 OR MORE.—If the amount of appropriations for this part in a fiscal year is $30,000,000 or more, the Secretary shall divide such funding evenly among all States.

SEC. 1282.[300d–82] AUTHORIZATION OF APPROPRIATIONS.

For the purpose of carrying out this part, there is authorized to be appropriated $100,000,000 for each of fiscal years 2010 through 2015.

PUBLIC HEALTH SERVICE ACT

As Amended Through P.L. 112–240, Enacted January 2, 2013

TITLE XIII—HEALTH MAINTENANCE ORGANIZATIONS

REQUIREMENTS FOR HEALTH MAINTENANCE ORGANIZATIONS.

SEC. 1301.[300e] (a) For purposes of this title, the term "health maintenance organization" means a public or private entity which is organized under the laws of any State and which (1) provides basic and supplemental health services to its members in the manner prescribed by subsection (b), and (2) is organized and operated in the manner prescribed by subsection (c).

(b) A health maintenance organization shall provide, without limitations as to time or cost other than those prescribed by or under this title, basic and supplemental health services to its members in the following manner:

(1) Each member is to be provided basic health services for a basic health services payment which (A) is to be paid on a periodic basis without regard to the dates health services (within the basic health services) are provided; (B) is fixed without regard to the frequency, extent, or kind of health service (within the basic health services) actually furnished; (C) except in the case of basic health services provided a member who is a full-time student (as defined by the Secretary) at an accredited institution of higher education, is fixed under a community rating system; and (D) may be supplemented by additional nominal payments which may be required for the provision of specific services (within the basic health services), except that such payments may not be required where or in such a manner that they serve (as determined under regulations of the Secretary) as a barrier to the delivery of health services. Such additional nominal payments shall be fixed in accordance with the regulations of the Secretary. If a health maintenance organization offers to its members the opportunity to obtain basic health services through a physician not described in subsection (b)(3)(A), the organization may require, in addition to payments described in clause (D) of this paragraph, a reasonable deductible to be paid by a member when obtaining a basic health service from such a physician. A health maintenance organization may include a health service, defined as a supplemental health service by section 1302(2), in the basic health services provided its members for a basic health services payment described in the first sentence. In the case of an entity which before it became a qualified health maintenance organization (within the meaning of section 1310(d)) provided comprehensive health services on a prepaid basis, the requirement of clause (C) shall not apply to such entity until the expiration

of the forty-eight month period beginning with the month following the month in which the entity became such a qualified health organization. The requirements of this paragraph respecting the basic health services payment shall not apply to the provision of basic health services to a member for an illness or injury for which the member is entitled to benefits under a workmen's compensation law or an insurance policy but only to the extent such benefits apply to such services. For the provision of such services for an illness or injury for which a member is entitled to benefits under such a law, the health maintenance organization may, if authorized by such law, charge or authorize the provider of such services to charge, in accordance with the charges allowed under such law, the insurance carrier, employer, or other entity which under such law is to pay for the provision of such services or, to the extent that such member has been paid under such law for such services, such member. For the provision of such services for an illness or injury for which a member is entitled to benefits under an insurance policy, a health maintenance organization may charge or authorize the provider of such services to charge the insurance carrier under such policy or, to the extent that such member has been paid under such policy for such services, such member.

(2) For such payment or payments (hereinafter in this title referred to as "supplemental health services payments") as the health maintenance organization may require in addition to the basic health services payment, the organization may provide to each of its members any of the health services which are included in supplemental health services (as defined in section 1302(2)). Supplemental health services payments which are fixed on a prepayment basis shall be fixed under a community rating system unless the supplemental health services payment is for a supplemental health service provided a member who is a full-time student (as defined by the Secretary) at an accredited institution of higher education, except that, in the case of an entity which before it became a qualified health maintenance organization (within the meaning of section 1310(d)) provided comprehensive health services on a prepaid basis, the requirement of this sentence shall not apply to such entity during the forty-eight month period beginning with the month following the month in which the entity became such a qualified health maintenance organization.

(3)(A) Except as provided in subparagraph (B), at least 90 percent of the services of a physician which are provided as basic health services shall be provided through—

(i) members of the staff of the health maintenance organization,

(ii) a medical group (or groups),

(iii) an individual practice association (or associations),

(iv) physicians or other health professionals who have contracted with the health maintenance organization for the provision of such services, or

(v) any combination of such staff, medical group (or groups), individual practice association (or associations) or

physicians or other health professionals under contract with the organization.

(B) Subparagraph (A) does not apply to the provision of the services of a physician—

(i) which the health maintenance organization determines, in conformity with regulations of the Secretary, are unusual or infrequently used, or

(ii) which are provided a member of the organization in a manner other than that prescribed by subparagraph (A) because of an emergency which made it medically necessary that the service be provided to the member before it could be provided in a manner prescribed by subparagraph (A).

(C) Contracts between a health maintenance organization and health professionals for the provision of basic and supplemental health services shall include such provisions as the Secretary may require (including provisions requiring appropriate continuing education).

(D) Contracts between a health maintenance organization and health professionals for the provision of basic and supplemental health services shall include such provisions as the Secretary may require, but only to the extent that such requirements are designed to insure the delivery of quality health care services and sound fiscal management.

(4) Basic health services (and only such supplemental health services as members have contracted for) shall within the area served by the health maintenance organization be available and accessible to each of its members with reasonable promptness and in a manner which assures continuity, and when medically necessary be available and accessible twenty-four hours a day and seven days a week, except that a health maintenance organization which has a service area located wholly in a nonmetropolitan area may make a basic health service available outside its service area if that basic health service is not a primary care or emergency health care service and if there is an insufficient number of providers of that basic health service within the service area who will provide such service to members of the health maintenance organization. A member of a health maintenance organization shall be reimbursed by the organization for his expenses in securing basic and supplemental health services other than through the organization if the services were medically necessary and immediately required because of an unforeseen illness, injury, or condition.

(5) To the extent that a natural disaster, war, riot, civil insurrection, or any other similar event not within the control of a health maintenance organization (as determined under regulations of the Secretary) results in the facilities, personnel, or financial resources of a health maintenance organization not being available to provide or arrange for the provision of a basic or supplemental health service in accordance with the requirements of paragraphs (1) through (4) of this subsection, such requirements only require the organization to make a good-faith effort to provide or arrange for the provision of such

service within such limitation on its facilities, personnel, or resources.

(6) A health maintenance organization that otherwise meets the requirements of this title may offer a high-deductible health plan (as defined in section 220(c)(2) of the Internal Revenue Code of 1986).

(c) Each health maintenance organization shall—

(1)(A) have—

(i) a fiscally sound operation, and

(ii) adequate provision against the risk of insolvency, which is satisfactory to the Secretary, and (B) have administrative and managerial arrangements satisfactory to the Secretary;

(2) assume full financial risk on a prospective basis for the provision of basic health services, except that a health maintenance organization may (A) obtain insurance or make other arrangements for the cost of providing to any member basic health services the aggregate value of which exceeds $5,000 in any year, (B) obtain insurance or make other arrangements for the cost of basic health services provided to its members other than through the organization because medical necessity required their provision before they could be secured through the organization, (C) obtain insurance or make other arrangements for not more than 90 per centum of the amount by which its costs for any of its fiscal years exceed 115 per centum of its income for such fiscal year, and (D) make arrangements with physicians or other health professionals, health care institutions, or any combination of such individuals or institutions to assume all or part of the financial risk on a prospective basis for the provision of basic health services by the physicians or other health professionals or through the institutions;

(3)(A) enroll persons who are broadly representative of the various age, social, and income groups within the area it serves, except that in the case of a health maintenance organization which has a medically underserved population located (in whole or in part) in the area it serves, not more than 75 per centum of the members of that organization may be enrolled from the medically underserved population unless the area in which such population resides is also a rural area (as designated by the Secretary), and (B) carry out enrollment of members who are entitled to medical assistance under a State plan approved under title XIX of the Social Security Act in accordance with procedures approved under regulations promulgated by the Secretary;

(4) not expel or refuse to re-enroll any member because of his health status or his requirements for health services;

(5) be organized in such a manner that provides meaningful procedures for hearing and resolving grievances between the health maintenance organization (including the medical group or groups and other health delivery entities providing health services for the organization) and the members of the organization;

(6) have organizational arrangements, established in accordance with regulations of the Secretary, for an ongoing

quality assurance program for its health services which program (A) stresses health outcomes, and (B) provides review by physicians and other health professionals of the process followed in the provision of health services;

(7) adopt at least one of the following arrangements to protect its members from incurring liability for payment of any fees which are the legal obligation of such organization—

(A) a contractual arrangement with any hospital that is regularly used by the members of such organization prohibiting such hospital from holding any such member liable for payment of any fees which are the legal obligation of such organization;

(B) insolvency insurance, acceptable to the Secretary;

(C) adequate financial reserve, acceptable to the Secretary; and

(D) other arrangements, acceptable to the Secretary, to protect members,

except that the requirements of this paragraph shall not apply to a health maintenance organization if applicable State law provides the members of such organization with protection from liability for payment of any fees which are the legal obligation of such organization; and

(8) provide, in accordance with regulations of the Secretary (including safeguards concerning the confidentiality of the doctor-patient relationship), an effective procedure for developing, compiling, evaluating, and reporting to the Secretary, statistics and other information (which the Secretary shall publish and disseminate on an annual basis and which the health maintenance organization shall disclose, in a manner acceptable to the Secretary, to its members and the general public) relating to (A) the cost of its operations, (B) the patterns of utilization of its services, (C) the availability, accessibility, and acceptability of its services, (D) to the extent practical, developments in the health status of its members, and (E) such other matters as the Secretary may require.

The Secretary shall issue regulations stating the circumstances under which the Secretary, in administering paragraph (1)(A), will consider the resources of an organization which owns or controls a health maintenance organization. Such regulations shall require as a condition to consideration of resources that an organization which owns or controls a health maintenance organization shall provide satisfactory assurances that it will assume the financial obligations of the health maintenance organization.

(d) An organization that offers health benefits coverage shall not be considered as failing to meet the requirements of this section notwithstanding that it provides, with respect to coverage offered in connection with a group health plan in the small or large group market (as defined in section 2791(e)), an affiliation period consistent with the provisions of section 2701(g).

DEFINITIONS.

SEC. 1302.[300e–1] For purposes of this title:

(1) The term "basic health services" means—

(A) physician services (including consultant and referral services by a physician);

(B) inpatient and outpatient hospital services;

(C) medically necessary emergency health services;

(D) short-term (not to exceed twenty visits), outpatient evaluative and crisis intervention mental health services;

(E) medical treatment and referral services (including referral services to appropriate ancillary services) for the abuse of or addiction to alcohol and drugs;

(F) diagnostic laboratory and diagnostic and therapeutic radiologic services;

(G) home health services; and

(H) preventive health services (including (i) immunizations, (ii) well-child care from birth, (iii) periodic health evaluations for adults, (iv) voluntary family planning services, (v) infertility services, and (vi) children's eye and ear examinations conducted to determine the need for vision and hearing correction).

Such term does not include a health service which the Secretary, upon application of a health maintenance organization, determines is unusual and infrequently provided and not necessary for the protection of individual health. The Secretary shall publish in the Federal Register each determination made by him under the preceding sentence. If a service of a physician described in the preceding sentence may also be provided under applicable State law by a dentist, optometrist, podiatrist, psychologist, or other health care personnel a health maintenance organization may provide such service through a dentist, optometrist, podiatrist, psychologist, or other health care personnel (as the case may be) licensed to provide such service. Such term includes a health service directly associated with an organ transplant only if such organ transplant was required to be included in basic health services on April 15, 1985. For purposes of this paragraph, the term "home health services" means health services provided at a member's home by health care personnel, as prescribed or directed by the responsible physician or other authority designated by the health maintenance organization.

(2) The term "supplemental health services" means any health service which is not included as a basic health service under paragraph (1) of this section. If a health service provided by a physician may also be provided under applicable State law by a dentist, optometrist, podiatrist, psychologist, or other health care personnel, a health maintenance organization may provide such service through an optometrist, dentist, podiatrist, psychologist, or other health care personnel (as the case may be) licensed to provide such service.

(3) The term "member" when used in connection with a health maintenance organization means an individual who has entered into a contractual agreement, or on whose behalf a contractual arrangement has been entered into, with the organization under which the organization assumes the responsibility for the provision to such individual of basic health services and of such supplemental health services as may be contracted for.

(4) The term "medical group" means a partnership, association, or other group—

(A) which is composed of health professionals licensed to practice medicine or osteopathy and of such other licensed health professionals (including dentists, optometrists, podiatrists, and psychologists) as are necessary for the provision of health services for which the group is responsible;

(B) a majority of the members of which are licensed to practice medicine or osteopathy; and

(C) the members of which (i) as their principal professional activity engage in the coordinated practice of their profession and as a group responsibility have substantial responsibility for the delivery of health services to members of a health maintenance organization, except that this clause does not apply before the end of the forty-eight month period beginning after the month in which the health maintenance oranization[1] becomes a qualified health maintenance organization as defined in section 1310(d), or as authorized by the Secretary in accordance with regulations that take into consideration the usual circumstances of the group; (ii) pool their income from practice as members of the group and distribute it among themselves according to a prearranged salary or drawing account or other similar plan unrelated to the provision of specific health services; (iii) share medical and other records and substantial portions of major equipment and of professional, technical, and administrative staff; (iv) arrange for and encourage continuing education in the field of clinical medicine and related areas for the members of the group; and (v) establish an arrangement whereby a member's enrollment status is not known to the health professional who provides health services to the member.

(5) The term "individual practice association" means a partnership, corporation, association, or other legal entity which has entered into a services arrangement (or arrangements) with persons who are licensed to practice medicine, osteopathy, dentistry, podiatry, optometry, psychology, or other health profession in a State and a majority of whom are licensed to practice medicine or osteopathy. Such an arrangement shall provide—

(A) that such persons shall provide their professional services in accordance with a compensation arrangement established by the entity; and

(B) to the extent feasible, for the sharing by such persons of medical and other records, equipment, and professional, technical, and administrative staff.

(6) The term "health systems agency" means an entity which is designated in accordance with section 1515 of this Act.

(7) The term "medically underserved population" means the population of an urban or rural area designated by the Secretary as an area with a shortage of personal health services or a population group designated by the Secretary as having a shortage of such services. Such a designation may be made by the Secretary only after consideration of the comments (if any) of (A) each State health planning and development agency which covers (in whole or in part) such urban or rural area or the area in which such popu-

[1] So in law. Probably should be "organization".

lation group resides, and (B) each health systems agency designated for a health service area which covers (in whole or in part) such urban or rural area or the area in which such population group resides.

(8)(A) The term "community rating system" means the systems, described in subparagraphs (B) and (C), of fixing rates of payments for health services. A health maintenance organization may fix its rates of payments under the system described in subparagraph (B) or (C) or under both such systems, but a health maintenance organization may use only one such system for fixing its rates of payments for any one group.

(B) A system of fixing rates of payment for health services may provide that the rates shall be fixed on a per-person or per-family basis and may authorize the rates to vary with the number of persons in a family, but, except as authorized in subparagraph (D), such rates must be equivalent for all individuals and for all families of similar composition.

(C) A system of fixing rates of payment for health services may provide that the rates shall be fixed for individuals and families by groups. Except as authorized in subparagraph (D), such rates must be equivalent for all individuals in the same group and for all families of similar composition in the same group. If a health maintenance organization is to fix rates of payment for individuals and families by groups, it shall—

(i)(I) classify all of the members of the organization into classes based on factors which the health maintenance organization determines predict the differences in the use of health services by the individuals or families in each class and which have not been disapproved by the Secretary,

(II) determine its revenue requirements for providing services to the members of each class established under subclause (I), and

(III) fix the rates of payments for the individuals and families of a group on the basis of a composite of the organization's revenue requirements determined under subclause (II) for providing services to them as members of the classes established under subclause (I), or

(ii) fix the rates of payments for the individuals and families of a group on the basis of the organization's revenue requirements for providing services to the group, except that the rates of payments for the individuals and families of a group of less than 100 persons may not be fixed at rates greater than 110 percent of the rate that would be fixed for such individuals and families under subparagraph (B) or clause (i) of this subparagraph.

The Secretary shall review the factors used by each health maintenance organization to establish classes under clause (i). If the Secretary determines that any such factor may not reasonably be used to predict the use of the health services by individuals and families, the Secretary shall disapprove such factor for such purpose. If a health maintenance organization is to fix rates of payment for a group under clause (ii), it shall, upon request of the entity with which it contracts to provide services to such group, disclose to that

entity the method and data used in calculating the rates of payment.

(D) The following differentials in rates of payments may be established under the systems described in subparagraphs (B) and (C):

(i) Nominal differentials in such rates may be established to reflect differences in marketing costs and the different administrative costs of collecting payments from the following categories of members:

(I) Individual members (including their families).

(II) Small groups of members (as determined under regulations of the Secretary).

(III) Large groups of members (as determined under regulations of the Secretary).

(ii) Nominal differentials in such rates may be established to reflect the compositing of the rates of payment in a systematic manner to accommodate group purchasing practices of the various employers.

(iii) Differentials in such rates may be established for members enrolled in a health maintenance organization pursuant to a contract with a governmental authority under section 1079 or 1086 of title 10, United States Code, or under any other governmental program (other than the health benefits program authorized by chapter 89 of title 5, United States Code) or any health benefits program for employees of States, political subdivision of States, and other public entities.

(9) The term "non-metropolitan area" means an area no part of which is within an area designated as a standard metropolitan statistical area by the Office of Management and Budget and which does not contain a city whose population exceeds fifty thousand individuals.

LOANS AND LOAN GUARANTEES FOR INITIAL COSTS OF OPERATION.

SEC. 1305.[300e–4] (a) The Secretary may—

(1) make loans to public or private health maintenance organizations to assist them in meeting the amount by which their costs of operation during a period not to exceed the first sixty months of their operation exceed their revenues in that period;

(2) make loans to public or private health maintenance organizations to assist them in meeting the amount by which their costs of operation, which the Secretary determines are attributable to significant expansion in their membership or area served and which are incurred during a period not to exceed the first sixty months of their operation after such expansion, exceed their revenues in that period which the Secretary determines are attributable to such expansion; and

(3) guarantee to non-Federal lenders payment of the principal of and the interest on loans made to private health maintenance organizations for the amounts referred to in paragraphs (1) and (2).

No loan or loan guarantee may be made under this subsection for the costs of operation of a health maintenance organization unless

the Secretary determines that the organization has made all reasonable attempts to meet such costs, and unless the Secretary has made a grant or loan to, entered into a contract with, or guaranteed a loan for, the organization in fiscal year 1981, 1982, 1983, 1984, or 1985 under this section or section 1304(b) (as in effect before October 1, 1985).

(b)(1) Except as provided in paragraph (2), the aggregate amount of principal of loans made or guaranteed, or both, under subsection (a) for a health maintenance organization may not exceed $7,000,000. In any twelve-month period the amount disbursed to a health maintenance organization under this section (either directly by the Secretary, by an escrow agent under the terms of an escrow agreement, or by a lender under a guaranteed loan) may not exceed $3,000,000.

(2) The cumulative total of the principal of the loans outstanding at any time which have been directly made or with respect to which guarantees have been issued under subsection (a) may not exceed such limitations as may be specified in appropriation Acts.

(c) Loans under this section shall be made from the fund established under section 1308(e).

(d) No loan may be made or guaranteed under this section after September 30, 1986.

(e) Of the sums used for loans under this section in any fiscal year from the loan fund established under section 1308(e), not less than 20 per centum shall be used for loans for projects (1) for the initial operation of health maintenance organizations which the Secretary determines have not less than 66 per centum of their membership drawn from residents of nonmetropolitan areas, and (2) the applications for which meet the requirements of this title for approval.

(f) In considering applications for loan guarantees under this section, the Secretary shall give special consideration to applications for health maintenance organizations which will serve medically underserved populations.

APPLICATION REQUIREMENTS.

SEC. 1306.[300e–5] (a) No loan or loan guarantee may be made under this title unless an application therefor has been submitted to and approved by the Secretary.

(b) The Secretary may not approve an application for a loan or loan guarantee under this title unless—

(1) such application meets the requirements of section 1308;

(2) in the case of an application for assistance under section 1305, he determines that the applicant making the application would not be able to complete the project or undertaking for which the application is submitted without the assistance applied for;

(3) the application contains satisfactory specification of the existing or anticipated (A) population group or groups to be served by the proposed or existing health maintenance organization described in the application, (B) membership of such or-

ganization, (C) methods, terms, and periods of the enrollment of members of such organization, (D) estimated costs per member of the health and educational services to be provided by such organization and the nature of such costs, (E) sources of professional services for such organization, and organizational arrangements of such organization for providing health and educational services, (F) organizational arrangements of such organization for an ongoing quality assurance program in conformity with the requirements of section 1301(c), (G) sources of prepayment and other forms of payment for the services to be provided by such organization, (H) facilities, and additional capital investments and sources of financing therefor, available to such organization to provide the level and scope of services proposed, (I) administrative, managerial, and financial arrangements and capabilities of such organization, (J) role for members in the planning and policymaking for such organization, (K) grievance procedures for members of such organization, and (L) evaluations of the support for and acceptance of such organization by the population to be served, the sources of operating support, and the professional groups to be involved or affected thereby;

(4) contains or is supported by assurances satisfactory to the Secretary that the applicant making the application will, in accordance with such criteria as the Secretary shall by regulation prescribe, enroll, and maintain an enrollment of the maximum number of members that its available and potential resources (as determined under regulations of the Secretary) will enable it to effectively serve;

(5) in the case of an application made for a project which previously received a grant, contract, loan, or loan guarantee under this title, such application contains or is supported by assurances satisfactory to the Secretary that the applicant making the application has the financial capability to adequately carry out the purposes of such project and has developed and operated such project in accordance with the requirements of this title and with the plans contained in previous applications for such assistance;

(6) the application contains such assurances as the Secretary may require respecting the intent and the ability of the applicant to meet the requirements of paragraphs (1) and (2) of section 1301(b) respecting the fixing of basic health services payments and supplemental health services payments under a community rating system; and

(7) the application is submitted in such form and manner, and contains such additional information, as the Secretary shall prescribe in regulations.

An organization making multiple applications for more than one loan or loan guarantee under this title, simultaneously or over the course of time, shall not be required to submit duplicate or redundant information but shall be required to update the specifications (required by paragraph (3)) respecting the existing or proposed health maintenance organization in such manner and with such frequency as the Secretary may by regulation prescribe. In determining, for purposes of paragraph (2), whether an applicant would

be able to complete a project or undertaking without the assistance applied for, the Secretary shall not consider any asset of the applicant the obligation of which for such undertaking or project would jeopardize the fiscal soundness of the applicant.

(c) The Secretary shall by regulation establish standards and procedures for health systems agencies to follow in reviewing and commenting on applications for loans and loan guarantees under this title.

ADMINISTRATION OF ASSISTANCE PROGRAMS.

SEC. 1307.[300e–6] (a)(1) Each recipient of a loan or loan guarantee under this title shall keep such records as the Secretary shall prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of the loan (directly made or guaranteed), the total cost of the undertaking in connection with which the loan was given or used, the amount of that portion of the cost of the undertaking supplied by other sources, and such other records as will facilitate an effective audit.

(2) The Secretary, or any of his duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of the recipients of a loan or loan guarantee under this title which relate to such assistance.

(b) Upon expiration of the period for which a loan or loan guarantee was provided an entity under this title, such entity shall make a full and complete report to the Secretary in such manner as he may by regulation prescribe. Each such report shall contain, among such other matters as the Secretary may by regulation require, descriptions of plans, developments, and operations relating to the matters referred to in section 1306(b)(3).

(d)[2] An entity which provides health services to a defined population on a prepaid basis and which has members who are entitled to insurance benefits under title XVIII of the Social Security Act or to medical assistance under a State plan approved under title XIX of such Act may be considered as a health maintenance organization for purposes of receiving assistance under this title if—

(1) with respect to its members who are entitled to such insurance benefits or to such medical assistance it (A) provides health services in accordance with section 1301(b), except that (i) it does not furnish to those members the health services (within the basic health services) for which it may not be compensated under such title XVIII or such State plan, and (ii) it does not fix the basic or supplemental health services payment for such members under a community rating system, and (B) is organized and operated in the manner prescribed by section 1301(c), except that it does not assume full financial risk on a prospective basis for the provision to such members of basic or supplemental health services with respect to which it is not required under such title XVIII or such State plan to assume such financial risk; and

[2] Former subsection (c) was repealed by section 803(a) of Public Law 99–660.

(2) with respect to its other members it provides health services in accordance with section 1301(b) and is organized and operated in the manner prescribed by section 1301(c).

An entity which provides health services to a defined population on a prepaid basis and which has members who are enrolled under the health benefits program authorized by chapter 89 of title 5, United States Code, may be considered as a health maintenance organization for purposes of receiving assistance under this title if with respect to its other members it provides health services in accordance with section 1301(b) and is organized and operated in the manner prescribed by section 1301(c).

GENERAL PROVISIONS RELATING TO LOAN GUARANTEES AND LOANS.

SEC. 1308.[300e–7] (a)(1) The Secretary may not approve an application for a loan guarantee under this title unless he determines that (A) the terms, conditions, security (if any), and schedule and amount of repayments with respect to the loan are sufficient to protect the financial interests of the United States and are otherwise reasonable, including a determination that the rate of interest does not exceed such per centum per annum on the principal obligation outstanding as the Secretary determines to be reasonable, taking into account the range of interest rates prevailing in the private market for loans with similar maturities, terms, conditions, and security and the risks assumed by the United States, and (B) the loan would not be available on reasonable terms and conditions without the guarantee under this title.

(2)(A) The United States shall be entitled to recover from the applicant for a loan guarantee under this title the amount of any payment made pursuant to such guarantee, unless the Secretary for good cause waives such right of recovery; and, upon making any such payment, the United States shall be subrogated to all of the rights of the recipient of the payments with respect to which the guarantee was made.

(B) To the extent permitted by subparagraph (C), any terms and conditions applicable to a loan guarantee under this title (including terms and conditions imposed under subparagraph (D)) may be modified by the Secretary to the extent he determines it to be consistent with the financial interest of the United States.

(C) Any loan guarantee made by the Secretary under this title shall be incontestable (i) in the hands of an applicant on whose behalf such guarantee is made unless the applicant engaged in fraud or misrepresentation in securing such guarantee, and (ii) as to any person (or his successor in interest) who makes or contracts to make a loan to such applicant in reliance thereon unless such person (or his successor in interest) engaged in fraud or misrepresentation in making or contracting to make such loan.

(D) guarantees of loans under this title shall be subject to such further terms and conditions as the Secretary determines to be necessary to assure that the purposes of this title will be achieved.

(b)(1) The Secretary may not approve an application for a loan under this title unless—

(A) the Secretary is reasonably satisfied that the applicant therefor will be able to make payments of principal and interest thereon when due, and

(B) the applicant provides the Secretary with reasonable assurances that there will be available to it such additional funds as may be necessary to complete the project or undertaking with respect to which such loan is requested.

(2) Any loan made under this title shall (A) have such security, (B) have such maturity date, (C) be repayable in such installments, (D) on the date the loan is made, bear interest at a rate comparable to the rate of interest prevailing on such date with respect to marketable obligations of the United States of comparable maturities, adjusted to provide for appropriate administrative charges, and (E) be subject to such other terms and conditions (including provisions for recovery in case of default), as the Secretary determines to be necessary to carry out the purposes of this title while adequately protecting the financial interests of the United States. On the date disbursements are made under a loan after the initial disbursement under the loan, the Secretary may change the rate of interest on the amount of the loan disbursed on that date to a rate which is comparable to the rate of interest prevailing on the date the subsequent disbursement is made with respect to marketable obligations of the United States of comparable maturities, adjusted to provide for appropriate administrative charges.

(3) The Secretary may, for good cause but with due regard to the financial interests of the United States, waive any right of recovery which he has by reason of the failure of a borrower to make payments of principal of and interest on a loan made under this title, except that if such loan is sold and guaranteed, any such waiver shall have no effect upon the Secretary's guarantee of timely payment of principal and interest.

(c)(1) The Secretary may from time to time, but with due regard to the financial interests of the United States, sell loans made by him under this title.

(2) The Secretary may agree, prior to his sale of any such loan, to guarantee to the purchaser (and any successor in interest of the purchaser) compliance by the borrower with the terms and conditions of such loan. Any such agreement shall contain such terms and conditions as the Secretary considers necessary to protect the financial interests of the United States or as otherwise appropriate. Any such agreement may (A) provide that the Secretary shall act as agent of any such purchaser for the purpose of collecting from the borrower to which such loan was made and paying over to such purchaser, any payments of principal and interest payable by such organization under such loan; and (B) provide for the repurchase by the Secretary of any such loan on such terms and conditions as may be specified in the agreement. The full faith and credit of the United States is pledged to the payment of all amounts which may be required to be paid under any guarantee under this paragraph.

(3) After any loan under this title to a public health maintenance organization has been sold and guaranteed under this subsection, interest paid on such loan which is received by the purchaser thereof (or his successor in interest) shall be included in the gross income of the purchaser of the loan (or his successor in inter-

est) for the purpose of chapter 1 of the Internal Revenue Code of 1954.

(4) Amounts received by the Secretary as proceeds from the sale of loans under this subsection shall be deposited in the loan fund established under subsection (e).

(5) Any reference in this title (other than in this subsection and in subsection (d)) to a loan guarantee under this title does not include a loan guarantee made under this subsection.

(d)(1) There is established in the Treasury a loan guarantee fund (hereinafter in this subsection referred to as the "fund") which shall be available to the Secretary without fiscal year limitation, in such amounts as may be specified from time to time in appropriation Acts, to enable him to discharge his responsibilities under loan guarantees issued by him under this title and to take the action authorized by subsection (f). There are authorized to be appropriated from time to time such amounts as may be necessary to provide the sums required for the fund. To the extent authorized in appropriation Acts, there shall also be deposited in the fund amounts received by the Secretary in connection with loan guarantees under this title and other property or assets derived by him from his operations respecting such loan guarantees, including any money derived from the sale of assets.

(2) If at any time the sums in the funds are insufficient to enable the Secretary to discharge his responsibilities under guarantees issued by him before October 1, 1986, under this title and to take the action authorized by subsection (f), he is authorized to issue to the Secretary of the Treasury notes or other obligations in such forms and denominations, bearing such maturities, and subject to such terms and conditions, as may be prescribed by the Secretary with the approval of the Secretary of Treasury. Such notes or other obligations shall bear interest at a rate determined by the Secretary of the Treasury, taking into consideration the current average market yield on outstanding marketable obligations of the United States of comparable maturities during the month preceding the issuance of the notes or other obligations. The Secretary of the Treasury shall purchase any notes and other obligations issued under this paragraph and for that purpose he may use as a public debt transaction the proceeds from the sale of any securities issued under the Second Liberty Bond Act, and the purposes for which the securities may be issued under that Act are extended to include any purchase of such notes and obligations. The Secretary of the Treasury may at any time sell any of the notes or other obligations acquired by him under this paragraph. All redemptions, purchases, and sales by the Secretary of the Treasury of such notes or other obligations shall be treated as public debt transactions of the United States. Sums borrowed under this paragraph shall be deposited in the fund and redemption of such notes and obligations shall be made by the Secretary from the fund.

(e) There is established in the Treasury a loan fund (hereinafter in this subsection referred to as the "fund") which shall be available to the Secretary without fiscal year limitation, in such amounts as may be specified from time to time in appropriation Acts, to enable him to make loans under this title and to take the action authorized by subsection (f). There shall also be deposited in

the fund amounts received by the Secretary as interest payments and repayment of principal on loans made under this title and other property or assets derived by him from his operations respecting such loans, from the sale of loans under subsection (c) of this section, or from the sale of assets.

(f) The Secretary may take such action as he deems appropriate to protect the interest of the United States in the event of a default on a loan made or guaranteed under this title, including taking possession of, holding, and using real property pledged as security for such a loan or loan guarantee.

AUTHORIZATIONS OF APPROPRIATIONS.

SEC. 1309.[300e–8] (a) For grants under section 1317 there is authorized to be appropriated $1,000,000 for each of the fiscal years 1982, 1983, and 1984.

(b) To meet the obligations of the loan fund established under section 1308(e) resulting from defaults on loans made from the fund and to meet the other obligations of the fund, there is authorized to be appropriated to the loan fund for fiscal years 1987, 1988, and 1989, such sums as may be necessary.

EMPLOYEES' HEALTH BENEFITS PLANS.

SEC. 1310.[3][300e–9] (a) In accordance with regulations which the Secretary shall prescribe—

(1) each employer—

(A) which is required during any calendar quarter to pay its employees the minimum wage prescribed by section 6 of the Fair Labor Standards Act of 1938 (or would be required to pay its employees such wage but for section 13(a) of such Act), and

(B) which during such calendar quarter employed an average number of employees of not less than 25, and

(2) any State and each political subdivision thereof which during any calendar quarter employed an average number of employees of not less than 25, as a condition of payment to the State of funds under section 317, 318, or 1002,

which offers to its employees in the calendar year beginning after such calendar quarter the option of membership in a qualified health maintenance organization which is engaged in the provision of basic health services in a health maintenance organization service area in which at least 25 of such employees reside shall meet the requirements of subsection (b) with respect to any qualified health maintenance organization offered by the employer or State or political subdivision.

[3] Section 1310 as shown above was added by section 7(b) of Public Law 100–517. Such section provided in part as follows: "Effective 7 years after the date of the enactment of this Act, section 1310 (42 U.S.C. 300e–9) is amended to read as follows".

Section 7(a)(3) of such Public Law provides that nothing in section 1310 shall be construed to supersede any provision of a collective bargaining agreement in effect on.

Section 9 of such Public Law provides as follows: "With respect to abortion services, the Secretary of Health and Human Services shall not promulgate or issue any regulations, policy statements, or interpretations or develop any practices concerning the performance of medically necessary procedures if such regulations, policy statements, interpretations, or practices would be inconsistent with those in effect on.".

(b)(1) If a health benefits plan offered by an employer or a State or political subdivision includes contributions for services offered under the plan, the employer or State or political subdivision shall make a contribution under the plan for services offered by a qualified health maintenance organization in an amount which does not financially discriminate against an employee who enrolls in such organization. For purposes of the preceding sentence, an employer's or a State's or political subdivision's contribution does not financially discriminate if the employer's or State's or political subdivision's method of determining the contributions on behalf of all employees is reasonable and is designed to assure employees a fair choice among health benefits plans.

(2) Each employer or State or political subdivision which provides payroll deductions as a means of paying employees' contributions for health benefits or which provides a health benefits plan to which an employee contribution is not required shall, with the consent of an employee who exercises option of membership in a qualified health maintenance organization, arrange for the employee's contribution for membership in the organization to be paid through payroll deductions.

(3) No employer or State or political subdivision shall be required to pay more for health benefits as a result of the application of this subsection than would otherwise be required by any prevailing collective bargaining agreement or other legally enforceable contract for the provision of health benefits between the employer or State or political subdivision and its employees.

(c) For purposes of this section, the term "qualified health maintenance organization" means (1) a health maintenance organization which has provided assurances satisfactory to the Secretary that it provides basic and supplemental health services to its members in the manner prescribed by section 1301(b) and that it is organized and operated in the manner prescribed by section 1301(c), and (2) an entity which proposes to become a health maintenance organization and which the Secretary determines will when it becomes operational provide basic and supplemental health services to its members in the manner prescribed by section 1301(b) and will be organized and operated in the manner prescribed by section 1301(c).

(d)(1) Any employer who knowingly does not comply with one or more of the requirements of paragraph (1) or (2) of subsection (b) shall be subject to a civil penalty of not more than $10,000. If such noncompliance continues, a civil penalty may be assessed and collected under this subsection for each thirty-day period such noncompliance continues. Such penalty may be assessed by the Secretary and collected in a civil action brought by the United States in a United States district court.

(2) In any proceeding by the Secretary to assess a civil penalty under this subsection, no penalty shall be assessed until the employer charged shall have been given notice and an opportunity to present its views on such charge. In determining the amount of the penalty, or the amount agreed upon in compromise, the Secretary shall consider the gravity of the noncompliance and the demonstrated good faith of the employer charged in attempting to

achieve rapid compliance after notification by the Secretary of a noncompliance.

(3) In any civil action brought to review the assessment of a civil penalty assessed under this subsection, the court shall, at the request of any party to such action, hold a trial de novo on the assessment of such civil penalty and in any civil action to collect such a civil penalty, the court shall, at the request of any party to such action, hold a trial de novo on the assessment of such civil penalty unless in a prior civil action to review the assessment of such penalty the court held a trial de novo on such assessment.

(e) For purposes of this section, the term "employer" does not include (1) the Government of the United States, the government of the District of Columbia or any territory or possession of the United States, a State or any political subdivision thereof, or any agency or instrumentality (including the United States Postal Service and Postal Rate Commission) of any of the foregoing, except that such term includes nonappropriated fund instrumentalities of the Government of the United States; or (2) a church, convention or association of churches, or any organization operated, supervised or controlled by a church, convention or association of churches which organization (A) is an organization described in section 501(c)(3) of the Internal Revenue Code of 1986, and (B) does not discriminate (i) in the employment, compensation, promotion, or termination of employment of any personnel, or (ii) in the extension of staff or other privileges to any physician or other health personnel, because such persons seek to obtain or obtained health care, or participate in providing health care, through a health maintenance organization.

(f) If the Secretary, after reasonable notice and opportunity for a hearing to a State, finds that it or any of its political subdivisions has failed to comply with paragraph (1) or (2) of subsection (b), the Secretary shall terminate payments to such State under sections 317, 318, and 1002 and notify the Governor of such State that further payments under such sections will not be made to the State until the Secretary is satisfied that there will no longer be any such failure to comply.

RESTRICTIVE STATE LAWS AND PRACTICES.

SEC. 1311.[300e–10] (a) In the case of any entity—

(1) which cannot do business as a health maintenance organization in a State in which it proposes to furnish basic and supplemental health services because that State by law, regulation, or otherwise—

(A) requires as a condition to doing business in that State that a medical society approve the furnishing of services by the entity,

(B) requires that physicians constitute all or a percentage of its governing body,

(C) requires that all physicians or a percentage of physicians in the locale participate or be permitted to participate in the provision of services for the entity,

(D) requires that the entity meet requirements for insurers of health care services doing business in that State

respecting initial capitalization and establishment of financial reserves against insolvency, or

(E) imposes requirements which would prohibit the entity from complying with the requirements of this title, and

(2) for which a grant, contract, loan, or loan guarantee was made under this title or which is a qualified health maintenance organization for purposes of section 1310 (relating to employees' health benefits plans),

such requirements shall not apply to that entity so as to prevent it from operating as a health maintenance organization in accordance with section 1301.

(b) No State may establish or enforce any law which prevents a health maintenance organization for which a grant, contract, loan, or loan guarantee was made under this title or which is a qualified health maintenance organization for purposes of section 1310 (relating to employees' health benefits plans), from soliciting members through advertising its services, charges, or other nonprofessional aspects of its operation. This subsection does not authorize any advertising which identifies, refers to, or makes any qualitative judgment concerning, any health professional who provides services for a health maintenance organization.

(c) The Secretary shall, within 6 months after the date of the enactment of this subsection, develop a digest of State laws, regulations, and practices pertaining to development, establishment, and operation of health maintenance organizations which shall be updated at least annually and relevant sections of which shall be provided to the Governor of each State annually. Such digest shall indicate which State laws, regulations, and practices appear to be inconsistent with the operation of this section. The Secretary shall also insure that appropriate legal consultative assistance is available to the States for the purpose of complying with the provisions of this section.

CONTINUED REGULATION OF HEALTH MAINTENANCE ORGANIZATIONS.

SEC. 1312.[300e–11] (a) If the Secretary determines that an entity which received a grant, contract, loan, or loan guarantee under this title as a health maintenance organization or which was included in a health benefits plan offered to employees pursuant to section 1310—

(1) fails to provide basic and supplemental services to its members,

(2) fails to provide such services in the manner prescribed by section 1301(b), or

(3) is not organized or operated in the manner prescribed by section 1301(c),

the Secretary may take the action authorized by subsection (b).

(b)(1) If the Secretary makes, with respect to any entity which provided assurances to the Secretary under section 1310(d)(1), a determination described in subsection (a), the Secretary shall notify the entity in writing of the determination. Such notice shall specify the manner in which the entity has not complied with such assurances and direct that the entity initiate (within 30 days of the date

the notice is issued by the Secretary or within such longer period as the Secretary determines is reasonable) such action as may be necessary to bring (within such period as the Secretary shall prescribe) the entity into compliance with the assurances. If the entity fails to initiate corrective action within the period prescribed by the notice or fails to comply with the assurances within such period as the Secretary prescribes, then after the Secretary provides the entity a reasonable opportunity for reconsideration of his determination, including, at the entity's election, a fair hearing (A) the entity shall not be a qualified health maintenance organization for purposes of section 1310 until such date as the Secretary determines that it is in compliance with the assurances, and (B) each employer which has offered membership in the entity in compliance with section 1310, each lawfully recognized collective bargaining representative or other employee representative which represents the employees of each such employer, and the members of such entity shall be notified by the entity that the entity is not a qualified health maintenance organization for purposes of such section. The notice required by clause (B) of the preceding sentence shall contain, in readily understandable language, the reasons for the determination that the entity is not a qualified health maintenance organization. The Secretary shall publish in the Federal Register each determination referred to in this paragraph.

(2) If the Secretary makes, with respect to an entity which has received a grant, contract, loan, or loan guarantee under this title, a determination described in subsection (a), the Secretary may, in addition to any other remedies available to him, bring a civil action in the United States district court for the district in which such entity is located to enforce its compliance with the assurances it furnished respecting the provision of basic and supplemental health services or its organization or operation, as the case may be, which assurances were made in connection with its application under this title for the grant, contract, loan, or loan guarantee.

LIMITATION ON SOURCE OF FUNDING FOR HEALTH MAINTENANCE ORGANIZATIONS.

SEC. 1313.[300e–12] No funds appropriated under any provision of this Act (except as provided in sections 329 and 330) other than this title may be used—

(1) for grants or contracts for surveys or other activities to determine the feasibility of developing or expanding health maintenance organizations or other entities which provide, directly or indirectly, health services to a defined population on a prepaid basis;

(2) for grants or contracts, or for payments under loan guarantees, for planning projects for the establishment or expansion of such organizations or entities;

(3) for grants or contracts, or for payments under loan guarantees, for projects for the initial development or expansion of such organizations or entities; or

(4) for loans, or for payments under loan guarantees, to assist in meeting the costs of the initial operation after establishment or expansion of such organizations or entities or in meet-

ing the costs of such organizations in acquiring or constructing ambulatory health care facilities.

ANNUAL REPORT.

SEC. 1315.[300e–14] (a) The Secretary shall periodically review the programs of assistance authorized by this title and make an annual report to the Congress of a summary of the activities under each program. The Secretary shall include in such summary—

(1) a summary of each grant, contract, loan, or loan guarantee made under this title in the period covered by the report and a list of the health maintenance organizations which during such period became qualified health maintenance organizations for purposes of section 1310;

(2) the statistics and other information reported in such period to the Secretary in accordance with section 1301(c)(11);

(3) findings with respect to the ability of the health maintenance organizations assisted under this title—

(A) to operate on a fiscally sound basis without continued Federal financial assistance,

(B) to meet the requirements of section 1301(c) respecting their organization and operation,

(C) to provide basic and supplemental health services in the manner prescribed by section 1301(b),

(D) to include indigent and high-risk individuals in their membership, and

(E) to provide services to medically underserved populations; and

(4) findings with respect to—

(A) the operation of distinct categories of health maintenance organizations in comparison with each other,

(B) health maintenance organizations as a group in comparison with alternative forms of health care delivery, and

(C) the impact that health maintenance organizations, individually, by category, and as a group, have on the health of the public.

(b) The Office of Management and Budget may review the Secretary's report under subsection (a) before its submission to the Congress, but the Office may not revise the report or delay its submission, and it may submit to the Congress its comments (and those of other departments or agencies of the Government) respecting such report.

TRAINING AND TECHNICAL ASSISTANCE.

SEC. 1317.[300e–16] (a)(1) The Secretary shall establish a National Health Maintenance Organization Intern Program (hereinafter in this subsection referred to as the "Program") for the purpose of providing training to individuals to become administrators and medical directors of health maintenance organizations or to assume other managerial positions with health maintenance organizations. Under the Program the Secretary may directly provide internships for such training and may make grants to or enter into

contracts with health maintenance organizations and other entities to provide such internships.

(2) No internship may be provided by the Secretary and no grant may be made or contract entered into by the Secretary for the provision of internships unless an application therefor has been submitted to and approved by the Secretary. Such an application shall be in such form and contain such information, and be submitted to the Secretary in such manner, as the Secretary shall prescribe. Section 1306 does not apply to an application submitted under this section.

(3) Internships under the Program shall provide for such stipends and allowances (including travel and subsistence expenses and dependency allowances) for the recipients of the internships as the Secretary deems necessary. An internship provided an individual for training at a health maintenance organization or any other entity shall also provide for payments to be made to the organization or other entity for the cost of support services (including the cost of salaries, supplies, equipment, and related items) provided such individual by such organization or other entity. The amount of any such payments to any organization or other entity shall be determined by the Secretary and shall bear a direct relationship to the reasonable costs of the organization or other entity for establishing and maintaining its training programs.

(4) Payments under grants under the Program may be made in advance or by way of reimbursement, and at such intervals and on such conditions, as the Secretary finds necessary.

(b) The Secretary shall provide technical assistance (1) to entities intending to become a qualified health maintenance organization within the meaning of section 1310(d), and (2) to health maintenance organizations. The Secretary may provide such technical assistance through grants to public and nonprofit private entities and contracts with public and private entities.

(c) The authority of the Secretary to enter into contracts under subsections (a) and (b) shall be effective for any fiscal year only to such extent or in such amounts as are provided in advance by appropriation Acts.

FINANCIAL DISCLOSURE.

SEC. 1318.[300e–17] (a) Each health maintenance organization shall, in accordance with regulations of the Secretary, report to the Secretary financial information which shall include the following:

(1) Such information as the Secretary may require demonstrating that the health maintenance organization has a fiscally sound operation.

(2) A copy of the report, if any, filed with the Centers for Medicare & Medicaid Services containing the information required to be reported under section 1124 of the Social Security Act by disclosing entities and the information required to be supplied under section 1902(a)(38) of such Act.

(3) A description of transactions, as specified by the Secretary, between the health maintenance organization and a party in interest. Such transactions shall include—

(A) any sale or exchange, or leasing of any property between the health maintenance organization and a party in interest;

(B) any furnishing for consideration of goods, services (including management services), or facilities between the health maintenance organization and a party in interest, but not including salaries paid to employees for services provided in the normal course of their employment and health services provided to members by hospitals and other providers and by staff, medical group (or groups), individual practice association (or associations), or any combination thereof; and

(C) any lending of money or other extension of credit between a health maintenance organization and a party in interest.

The Secretary may require that information reported respecting a health maintenance organization which controls, is controlled by, or is under common control with, another entity be in the form of a consolidated financial statement for the organization and such entity.

(b) For the purposes of this section the term "party in interest" means:

(1) any director, officer, partner, or employee responsible for management or administration of a health maintenance organization, any person who is directly or indirectly the beneficial owner of more than 5 per centum of the equity of the organization, any person who is the beneficial owner of a mortgage, deed of trust, note, or other interest secured by, and valuing more than 5 per centum of the health maintenance organization, and, in the case of a health maintenance organization organized as a nonprofit corporation, an incorporator or member of such corporation under applicable State corporation law;

(2) any entity in which a person described in paragraph (1)—

(A) is an officer or director;

(B) is a partner (if such entity is organized as a partnership);

(C) has directly or indirectly a beneficial interest of more than 5 per centum of the equity; or

(D) has a mortgage, deed of trust, note, or other interest valuing more than 5 per centum of the assets of such entity;

(3) any person directly or indirectly controlling, controlled by, or under common control with a health maintenance organization; and

(4) any spouse, child, or parent of an individual described in paragraph (1).

(c) Each health maintenance organization shall make the information reported pursuant to subsection (a) available to its enrollees upon reasonable request.

(d) The Secretary shall, as he deems necessary, conduct an evaluation of transactions reported to the Secretary under subsection (a)(3) for the purpose of determining their adverse impact, if any, on the fiscal soundness and reasonableness of charges to the

health maintenance organization with respect to which they transpired. The Secretary shall evaluate the reported transactions of not less than five, or if there are more than twenty health maintenance organizations reporting such transactions, not less than one-fourth of the health maintenance organizations reporting any such transactions under subsection (a)(3).

(f)[4] Nothing in this section shall be construed to confer upon the Secretary any authority to approve or disapprove the rates charged by any health maintenance organization.

(g) Any health maintenance organization failing to file with the Secretary the annual financial statement required in subsection (a) shall be ineligible for any Federal assistance under this title until such time as such statement is received by the Secretary and shall not be a qualified health maintenance organization for purposes of section 1310.

(h) Whoever knowingly and willfully makes or causes to be made any false statement or representation of a material fact in any statement filed pursuant to this section shall be guilty of a felony and upon conviction thereof shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

[4] Subsection (e) was repealed by section 810 of Public Law 99–660.

TITLE XV—PREVENTIVE HEALTH MEASURES WITH RESPECT TO BREAST AND CERVICAL CANCERS

SEC. 1501.[300k] ESTABLISHMENT OF PROGRAM OF GRANTS TO STATES.

(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make grants to States on the basis of an established competitive review process for the purpose of carrying out programs—

(1) to screen women for breast and cervical cancer as a preventive health measure;

(2) to provide appropriate referrals for medical treatment of women screened pursuant to paragraph (1) and to ensure, to the extent practicable, the provision of appropriate follow-up services and support services such as case management;

(3) to develop and disseminate public information and education programs for the detection and control of breast and cervical cancer;

(4) to improve the education, training, and skills of health professionals (including allied health professionals) in the detection and control of breast and cervical cancer;

(5) to establish mechanisms through which the States can monitor the quality of screening procedures for breast and cervical cancer, including the interpretation of such procedures; and

(6) to evaluate activities conducted under paragraphs (1) through (5) through appropriate surveillance or program-monitoring activities.

(b) GRANT AND CONTRACT AUTHORITY OF STATES.—

(1) IN GENERAL.—A State receiving a grant under subsection (a) may, subject to paragraphs (2) and (3), expend the grant to carry out the purpose described in such subsection through grants to public and nonprofit private entities and through contracts with public and private entities.

(2) CERTAIN APPLICATIONS.—If a nonprofit private entity and a private entity that is not a nonprofit entity both submit applications to a State to receive an award of a grant or contract pursuant to paragraph (1), the State may give priority to the application submitted by the nonprofit private entity in any case in which the State determines that the quality of

such application is equivalent to the quality of the application submitted by the other private entity.

(3) PAYMENTS FOR SCREENINGS.—The amount paid by a State to an entity under this subsection for a screening procedure under subsection (a)(1) may not exceed the amount that would be paid under part B of title XVIII of the Social Security Act if payment were made under such part for furnishing the procedure to a woman enrolled under such part.

(c) SPECIAL CONSIDERATION FOR CERTAIN STATES.—In making grants under subsection (a) to States whose initial grants under such subsection are made for fiscal year 1995 or any subsequent fiscal year, the Secretary shall give special consideration to any State whose proposal for carrying out programs under such subsection—

(1) has been approved through a process of peer review; and

(2) is made with respect to geographic areas in which there is—

(A) a substantial rate of mortality from breast or cervical cancer; or

(B) a substantial incidence of either of such cancers.

(d) COORDINATING COMMITTEE REGARDING YEAR 2020 HEALTH OBJECTIVES.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish a committee to coordinate the activities of the agencies of the Public Health Service (and other appropriate Federal agencies) that are carried out toward achieving the objectives established by the Secretary for reductions in the rate of mortality from breast and cervical cancer in the United States by the year 2020. Such committee shall be comprised of Federal officers or employees designated by the heads of the agencies involved to serve on the committee as representatives of the agencies, and such representatives from other public or private entities as the Secretary determines to be appropriate.

SEC. 1502.[300l] REQUIREMENT OF MATCHING FUNDS.

(a) IN GENERAL.—The Secretary may not make a grant under section 1501 unless the State involved agrees, with respect to the costs to be incurred by the State in carrying out the purpose described in such section, to make available non-Federal contributions (in cash or in kind under subsection (b)) toward such costs in an amount equal to not less than $1 for each $3 of Federal funds provided in the grant. Such contributions may be made directly or through donations from public or private entities.

(b) DETERMINATION OF AMOUNT OF NON-FEDERAL CONTRIBUTION.—

(1) IN GENERAL.—Non-Federal contributions required in subsection (a) may be in cash or in kind, fairly evaluated, including equipment or services (and excluding indirect or overhead costs). Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

(2) MAINTENANCE OF EFFORT.—In making a determination of the amount of non-Federal contributions for purposes of subsection (a), the Secretary may include only non-Federal contributions in excess of the average amount of non-Federal contributions made by the State involved toward the purpose described in section 1501 for the 2-year period preceding the first fiscal year for which the State is applying to receive a grant under such section.

(3) INCLUSION OF RELEVANT NON-FEDERAL CONTRIBUTIONS FOR MEDICAID.—In making a determination of the amount of non-Federal contributions for purposes of subsection (a), the Secretary shall, subject to paragraphs (1) and (2) of this subsection, include any non-Federal amounts expended pursuant to title XIX of the Social Security Act by the State involved toward the purpose described in paragraphs (1) and (2) of section 1501(a).

SEC. 1502A.[300l–1] REQUIREMENT REGARDING MEDICAID.

The Secretary may not make a grant under section 1501 for a program in a State unless the State plan under title XIX of the Social Security Act for the State includes the screening procedures specified in subparagraphs (A) and (B) of section 1503(a)(2) as medical assistance provided under the plan.

SEC. 1503.[300m] REQUIREMENTS WITH RESPECT TO TYPE AND QUALITY OF SERVICES.

(a) REQUIREMENT OF PROVISION OF ALL SERVICES BY DATE CERTAIN.—The Secretary may not make a grant under section 1501 unless the State involved agrees—

(1) to ensure that, initially and throughout the period during which amounts are received pursuant to the grant, not less than 60 percent of the grant is expended to provide each of the services or activities described in paragraphs (1) and (2) of section 1501(a), including making available screening procedures for both breast and cervical cancers;

(2) subject to subsection (b), to ensure that—

(A) in the case of breast cancer, both a physical examination of the breasts and the screening procedure known as a mammography are conducted; and

(B) in the case of cervical cancer, both a pelvic examination and the screening procedure known as a pap smear are conducted;

(3) to ensure that, by the end of any second fiscal year of payments pursuant to the grant, each of the services or activities described in section 1501(a) is provided; and

(4) to ensure that not more than 40 percent of the grant is expended to provide the services or activities described in paragraphs (3) through (6) of such section.

(b) USE OF IMPROVED SCREENING PROCEDURES.—The Secretary may not make a grant under section 1501 unless the State involved agrees that, if any screening procedure superior to a procedure described in subsection (a)(2) becomes commonly available and is recommended for use, any entity providing screening procedures pursuant to the grant will utilize the superior procedure rather than the procedure described in such subsection.

(c)[1] QUALITY ASSURANCE REGARDING SCREENING PROCEDURES.—The Secretary may not make a grant under section 1501 unless the State involved agrees that the State will, in accordance with applicable law, assure the quality of screening procedures conducted pursuant to such section.

(d) WAIVER OF SERVICES REQUIREMENT ON DIVISION OF FUNDS.—

(1) IN GENERAL.—The Secretary shall establish a demonstration project under which the Secretary may waive the requirements of paragraphs (1) and (4) of subsection (a) for not more than 5 States, if—

(A) the State involved will use the waiver to leverage non-Federal funds to supplement each of the services or activities described in paragraphs (1) and (2) of section 1501(a);

(B) the application of such requirement would result in a barrier to the enrollment of qualifying women;

(C) the State involved—

(i) demonstrates, to the satisfaction of the Secretary, the manner in which the State will use such waiver to expand the level of screening and follow-up services provided immediately prior to the date on which the waiver is granted; and

(ii) provides assurances, satisfactory to the Secretary, that the State will, on an annual basis, demonstrate, through such documentation as the Secretary may require, that the State has used such waiver as described in clause (i);

(D) the State involved submits to the Secretary—

(i) assurances, satisfactory to the Secretary, that the State will maintain the average annual level of State fiscal year expenditures for the services and activities described in paragraphs (1) and (2) of section 1501(a) for the period for which the waiver is granted, and for the period for which any extension of such wavier is granted, at a level that is not less than—

(I) the level of the State fiscal year expenditures for such services and activities for the fiscal year preceding the first fiscal year for which the waiver is granted; or

(II) at the option of the State and upon approval by the Secretary, the average level of the State expenditures for such services and activities for the 3-fiscal year period preceding the first fiscal year for which the waiver is granted; and

(ii) a plan, satisfactory to the Secretary, for maintaining the level of activities carried out under the

[1] Section 101(c)(2) of Public Law 103–183 (107 Stat. 2228) provides as follows:

"(2) TRANSITION RULE REGARDING MAMMOGRAPHIES.—With respect to the screening procedure for breast cancer known as a mammography, the requirements in effect on the day before the date of the enactment of this Act under section 1503(c) of the Public Health Service Act remain in effect (for an individual or facility conducting such procedures pursuant to a grant to a State under section 1501 of such Act) until there is in effect for the facility a certificate (or provisional certificate) issued under section 354 of such Act.".

waiver after the expiration of the waiver and any extension of such waiver;

(E) the Secretary finds that granting such a waiver to a State will increase the number of women in the State that receive each of the services or activities described in paragraphs (1) and (2) of section 1501(a), including making available screening procedures for both breast and cervical cancers; and

(F) the Secretary finds that granting such a waiver to a State will not adversely affect the quality of each of the services or activities described in paragraphs (1) and (2) of section 1501(a).

(2) DURATION OF WAIVER.—

(A) IN GENERAL.—In granting waivers under paragraph (1), the Secretary—

(i) shall grant such waivers for a period that is not less than 1 year but not more than 2 years; and

(ii) upon request of a State, may extend a waiver for an additional period that is not less than 1 year but not more than 2 years in accordance with subparagraph (B).

(B) ADDITIONAL PERIOD.—The Secretary, upon the request of a State that has received a waiver under paragraph (1), shall, at the end of the waiver period described in subparagraph (A)(i), review performance under the waiver and may extend the waiver for an additional period if the Secretary determines that—

(i) without an extension of the waiver, there will be a barrier to the enrollment of qualifying women;

(ii) the State requesting such extended waiver will use the waiver to leverage non-Federal funds to supplement the services or activities described in paragraphs (1) and (2) of section 1501(a);

(iii) the waiver has increased, and will continue to increase, the number of women in the State that receive the services or activities described in paragraphs (1) and (2) of section 1501(a);

(iv) the waiver has not, and will not, result in lower quality in the State of the services or activities described in paragraphs (1) and (2) of section 1501(a); and

(v) the State has maintained the average annual level of State fiscal expenditures for the services and activities described in paragraphs (1) and (2) of section 1501(a) for the period for which the waiver was granted at a level that is not less than—

(I) the level of the State fiscal year expenditures for such services and activities for the fiscal year preceding the first fiscal year for which the waiver is granted; or

(II) at the option of the State and upon approval by the Secretary, the average level of the State expenditures for such services and activities

for the 3-fiscal year period preceding the first fiscal year for which the waiver is granted.

(3) REPORTING REQUIREMENTS.—The Secretary shall include as part of the evaluations and reports required under section 1508, the following:

(A) A description of the total amount of dollars leveraged annually from Non-Federal entities in States receiving a waiver under paragraph (1) and how these amounts were used.

(B) With respect to States receiving a waiver under paragraph (1), a description of the percentage of the grant that is expended on providing each of the services or activities described in—

(i) paragraphs (1) and (2) of section 1501(a); and

(ii) paragraphs (3) through (6) of section 1501(a).

(C) A description of the number of States receiving waivers under paragraph (1) annually.

(D) With respect to States receiving a waiver under paragraph (1), a description of—

(i) the number of women receiving services under paragraphs (1), (2), and (3) of section 1501(a) in programs before and after the granting of such waiver; and

(ii) the average annual level of State fiscal expenditures for the services and activities described in paragraphs (1) and (2) of section 1501(a) for the year preceding the first year for which the waiver was granted.

(4) LIMITATION.—Amounts to which a waiver applies under this subsection shall not be used to increase the number of salaried employees.

(5) DEFINITIONS.—In this subsection:

(A) INDIAN TRIBE.—The term "Indian tribe" has the meaning given the term in section 4 of the Indian Health Care Improvement Act (25 U.S.C. 1603).

(B) TRIBAL ORGANIZATION.—The term "tribal organization" has the meaning given the term in section 4 of the Indian Health Care Improvement Act.

(C) STATE.—The term "State" means each of the several States of the United States, the District of Columbia, the Commonwealth of Puerto Rico, American Samoa, the Commonwealth of the Northern Mariana Islands, the Republic of the Marshall Islands, the Federated States of Micronesia, the Republic of Palau, an Indian tribe, and a tribal organization.

(6) SUNSET.—The Secretary may not grant a waiver or extension under this subsection after September 30, 2012.

SEC. 1504.[300n] ADDITIONAL REQUIRED AGREEMENTS.

(a) PRIORITY FOR LOW-INCOME WOMEN.—The Secretary may not make a grant under section 1501 unless the State involved agrees that low-income women will be given priority in the provision of services and activities pursuant to paragraphs (1) and (2) of section 1501(a).

(b) LIMITATION ON IMPOSITION OF FEES FOR SERVICES.—The Secretary may not make a grant under section 1501 unless the State involved agrees that, if a charge is imposed for the provision of services or activities under the grant, such charge—

(1) will be made according to a schedule of charges that is made available to the public;

(2) will be adjusted to reflect the income of the woman involved; and

(3) will not be imposed on any woman with an income of less than 100 percent of the official poverty line, as established by the Director of the Office of Management and Budget and revised by the Secretary in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1981.

(c) STATEWIDE PROVISION OF SERVICES.—

(1) IN GENERAL.—The Secretary may not make a grant under section 1501 unless the State involved agrees that services and activities under the grant will be made available throughout the State, including availability to members of any Indian tribe or tribal organization (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act).

(2) WAIVER.—The Secretary may waive the requirement established in paragraph (1) for a State if the Secretary determines that compliance by the State with the requirement would result in an inefficient allocation of resources with respect to carrying out the purpose described in section 1501(a).

(3) GRANTS TO TRIBES AND TRIBAL ORGANIZATIONS.—

(A) The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make grants to tribes and tribal organizations (as such terms are used in paragraph (1)) for the purpose of carrying out programs described in section 1501(a). This title applies to such a grant (in relation to the jurisdiction of the tribe or organization) to the same extent and in the same manner as such title applies to a grant to a State under section 1501 (in relation to the jurisdiction of the State).

(B) If a tribe or tribal organization is receiving a grant under subparagraph (A) and the State in which the tribe or organization is located is receiving a grant under section 1501, the requirement established in paragraph (1) for the State regarding the tribe or organization is deemed to have been waived under paragraph (2).

(d) RELATIONSHIP TO ITEMS AND SERVICES UNDER OTHER PROGRAMS.—The Secretary may not make a grant under section 1501 unless the State involved agrees that the grant will not be expended to make payment for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to such item or service—

(1) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program; or

(2) by an entity that provides health services on a prepaid basis.

(e) COORDINATION WITH OTHER BREAST AND CERVICAL CANCER PROGRAMS.—The Secretary may not make a grant under section 1501 unless the State involved agrees that the services and activities funded through the grant shall be coordinated with other Federal, State, and local breast and cervical cancer programs.

(f) LIMITATION ON ADMINISTRATIVE EXPENSES.—The Secretary may not make a grant under section 1501 unless the State involved agrees that not more than 10 percent of the grant will be expended for administrative expenses with respect to the grant.

(g) RESTRICTIONS ON USE OF GRANT.—The Secretary may not make a grant under section 1501 unless the State involved agrees that the grant will not be expended to provide inpatient hospital services for any individual.

(h) RECORDS AND AUDITS.—The Secretary may not make a grant under section 1501 unless the State involved agrees that—

(1) the State will establish such fiscal control and fund accounting procedures as may be necessary to ensure the proper disbursal of, and accounting for, amounts received by the State under such section; and

(2) upon request, the State will provide records maintained pursuant to paragraph (1) to the Secretary or the Comptroller of the United States for purposes of auditing the expenditures by the State of the grant.

(i) REPORTS TO SECRETARY.—The Secretary may not make a grant under section 1501 unless the State involved agrees to submit to the Secretary such reports as the Secretary may require with respect to the grant.

SEC. 1505.[300n–1] DESCRIPTION OF INTENDED USES OF GRANT.

The Secretary may not make a grant under section 1501 unless—

(1) the State involved submits to the Secretary a description of the purposes for which the State intends to expend the grant;

(2) the description identifies the populations, areas, and localities in the State with a need for the services or activities described in section 1501(a);

(3) the description provides information relating to the services and activities to be provided, including a description of the manner in which the services and activities will be coordinated with any similar services or activities of public and private entities; and

(4) the description provides assurances that the grant funds will be used in the most cost-effective manner.

SEC. 1506.[300n–2] REQUIREMENT OF SUBMISSION OF APPLICATION.

The Secretary may not make a grant under section 1501 unless an application for the grant is submitted to the Secretary, the application contains the description of intended uses required in section 1505, and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this title.

SEC. 1507.[300n–3] TECHNICAL ASSISTANCE AND PROVISION OF SUPPLIES AND SERVICES IN LIEU OF GRANT FUNDS.

(a) TECHNICAL ASSISTANCE.—The Secretary may provide training and technical assistance with respect to the planning, development, and operation of any program or service carried out pursuant to section 1501. The Secretary may provide such technical assistance directly or through grants to, or contracts with, public and private entities.

(b) PROVISION OF SUPPLIES AND SERVICES IN LIEU OF GRANT FUNDS.—

(1) IN GENERAL.—Upon the request of a State receiving a grant under section 1501, the Secretary may, subject to paragraph (2), provide supplies, equipment, and services for the purpose of aiding the State in carrying out such section and, for such purpose, may detail to the State any officer or employee of the Department of Health and Human Services.

(2) CORRESPONDING REDUCTION IN PAYMENTS.—With respect to a request described in paragraph (1), the Secretary shall reduce the amount of payments under the grant under section 1501 to the State involved by an amount equal to the costs of detailing personnel (including pay, allowances, and travel expenses) and the fair market value of any supplies, equipment, or services provided by the Secretary. The Secretary shall, for the payment of expenses incurred in complying with such request, expend the amounts withheld.

SEC. 1508.[300n–4] EVALUATIONS AND REPORTS.

(a) EVALUATIONS.—The Secretary shall, directly or through contracts with public or private entities, provide for annual evaluations of programs carried out pursuant to section 1501. Such evaluations shall include evaluations of—

(1) the extent to which States carrying out such programs are in compliance with section 1501(a)(2) and with section 1504(c); and

(2) the extent to which each State receiving a grant under this title is in compliance with section 1502, including identification of—

(A) the amount of the non-Federal contributions by the State for the preceding fiscal year, disaggregated according to the source of the contributions; and

(B) the proportion of such amount of non-Federal contributions relative to the amount of Federal funds provided through the grant to the State for the preceding fiscal year.

(b) REPORT TO CONGRESS.—The Secretary shall, not later than 1 year after the date of the enactment of the National Breast and Cervical Cancer Early Detection Program Reauthorization of 2007, and annually thereafter, submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report summarizing evaluations carried out pursuant to subsection (a) during the preceding fiscal year and making such recommendations for administrative and legislative initiatives with respect to this title as the Secretary determines to be appropriate, including recommendations

regarding compliance by the States with section 1501(a)(2) and with section 1504(c).

SEC. 1509.[300n–4a] SUPPLEMENTAL GRANTS FOR ADDITIONAL PREVENTIVE HEALTH SERVICES.

(a) DEMONSTRATION PROJECTS.—In the case of States receiving grants under section 1501, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make grants to not more than 3 such States to carry out demonstration projects for the purpose of—

(1) providing preventive health services in addition to the services authorized in such section, including screenings regarding blood pressure and cholesterol, and including health education;

(2) providing appropriate referrals for medical treatment of women receiving services pursuant to paragraph (1) and ensuring, to the extent practicable, the provision of appropriate follow-up services; and

(3) evaluating activities conducted under paragraphs (1) and (2) through appropriate surveillance or program-monitoring activities.

(b) STATUS AS PARTICIPANT IN PROGRAM REGARDING BREAST AND CERVICAL CANCER.—The Secretary may not make a grant under subsection (a) unless the State involved agrees that services under the grant will be provided only through entities that are screening women for breast or cervical cancer pursuant to a grant under section 1501.

(c) APPLICABILITY OF PROVISIONS OF GENERAL PROGRAM.—This title applies to a grant under subsection (a) to the same extent and in the same manner as such title applies to a grant under section 1501.

(d) FUNDING.—

(1) IN GENERAL.—Subject to paragraph (2), for the purpose of carrying out this section, there are authorized to be appropriated $3,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 through 2003.

(2) LIMITATION REGARDING FUNDING WITH RESPECT TO BREAST AND CERVICAL CANCER.—The authorization of appropriations established in paragraph (1) is not effective for a fiscal year unless the amount appropriated under section 1510(a) for the fiscal year is equal to or greater than $100,000,000.

SEC. 1510.[300n–5] FUNDING FOR GENERAL PROGRAM.

(a) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this title, there are authorized to be appropriated $50,000,000 for fiscal year 1991, such sums as may be necessary for each of the fiscal years 1992 and 1993, $150,000,000 for fiscal year 1994, such sums as may be necessary for each of the fiscal years 1995 through 2003, $225,000,000 for fiscal year 2008, $245,000,000 for fiscal year 2009, $250,000,000 for fiscal year 2010, $255,000,000 for fiscal year 2011, and $275,000,000 for fiscal year 2012.

(b) SET-ASIDE FOR TECHNICAL ASSISTANCE AND PROVISION OF SUPPLIES AND SERVICES.—Of the amounts appropriated under sub-

section (a) for a fiscal year, the Secretary shall reserve not more than 20 percent for carrying out section 1507.

December 13, 2013

PUBLIC HEALTH SERVICE ACT

As Amended Through P.L. 112–240, Enacted January 2, 2013

TITLE XVI—HEALTH RESOURCES DEVELOPMENT

PART A—LOANS AND LOAN GUARANTEES

AUTHORITY FOR LOANS AND LOAN GUARANTEES.

SEC. 1601.[300q] (a)(1) The Secretary, during the period ending September 30, 1982, may, in accordance with this part, make loans from the fund established under section 1602(d) to any public or nonprofit private entity for projects for—

(A) the discontinuance of unneeded hospital services or facilities;

(B) the conversion of unneeded hospital services and facilities to needed health services and medical facilities, including outpatient medical facilities and facilities for long-term care;

(C) the renovation and modernization of medical facilities, particularly projects for the prevention or elimination of safety hazards, projects to avoid noncompliance with licensure or accreditation standards, or projects to replace obsolete facilities;

(D) the construction of new outpatient medical facilities; and

(E) the construction of new inpatient medical facilities in areas which have experienced (as determined by the Secretary) recent rapid population growth.

(2)(A) The Secretary, during the period ending September 30, 1982, may, in accordance with this part, guarantee to—

(i) non-Federal lenders for their loans to public and nonprofit private entities for medical facilities projects described in paragraph (1), and

(ii) the Federal Financing Bank for its loans to public and nonprofit private entities for such projects,

payment of principal and interest on such loans.

(B) In the case of a guarantee of any loan to a public or nonprofit private entity under subparagraph (A)(i) which is located in an urban or rural poverty area, the Secretary may pay, to the holder of such loan and for and on behalf of the project for which the loan was made, amounts sufficient to reduce by not more than one-half the net effective interest rate otherwise payable on such loan if the Secretary finds that without such assistance the project could not be undertaken.

(b) The principal amount of a loan directly made or guaranteed under subsection (a) for a medical facilities project, when added to any other assistance provided such project under part B, may not exceed 90 per centum of the cost of such project unless the project is located in an area determined by the Secretary to be an urban

or rural poverty area, in which case the principal amount, when added to other assistance under part B, may cover up to 100 per centum of such costs.

(c) The cumulative total of the principal of the loans outstanding at any time with respect to which guarantees have been issued, or which have been directly made, may not exceed such limitations as may be specified in appropriation Acts.

(d) The Secretary, with the consent of the Secretary of Housing and Urban Development, shall obtain from the Department of Housing and Urban Development such assistance with respect to the administration of this part as will promote efficiency and economy thereof.

GENERAL PROVISIONS RELATING TO LOAN GUARANTEES AND LOANS.

SEC. 1602.[300q–2] (a)(1) The Secretary may not approve a loan guarantee for a project under this part unless he determines that (A) the terms, conditions, security (if any), and schedule and amount of repayments with respect to the loan are sufficient to protect the financial interests of the United States and are otherwise reasonable, including a determination that the rate of interest does not exceed such per centum per annum on the principal obligation outstanding as the Secretary determines to be reasonable, taking into account the range of interest rates prevailing in the private market for similar loans and the risks assumed by the United States, and (B) the loan would not be available on reasonable terms and conditions without the guarantee under this part.

(2)(A) The United States shall be entitled to recover from the applicant for a loan guarantee under this part the amount of any payment made pursuant to such guarantee, unless the Secretary for good cause waives such right of recovery; and, upon making any such payment, the United States shall be subrogated to all of the rights of the recipient of the payments with respect to which the guarantee was made.

(B) To the extent permitted by subparagraph (C), any terms and conditions applicable to a loan guarantee under this part (including terms and conditions imposed under subparagraph (D)) may be modified by the Secretary to the extent he determines it to be consistent with the financial interest of the United States.

(C) Any loan guarantee made by the Secretary under this part shall be incontestable (i) in the hands of an applicant on whose behalf such guarantee is made unless the applicant engaged in fraud or misrepresentation in securing such guarantee, and (ii) as to any person (or his successor in interest) who makes or contracts to make a loan to such applicant in reliance thereon unless such person (or his successor in interest) engaged in fraud or misrepresentation in making or contracting to make such loan.

(D) Guarantees of loans under this part shall be subject to such further terms and conditions as the Secretary determines to be necessary to assure that the purposes of this title will be achieved.

(b)(1) The Secretary may not approve a loan under this part unless—

(A) the Secretary is reasonably satisfied that the applicant under the project for which the loan would be made will be able to make payments of principal and interest thereon when due, and

(B) the applicant provides the Secretary with reasonable assurances that there will be available to it such additional funds as may be necessary to complete the project or undertaking with respect to which such loan is requested.

(2) Any loan made under this part shall (A) have such security, (B) have such maturity date, (C) be repayable in such installments, (D) bear interest at a rate comparable to the current rate of interest prevailing, on the date the loan is made, with respect to loans guaranteed under this part, minus any interest subsidy made in accordance with section 1601(a)(2)(B) with respect to a loan made for a project located in an urban or rural poverty area, and (E) be subject to such other terms and conditions (including provisions for recovery in case of default), as the Secretary determines to be necessary to carry out the purposes of this title while adequately protecting the financial interests of the United States.

(3) The Secretary may, for good cause but with due regard to the financial interests of the United States, waive any right of recovery which he has by reasons of the failure of a borrower to make payments of principal of and interest on a loan made under this part, except that if such loan is sold and guaranteed, any such waiver shall have no effect upon the Secretary's guarantee of timely payment of principal and interest.

(c)(1) The Secretary shall from time to time, but with due regard to the financial interests of the United States, sell loans made under this part either on the private market or to the Federal National Mortgage Association in accordance with section 302 of the Federal National Mortgage Association Charter Act or to the Federal Financing Bank.

(2) Any loan so sold shall be sold for an amount which is equal (or approximately equal) to the amount of the unpaid principal of such loans as of time of sale.

(3)(A) The Secretary is authorized to enter into an agreement with the purchaser of any loan sold under this part under which the Secretary agrees—

(i) to guarantee to such purchaser (and any successor in interest to such purchaser) payments of the principal and interest payable under such loan, and

(ii) to pay as an interest subsidy to such purchaser (and any successor in interest of such purchaser) amounts which, when added to the amount of interest payable on such loan, are equivalent to a reasonable rate of interest on such loan as determined by the Secretary after taking into account the range of prevailing interest rates in the private market on similar loans and the risks assumed by the United States.

(B) Any agreement under subparagraph (A)—

(i) may provide that the Secretary shall act as agent of any such purchaser, for the purpose of collecting from the entity to which such loan was made and paying over to such purchaser any payments of principal and interest payable by such entity under such loan;

(ii) may provide for the repurchase by the Secretary of any such loan on such terms and conditions as may be specified in the agreement;

(iii) shall provide that, in the event of any default by the entity to which such loan was made in payment of principal or interest due on such loan, the Secretary shall, upon notification to the purchaser (or to the successor in interest of such purchaser), have the option to close out such loan (and any obligations of the Secretary with respect thereto) by paying to the purchaser (or his successor in interest) the total amount of outstanding principal and interest due thereon at the time of such notification; and

(iv) shall provide that, in the event such loan is closed out as provided in clause (iii), or in the event of any other loss incurred by the Secretary by reason of the failure of such entity to make payments of principal or interest on such loan, the Secretary shall be subrogated to all rights of such purchaser for recovery of such loss from such entity.

(4) Amounts received by the Secretary as proceeds from the sale of loans under this subsection shall be deposited in the fund established under subsection (d).

(5) If any loan to a public entity under this part is sold and guaranteed by the Secretary under this subsection, interest paid on such loan after its sale and any interest subsidy paid, under paragraph (3)(A)(ii), by the Secretary with respect to such loan which is received by the purchaser of the loan (or the purchaser's successor in interest) shall be included in the gross income of the purchaser or successor for the purpose of chapter 1 of the Internal Revenue Code of 1954.

(d)(1) There is established in the Treasury a loan and loan guarantee fund (hereinafter in this subsection referred to as the "fund") which shall be available to the Secretary without fiscal year limitation, in such amounts as may be specified from time to time in appropriation Acts—

(A) to enable him to make loans under this part,

(B) to enable him to discharge his responsibilities under loan guarantees issued by him under this part,

(C) for payment of interest under section 1601(a)(2)(B) on loans guaranteed under this part,

(D) for repurchase of loans under subsection (c)(3)(B),

(E) for payment of interest on loans which are sold and guaranteed, and

(F) to enable the Secretary to take the action authorized by subsection (f).

There are authorized to be appropriated from time to time such amounts as may be necessary to provide the sums required for the fund. There shall also be deposited in the fund amounts received by the Secretary in connection with loans and loan guarantees under this part and other property or assets derived by him from his operations respecting such loans and loan guarantees, including any money derived from the sale of assets.

(2) If at any time the sums in the funds are insufficient to enable the Secretary—

(A) to make payments of interest under section 1601(a)(2)(B),

(B) to otherwise comply with guarantees under this part of loans to nonprofit private entities,

(C) in the case of a loan which was made, sold, and guaranteed under this part, to make to the purchaser of such loan payments of principal and interest on such loan after default by the entity to which the loan was made, or

(D) to repurchase loans under subsection (c)(3)(B),

(E) to make payments of interest on loans which are sold and guaranteed, and

(F) to enable the Secretary to take the action authorized by subsection (f),

he is authorized to issue to the Secretary of the Treasury notes or other obligations in such forms and denominations bearing such maturities, and subject to such terms and conditions, as may be prescribed by the Secretary with the approval of the Secretary of the Treasury. Such notes or other obligations shall bear interest at a rate determined by the Secretary of the Treasury, taking into consideration the current average market yield on outstanding marketable obligations of the United States of comparable maturities during the month preceding the issuance of the notes or other obligations. The Secretary of the Treasury shall purchase any notes and other obligations issued under this paragraph and for that purpose he may use as a public debt transaction the proceeds from the sale of any securities issued under the Second Liberty Bond Act, and the purposes for which the securities may be issued under that Act are extended to include any purchase of such notes and obligations. The Secretary of the Treasury may at any time sell any of the notes or other obligations acquired by him under this paragraph. All redemptions, purchases, and sales by the Secretary of the Treasury of such notes or other obligations shall be treated as public debt transactions of the United States. Sums borrowed under this paragraph shall be deposited in the fund and redemption of such notes and obligations shall be made by the Secretary from the fund.

(e)(1) The assets, commitments, obligations, and outstanding balances of the loan guarantee and loan fund established in the Treasury by section 626 shall be transferred to the fund established by subsection (d) of this section.

(2) To provide additional capitalization for the fund established under subsection (d) there are authorized to be appropriated to the fund, such sums as may be necessary for the fiscal years ending June 30, 1975, June 30, 1976, September 30, 1977, September 30, 1978, September 30, 1979, September 30, 1980, September 30, 1981, and September 30, 1982.

(f)(1) The Secretary may take such action as may be necessary to prevent a default on a loan made or guaranteed under this part or under title VI, including the waiver of regulatory conditions, deferral of loan payments, renegotiation of loans, and the expenditure of funds for technical and consultative assistance, for the temporary payment of the interest and principal on such a loan, and for other purposes. Any such expenditure made under the preceding sentence on behalf of a medical facility shall be made under

such terms and conditions as the Secretary shall prescribe, including the implementation of such organizational, operational, and financial reforms as the Secretary determines are appropriate and the disclosure of such financial or other information as the Secretary may require to determine the extent of the implementation of such reforms.

(2) The Secretary may take such action, consistent with State law respecting foreclosure procedures, as he deems appropriate to protect the interest of the United States in the event of a default on a loan made or guaranteed under this part or under title VI, including selling real property pledged as security for such a loan or loan guarantee and for a reasonable period of time taking possession of, holding, and using real property pledged as security for such a loan or loan guarantee.

PART B—PROJECT GRANTS

PROJECT GRANTS.

SEC. 1610.[300r] (a)(1)(A) The Secretary may make grants for construction or modernization projects designed to—

(i) eliminate or prevent in medical facilities imminent safety hazards as defined by Federal, State, or local fire, building, or life safety codes or regulations, or

(ii) avoid noncompliance by medical facilities with State or voluntary licensure or accreditation standards.

(B) A grant under subparagraph (A) may only be made to—

(i) a State or political subdivision of a State, including any city, town, county, borough, hospital district authority, or public or quasi-public corporation, for any medical facility owned or operated by the State or political subdivision; and

(ii) a nonprofit private entity for any medical facility owned or operated by the entity but only if the Secretary determines—

(I) the level of community service provided by the facility and the proportion of its patients who are unable to pay for services rendered in the facility is similar to such level and proportion in a medical facility of a State or political subdivision, and

(II) that without a grant under subparagraph (A) there would be a disruption of the provision of health care to low-income individuals.

(2) The amount of any grant under paragraph (1) may not exceed 75 per centum of the cost of the project for which the grant is made unless the project is located in an area determined by the Secretary to be an urban or rural poverty area, in which case the grant may cover up to 100 per centum of such costs.

(3) There are authorized to be appropriated for grants under paragraph (1) $40,000,000 for the fiscal year ending September 30, 1980, $50,000,000 for the fiscal year ending September 30, 1981, and $50,000,000 for the fiscal year ending September 30, 1982. Funds available for obligation under this subsection (as in effect before the date of the enactment of the Health Planning and Resources Development Amendments of 1979) in the fiscal year end-

ing September 30, 1979, shall remain available for obligation under this subsection in the succeeding fiscal year.

(b)(1) The Secretary may make grants to public and nonprofit private entities for projects for (A) construction or modernization of outpatient medical facilities which are located apart from hospitals and which will provide services for medically underserved populations, and (B) conversion of existing facilities into outpatient medical facilities or facilities for long-term care to provide services for such populations.

(2) The amount of any grant under paragraph (1) may not exceed 80 per centum of the cost of the project for which the grant is made unless the project is located in an area determined by the Secretary to be an urban or rural poverty area, in which case the grant may cover up to 100 per centum of such costs.

(3) There are authorized to be appropriated for grants under paragraph (1) $15,000,000 for the fiscal year ending September 30, 1981, and $15,000,000 for the fiscal year ending September 30, 1982.

PART C—GENERAL PROVISIONS

GENERAL REGULATIONS.

SEC. 1620.[300s] The Secretary shall by regulation—

(1) prescribe the manner in which he shall determine the priority among projects for which assistance is available under part A or B, based on the relative need of different areas for such projects and giving special consideration—

(A) to projects for medical facilities serving areas with relatively small financial resources and for medical facilities serving rural communities,

(B) in the case of projects for modernization of medical facilities, to projects for facilities serving densely populated areas,

(C) in the case of projects for construction of outpatient medical facilities, to projects that will be located in, and provide services for residents of, areas determined by the Secretary to be rural or urban poverty areas,

(D) to projects designed to (i) eliminate or prevent imminent safety hazards as defined by Federal, State, or local fire, building, or life safety codes or regulations, or (ii) avoid noncompliance with State or voluntary licensure or accreditation standards, and

(E) to projects for medical facilities which, alone or in conjunction with other facilities, will provide comprehensive health care, including outpatient and preventive care as well as hospitalization;

(2) prescribe for medical facilities projects assisted under part A or B general standards of construction, modernization, and equipment, which standards may vary on the basis of the class of facilities and their location; and

(3) prescribe the general manner in which easy entity which receives financial assistance under part A or B or has received financial assistance under part A or B or title VI shall be required to comply with the assurances required to be made

at the time such assistance was received and the means by which such entity shall be required to demonstrate compliance with such assurances.

An entity subject to the requirements prescribed pursuant to paragraph (3) respecting compliance with assurances made in connection with receipt of financial assistance shall submit periodically to the Secretary data and information which reasonably supports the entity's compliance with such assurances. The Secretary may not waive the requirement of the preceding sentence.

APPLICATIONS.

SEC. 1621.[300s–1] (a) No loan, loan guarantee, or grant may be made under part A or B for a medical facilities project unless an application for such project has been submitted to and approved by the Secretary. If two or more entities join in a project, an application for such project may be filed by any of such entities or by all of them.

(b)(1) An application for a medical facilities project shall be submitted in such form and manner as the Secretary shall by regulation prescribe and shall, except as provided in paragraph (2), set forth—

(A) in the case of a modernization project for a medical facility for continuation of existing health services, a finding by the State Agency of a continued need for such services, and, in the case of any other project for a medical facility, a finding by the State Agency of the need for the new health services to be provided through the medical facility upon completion of the project;

(B) in the case of an application for a grant, assurances satisfactory to the Secretary that (i) the applicant making the application would not be able to complete the project for which the application is submitted without the grant applied for, and (ii) in the case of a project to construct a new medical facility, it would be inappropriate to convert an existing medical facility to provide the services to be provided through the new medical facility;

(C) in the case of a project for the discontinuance of a service or facility or the conversion of a service or a facility, an evaluation of the impact of such discontinuance or conversion on the provision of health care in the health service area in which such service was provided or facility located;

(D) a description of the site of such project;

(E) plans and specifications therefor which meet the requirements of the regulations prescribed under section 1620(2);

(F) reasonable assurance that title to such site is or will be vested in one or more of the entities filing the application or in a public or other nonprofit entity which is to operate the facility on completion of the project;

(G) reasonable assurance that adequate financial support will be available for the completion of the project and for its maintenance and operation when completed, and, for the purpose of determining if the requirements of this subparagraph are met, Federal assistance provided directly to a medical facil-

ity which is located in an area determined by the Secretary to be an urban or rural poverty area or through benefits provided individuals served at such facility shall be considered as financial support;

(H) the type of assistance being sought under part A or B for the project;

(I) reasonable assurance that all laborers and mechanics employed by contractors or subcontractors in the performance of work on a project will be paid wages at rates not less than those prevailing on similar construction in the locality as determined by the Secretary of Labor in accordance with the Act of March 3, 1931 (40 U.S.C. 276a—276a–5, known as the Davis-Bacon Act), and the Secretary of Labor shall have with respect to such labor standards the authority and functions set forth in Reorganization Plan Numbered 14 of 1950 (15 FR 3176; 5 U.S.C. Appendix) and section 2 of the Act of June 13, 1934 (40 U.S.C. 276c);

(J) in the case of a project for the construction or modernization of an outpatient facility, reasonable assurance that the services of a general hospital will be available to patients at such facility who are in need of hospital care; and

(K) reasonable assurance that at all times after such application is approved (i) the facility or portion thereof to be constructed, modernized, or converted will be made available to all persons residing or employed in the area served by the facility, and (ii) there will be made available in the facility or portion thereof to be constructed, modernized, or converted a reasonable volume of services to persons unable to pay therefor and the Secretary, in determining the reasonableness of the volume of services provided, shall take into consideration the extent to which compliance is feasible from a financial viewpoint.

(2)(A) The Secretary may waive—

(i) the requirements of subparagraph (D) of paragraph (1) for compliance with modernization and equipment standards prescribed pursuant to section 1620(2), and

(ii) the requirement of subparagraph (E) of paragraph (1) respecting title to a project site,

in the case of an application for a project described in subparagraph (B) of this paragraph.

(B) A project referred to in subparagraph (A) is a project—

(i) for the modernization of an outpatient medical facility which will provide general purpose health services, which is not part of a hospital, and which will serve a medically underserved population as defined in section 1624 or as designated by a health systems agency, and

(ii) for which the applicant seeks a loan under part A the principal amount of which does not exceed $20,000.

RECOVERY.

SEC. 1622.[300s–1a] (a) If any facility with respect to which funds have been paid under this title shall, at any time within 20 years after the completion of construction or modernization—

(1) be sold or transferred to any entity (A) which is not qualified to file an application under section 1621 or 1642 or (B) which is not approved as a transferee by the State Agency of the State in which such facility is located, or its successor, or

(2) cease to be a public health center or a public or other nonprofit hospital, outpatient facility, facility for long-term care, or rehabilitation facility,

the United States shall be entitled to recover, whether from the transferor or the transferee (or, in the case of a facility which has ceased to be public or nonprofit, from the owners thereof) an amount determined under subsection (c).

(b) The transferor of a facility which is sold or transferred as described in subsection (a)(1), or the owner of a facility the use of which is changed as described in subsection (a)(2), shall provide the Secretary written notice of such sale, transfer, or change not later than the expiration of 10 days from the date on which such sale, transfer, or change occurs.

(c)(1) Except as provided in paragraph (2), the amount the United States shall be entitled to recover under subsection (a) is an amount bearing the same ratio to the then value (as determined by the agreement of the parties or in an action brought in the district court of the United States for the district for which the facility involved is situated) of so much of the facility as constituted an approved project or projects as the amount of the Federal participation bore to the cost of the construction or modernization of such project or projects.

(2)(A) After the expiration of—

(i) 180 days after the date of the sale, transfer, or change of use for which a notice is required by subsection (b) in the case of a facility which is sold or transferred or the use of which changes after the date of the enactment of this subsection, or

(ii) thirty days after the date of enactment of this subsection or if later 180 days after the date of the sale, transfer, or change of use for which a notice is required by subsection (b), in the case of a facility which was sold or transferred or the use of which changed before the date of the enactment of this subsection,

the amount which the United States is entitled to recover under paragraph (1) with respect to a facility shall be the amount prescribed by paragraph (1) plus interest, during the period described in subparagraph (B), at a rate (determined by the Secretary) based on the average of the bond equivalent of the weekly 90-day Treasury bill auction rate.

(B) The period referred to in subparagraph (A) is the period beginning—

(i) in the case of a facility which was sold or transferred or the use of which changed before the date of the enactment of this subsection, thirty days after such date or if later 180 days after the date of the sale, transfer, or change of use for which a notice is required by subsection (b),

(ii) in the case of a facility with respect to which notice is provided in accordance with subsection (b), upon the expiration of 180 days after the receipt of such notice, or

(iii) in the case of a facility with respect to which such notice is not provided as prescribed by subsection (b), on the date of the sale, transfer, or changes of use for which such notice was to be provided,

and ending on the date the amount the United States is entitled to under paragraph (1) is collected.

(d)(1) The Secretary may waive the recovery rights of the United States under subsection (a)(1) with respect to a facility in any State if the Secretary determines, in accordance with regulations, that the entity to which the facility was sold or transferred—

(A) has established an irrevocable trust—

(i) in an amount equal to the greater of twice the cost of the remaining obligation of the facility under clause (ii) of section 1621(b)(1)(K) or the amount, determined under subsection (c), that the United States is entitled to recover, and

(ii) which will only be used by the entity to provide the care required by clause (ii) of section 1621(b)(1)(K); and

(B) will meet the obligation of the facility under clause (i) of section 1621(b)(1)(K).

(2) The Secretary may waive the recovery rights of the United States under subsection (a)(2) with respect to a facility in any State if the Secretary determines, in accordance with regulations, that there is good cause for waiving such rights with respect to such facility.

(e) The right of recovery of the United States under subsection (a) shall not constitute a lien on any facility with respect to which funds have been paid under this title.

CONTROL OF OPERATIONS.

SEC. 1623.[300s–2] Except as otherwise specifically provided, nothing in this title shall be construed as conferring on any Federal officer, or employee the right to exercise any supervision or control over the administration, personnel, maintenance, or operation of any facility with respect to which any funds have been or may be expended under this title.

DEFINITIONS.

SEC. 1624.[300s–3] Except as provided in section 1642(e), for purposes of this title—

(1) The term "hospital" includes general, tuberculosis, and other types of hospitals, and related facilities, such as laboratories, outpatient departments, nurses' home facilities, extended care facilities, facilities related to programs for home health services, self-care units, and central service facilities, operated in connection with hospitals, and also includes education or training facilities for health professonal[1] personnel

[1] So in law. Probably should be "professional".

operated as an integral part of a hospital, but does not include any hospital furnishing primarily domiciliary care.

(2) The term "public health center" means a publicly owned facility for the provision of public health services, including related publicly owned facilities such as laboratories, clinics, and administrative offices operated in connection with such a facility.

(3) The term "nonprofit" as applied to any facility means a facility which is owned and operated by one or more nonprofit corporations or associations no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual.

(4) The term "outpatient medical facility" means a medical facility (located in or apart from a hospital) for the diagnosis or diagnosis and treatment of ambulatory patients (including ambulatory inpatients)—

(A) which is operated in connection with a hospital;

(B) in which patient care is under the professional supervision of persons licensed to practice medicine or surgery in the State, or in the case of dental diagnosis or treatment, under the professional supervision of persons licensed to practice dentistry in the State; or

(C) which offers to patients not requiring hospitalization the services of licensed physicians in various medical specialties and which provides to its patients a reasonably full range of diagnostic and treatment services.

(5) The term "rehabilitation facility" means a facility which is operated for the primary purpose of assisting in the rehabilitation of disabled persons through an integrated program of—

(A) medical evaluation and services, and

(B) psychological, social, or vocational evaluation and services,

under competent professional supervision, and in the case of which the major portion of the required evaluation and services is furnished within the facility; and either the facility is operated in connection with a hospital, or all medical and related health services are prescribed by, or are under the general direction of, persons licensed to practice medicine or surgery in the State.

(6) The term "facility for long-term care" means a facility (including a skilled nursing or intermediate care facility) providing in-patient care for convalescent or chronic disease patients who required skilled nursing or intermediate care and related medical services—

(A) which is a hospital (other than a hospital primarily for the care and treatment of mentally ill or tuberculosis patients) or is operated in connection with a hospital, or

(B) in which such care and medical services are prescribed by, or are performed under the general direction of, persons licensed to practice medicine or surgery in the State.

(7) The term "construction" means construction of new buildings and initial equipment of such buildings and, in any case in which it will help to provide a service not previously

provided in the community, equipment of any buildings; including architects' fees, but excluding the cost of off-site improvements and, except with respect to public health centers, the cost of the acquisition of land

(8) The term "cost" as applied to construction modernization, or conversion means the amount found by the Secretary to be necessary for construction, modernization, or conversion, respectively, under a project, except that, in the case of a modernization project or a project assisted under part D, such term does not include any amount found by the Secretary to be attributable to expansion of the bed capacity of any facility.

(9) The term "modernization" includes the alteration, expansion, major repair (to the extent permitted by regulations), remodeling, replacement, and renovation of existing buildings (including initial equipment thereof), and the replacement of obsolete equipment of existing buildings.

(10) The term "title,"[2] when used with reference to a site for a project, means a fee simple, or such other estate or interest (including a leasehold on which the rental does not exceed 4 per centum of the value of the land) as the Secretary finds sufficient to assure for a period of not less than twenty-five years' undisturbed use and possession for the purposes of construction, modernization, or conversion and operation of the project for a period of not less than (A) twenty years in the case of a project assisted under an allotment or grant under this title, or (B) the term of repayment of a loan made or guaranteed under this title in the case of a project assisted by a loan or loan guarantee.

(11) The term "medical facility" means a hospital, public health center, outpatient medical facility, rehabilitation facility, facility for long-term care, or other facility (as may be designated by the Secretary) for the provision of health care to ambulatory patients.

(12) The term "State Agency" means the State health planning and development agency of a State designated under title XV.

(13) The term "urban or rural poverty area" means an urban or rural geographical area (as defined by the Secretary) in which a percentage (as defined by the Secretary in accordance with the next sentence) of the residents of the area have incomes below the poverty level (as defined by the Secretary of Commerce). The percentage referred to in the preceding sentence shall be defined so that the percentage of the population of the United States residing in urban and rural poverty areas is—

(A) not more than the percentage of the total population of the United States with incomes below the poverty level (as so defined) plus five per centum, and

(B) not less than such percentage minus five per centum.

(14) The term "medically underserved population" means the population of an urban or rural area designated by the Sec-

[2] So in law. The comma probably should follow the ending quotations.

retary as an area with a shortage of health facilities or a population group designated by the Secretary as having a shortage of such facilities.

FINANCIAL STATEMENTS; RECORDS AND AUDIT.

SEC. 1625.[300s–4] (a) In the case of any facility for which an allotment payment, grant, loan, or loan guarantee has been made under this title, the applicant for such payment, grant, loan, or loan guarantee (or, if appropriate, such other person as the Secretary may prescribe) shall file at least annually with the State Agency for the State in which the facility is located a statement which shall be in such form, and contain such information, as the Secretary may require to accurately show—

(1) the financial operations of the facility, and

(2) the costs to the facility of providing health services in the facility and the charges made by the facility for providing such services,

during the period with respect to which the statement is filed.

(b)(1) Each entity receiving Federal assistance under this title shall keep such records as the Secretary shall prescribe, including records which fully disclose the amount and disposition by such entity of the proceeds of such assistance, the total cost of the project in connection with which such assistance is given or used, the amount of that portion of the cost of the project supplied by other sources, and such other records as will facilitate an effective audit.

(2) The Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of such entities which in the opinion of the Secretary or the Comptroller General may be related or pertinent to the assistance referred to in paragraph (1).

(c) Each such entity shall file at least annually with the Secretary a statement which shall be in such form, and contain such information, as the Secretary may require to accurately show—

(1) the financial operations of the facility constructed or modernized with such assistance, and

(2) the costs to such facility of providing health services in such facility, and the charges made for such services, during the period with respect to which the statement is filed.

TECHNICAL ASSISTANCE.

SEC. 1626.[300s–5] The Secretary shall provide (either through the Department of Health, Education, and Welfare or by contract) all necessary technical and other nonfinancial assistance to any public or other entity which is eligible to apply for assistance under this title to assist such entity in developing applications to be submitted to the Secretary under section 1621 or 1642. The Secretary shall make every effort to inform eligible applicants of the availability of assistance under this title.

ENFORCEMENT OF ASSURANCES.

SEC. 1627.[300s–6] The Secretary shall investigate and ascertain, on a periodic basis, with respect to each entity which is re-

ceiving financial assistance under this title or which has received financial assistance under title VI or this title, the extent of compliance by such entity with the assurances required to be made at the time such assistance was received. If the Secretary finds that such an entity has failed to comply with any such assurance, the Secretary shall report such noncompliance to the health systems agency for the health service area in which such entity is located and the State health planning and development agency of the State in which the entity is located and shall take any action authorized by law (including an action for specific performance brought by the Attorney General upon request of the Secretary) which will effect compliance by the entity with such assurances. An action to effectuate compliance with any such assurance may be brought by a person other than the Secretary only if a complaint has been filed by such person with the Secretary and the Secretary has dismissed such complaint or the Attorney General has not brought a civil action for compliance with such assurance within six months after the date on which the complaint was filed with the Secretary.

PART D—AREA HEALTH SERVICES DEVELOPMENT FUNDS

DEVELOPMENT GRANTS FOR AREA HEALTH SERVICES DEVELOPMENT FUNDS.

SEC. 1640.[300t] (a) The Secretary shall make in each fiscal year a grant to each health systems agency—

(1) with which there is in effect a designation agreement under section 1515(c),

(2) which has in effect an HSP and AIP reviewed by the Statewide Health Coordinating Council, and

(3) which, as determined under the review made under section 1535(c), is organized and operated in the manner prescribed by section 1512(b) and is performing its functions under section 1513 in a manner satisfactory to the Secretary,

to enable the agency to establish and maintain an Area Health Services Development Fund from which it may make grants and enter into contracts in accordance with section 1513(c)(3).

(b)(1) Except as provided in paragraph (2), the amount of any grant under subsection (a) shall be determined by the Secretary after taking into consideration the population of the health service area for which the health systems agency is designated, the average family income of the area, and the supply of health services in the area.

(2) The amount of any grant under subsection (a) to a health systems agency for any fiscal year may not exceed the product of $1 and the population of the health service area for which such agency is designated.

(c) No grant may be made under subsection (a) unless an application therefor has been submitted to, and approved by, the Secretary. Such an application shall be submitted in such form and manner and contain such information as the Secretary may require.

(d) For the purpose of making payments pursuant to grants under subsection (a), there are authorized to be appropriated $25,000,000 for the fiscal year ending June 30, 1975, $75,000,000

for the fiscal year ending June 30, 1976, $120,000,000 each for the fiscal years ending September 30, 1977, and September 30, 1978, $20,000,000 for the fiscal year ending September 30, 1981, and $30,000,000 for the fiscal year ending September 30, 1982.

PART E—PROGRAM TO ASSIST AND ENCOURAGE THE VOLUNTARY DISCONTINUANCE OF UNNEEDED HOSPITAL SERVICES AND THE CONVERSION OF UNNEEDED HOSPITAL SERVICES TO OTHER HEALTH SERVICES NEEDED BY THE COMMUNITY

ESTABLISHMENT OF PROGRAM.

SEC. 1641.[300t–11] The Secretary shall, by April 1, 1980, establish a program under which—

(1) grants and technical assistance may be provided to hospitals in operation on the date of the enactment of this part (A) for the discontinuance of unneeded hospital services, and (B) for the conversion of unneeded hospital services to other health services needed by the community; and

(2) grants may be provided to State Agencies designated under section 1521(b)(3) for reducing excesses in resources and facilities of hospitals.

GRANTS FOR DISCONTINUANCE AND CONVERSION.

SEC. 1642.[300t–12] (a)(1) A grant to a hospital under the program shall be subject to such terms and conditions as the Secretary may by regulation prescribe to assure that the grant is used for the purpose for which it was made.

(2) The amount of any such grant shall be determined by the Secretary. The recipient of such a grant may use the grant—

(A) in the case of a grantee which discontinues the provision of all hospital services or all inpatient hospital services or an identifiable part of a hospital facility which provides inpatient hospital services, for the liquidation of the outstanding debt on the facilities of the grantee used for the provision of the services or for the liquidation of the outstanding debt of the grantee on such identifiable part;

(B) in the case of a grantee which is discontinuing the provision of an inpatient hospital service converts or proposes to convert an identifiable part of a hospital facility used in the provision of the discontinued service to the delivery of other health services, for the planning, development (including construction and acquisition of equipment), and delivery of the health service;

(C) to provide reasonable termination pay for personnel of the grantee who will lose employment because of the discontinuance of hospital services made by the grantee, retraining of such personnel, assisting such personnel in securing employment, and other costs of implementing arrangements described in subsection (c); and

(D) for such other costs which the Secretary determines may need to be incurred by the grantee in discontinuing hospital services.

(b)(1) No grant may be made to a hospital unless an application therefor is submitted to and approved by the Secretary. Such an application shall be in such form and submitted in such manner as the Secretary may prescribe and shall include—

(A) a description of each service to be discontinued and, if a part of a hospital is to be discontinued or converted to another use in connection with such discontinuance, a description of such part;

(B) an evaluation of the impact of such discontinuance and conversion on the provision of health care in the health service area in which such service is provided;

(C) an estimate of the change in the applicant's costs which will result from such discontinuance and conversion; and

(D) reasonable assurance that all laborers and mechanics employed by contractors or subcontractors in the performance of work on a project will be paid wages at rates not less than those prevailing on similar construction in the locality as determined by the Secretary of Labor in accordance with the Act of March 3, 1931 (40 U.S.C. 276a—276a–5, known as the Davis-Bacon Act), and the Secretary of Labor shall have with respect to such labor standards the authority and functions set forth in Reorganization Plan Numbered 14 of 1950 (15 FR 3176; 5 U.S.C. Appendix) and section 2 of the Act of June 13, 1934 (40 U.S.C. 276c);

(E) such other information as the Secretary may require.

(2)(A) The health systems agency for the health service area in which is located a hospital applying for a grant under the program shall (i) in making the review of the applicant's application under section 1513(e), determine the need for each service or part proposed to be discontinued by the applicant, (ii) in the case of an application for the conversion of a facility, determine the need for each service which will be provided as a result of a conversion, and (iii) make a recommendation to the State Agency for the State in which the applicant is located respecting approval by the Secretary of the applicant's application.

(B) A State Agency which has received a recommendation from a health systems agency under subparagraph (A) respecting an application shall, after consideration of such recommendation, make a recommendation to the Secretary respecting the approval by the Secretary of the application. A State Agency's recommendation under this subparagraph respecting the approval of an application (i) shall be based upon (I) the need for each service or part proposed to be discontinued by the applicant, (II) in the case of an application for the conversion of a facility, the need for each service which will be provided as a result of the conversion, and (III) such other criteria as the Secretary may prescribe, and (ii) shall be accompanied by the health systems agency's recommendation made with respect to the approval of the application.

(C) In determining, under subparagraphs (A) and (B), the need for the service (or services) or part proposed to be discontinued or converted by an applicant for a grant, a health systems agency and State Agency shall give special consideration to the unmet needs and existing access patterns of urban or rural poverty populations.

(3)(A) The Secretary may not approve an application of a hospital for a grant—

(i) if a State Agency recommended that the application not be approved, or

(ii) if the Secretary is unable to determine that the cost of providing inpatient health services in the health service area in which the applicant is located will be less than if the inpatient health services proposed to be discontinued were not discontinued.

(B) In considering applications of hospitals for grants the Secretary shall consider the recommendations of health systems agencies and State Agencies and shall give special consideration to applications (i) which will assist health systems agencies and State Agencies to meet the goals in their health systems plans and State health plans, or (ii) which will result in the greatest reduction in hospital costs within a health service area.

(c)(1) Except as provided in paragraph (3), the Secretary may not approve an application submitted under subsection (b) unless the Secretary of Labor has certified that fair and equitable arrangements have been made to protect the interests of employees affected by the discontinuance of services against a worsening of their positions with respect to their employment, including arrangements to preserve the rights of employees under collective-bargaining agreements, continuation of collective-bargaining rights consistent with the provisions of the National Labor Relations Act, reassignment of affected employees to other jobs, retraining programs, protecting pension, health benefits, and other fringe benefits of affected employees, and arranging adequate severance pay, if necessary.

(2) The Secretary of Labor shall by regulation prescribe guidelines for arrangements for the protection of the interests of employees affected by the discontinuance of hospital services. The Secretary of Labor shall consult with the Secretary of Health, Education, and Welfare in the promulgation of such guidelines. Such guidelines shall first be promulgated not later than the promulgation of regulations by the Secretary for the administration of the grants authorized by section 1641.

(3) The Secretary of Labor shall review each application submitted under subsection (b) to determine if the arrangements described in paragraph (1) have been made and if they are satisfactory and shall notify the Secretary respecting his determination. Such review shall be completed within—

(A) ninety days from the date of the receipt of the application from the Secretary of Health, Education, and Welfare, or

(B) one hundred and twenty days from such date if the Secretary of Labor has by regulation prescribed the circumstances under which the review will require at least one hundred and twenty days.

If within the applicable period, the Secretary of Labor does not notify the Secretary of Health, Education, and Welfare respecting his determination, the Secretary of Health, Education, and Welfare shall review the application to determine if the applicant has made the arrangements described in paragraph (1) and if such arrangements are satisfactory. The Secretary may not approve the applica-

tion unless he determines that such arrangements have been made and that they are satisfactory.

(d) The records and audits requirements of section 705 shall apply with respect to grants made under subsection (a).

(e) For purposes of this part, the term "hospital" means, with respect to any fiscal year, an institution (including a distinct part of an institution participating in the programs established under title XVIII of the Social Security Act)—

(1) which satisfies paragraphs (1) and (7) of section 1861(e) of such Act,

(2) imposes charges or accepts payments for services provided to patients, and

(3) the average duration of a patient's stay in which was thirty days or less in the preceding fiscal year,

but such term does not include a Federal hospital or a psychiatric hospital (as described in section 1861(f)(1) of the Social Security Act).

GRANTS TO STATES FOR REDUCTION OF EXCESS HOSPITAL CAPACITY.

SEC. 1643.[300t–13] (a) For the purpose of demonstrating the effectiveness of various means for reducing excesses in resources and facilities of hospitals (referred to in this section as "excess hospital capacity"), the Secretary may make grants to State Agencies designated under section 1521(b)(3) to assist such Agencies in—

(1) identifying (by geographic region or by health service) excess hospital capacity,

(2) developing programs to inform the public of the costs associated with excess hospital capacity,

(3) developing programs to reduce excess hospital capacity in a manner which will produce the greatest savings in the cost of health care delivery,

(4) developing means to overcome barriers to the reduction of excess hospital capacity,

(5) in planning, evaluating, and carrying out programs to decertify health care facilities providing health services that are not appropriate, and

(6) any other activity related to the reduction of excess hospital capacity.

(b) Grants under subsection (a) shall be made on such terms and conditions as the Secretary may prescribe.

AUTHORIZATION OF APPROPRIATIONS.

SEC. 1644.[300t–14] To make payments under grants under sections 1642 and 1643 there are authorized to be appropriated $30,000,000 for the fiscal year ending September 30, 1980, $50,000,000 for the fiscal year ending September 30, 1981, and $75,000,000 for the fiscal year ending September 30, 1982, except that in any fiscal year not more than 10 percent of the amount appropriated under this section may be obligated for grants under section 1643.

December 13, 2013

PUBLIC HEALTH SERVICE ACT

As Amended Through P.L. 112–240, Enacted January 2, 2013

TITLE XVII—HEALTH INFORMATION AND HEALTH PROMOTION

GENERAL AUTHORITY.

SEC. 1701.[300u] (a) The Secretary shall—

(1) formulate national goals, and a strategy to achieve such goals, with respect to health information and health promotion, preventive health services, and education in the appropriate use of health care;

(2) analyze the necessary and available resources for implementing the goals and strategy formulated pursuant to paragraph (1), and recommend appropriate educational and quality assurance policies for the needed manpower resources identified by such analysis;

(3) undertake and support necessary activities and programs to—

(A) incorporate appropriate health education components into our society, especially into all aspects of education and health care,

(B) increase the application and use of health knowledge, skills, and practices by the general population in its patterns of daily living, and

(C) establish systematic processes for the exploration, development, demonstration, and evaluation of innovative health promotion concepts;

(4) undertake and support research and demonstrations respecting health information and health promotion, preventive health services, and education in the appropriate use of health care;

(5) undertake and support appropriate training in the operation of programs concerned with, health information and health promotion, preventive health services, and education in the appropriate use of health care;

(6) undertake and support, through improved planning and implementation of tested models and evaluation of results, effective and efficient programs respecting health information and health promotion, preventive health services, and education in the appropriate use of health care;

(7)(A) develop model programs through which employers in the public sector, and employers that are small businesses (as defined in section 3 of the Small Business Act), can provide for their employees a program to promote healthy behaviors and to discourage participation in unhealthy behaviors;

(B) provide technical assistance to public and private employers in implementing such programs (including private employers that are not small businesses and that will implement programs other than the programs developed by the Secretary pursuant to subparagraph (A)); and

(C) in providing such technical assistance, give preference to small businesses;

(8) foster the exchange of information respecting, and foster cooperation in the conduct of, research, demonstration, and training programs respecting health information and health promotion, preventive health services, and education in the appropriate use of health care;

(9) provide technical assistance in the programs referred to in paragraph (8);

(10) use such other authorities for programs respecting health information and health promotion, preventive health services, and education in the appropriate use of health care as are available and coordinate such use with programs conducted under this title; and

(11) establish in the Office of the Assistant Secretary for Health an Office of Disease Prevention and Health Promotion, which shall—

(A) coordinate all activities within the Department which relate to disease prevention, health promotion, preventive health services, and health information and education with respect to the appropriate use of health care;

(B) coordinate such activities with similar activities in the private sector;

(C) establish a national information clearinghouse to facilitate the exchange of information concerning matters relating to health information and health promotion, preventive health services (which may include information concerning models and standards for insurance coverage of such services), and education in the appropriate use of health care, to facilitate access to such information, and to assist in the analysis of issues and problems relating to such matters; and

(D) support projects, conduct research, and disseminate information relating to preventive medicine, health promotion, and physical fitness and sports medicine.

The Secretary shall appoint a Director for the Office of Disease Prevention and Health Promotion established pursuant to paragraph (11) of this subsection. The Secretary shall administer this title in cooperation with health care providers, educators, voluntary organizations, businesses, and State and local health agencies in order to encourage the dissemination of health information and health promotion activities.

(b) For the purpose of carrying out this section and sections 1702 through 1705, there are authorized to be appropriated $10,000,000 for fiscal year 1992, and such sums as may be necessary for each of the fiscal years 1993 through 2002.

(c) No grant may be made or contract entered into under this title unless an application therefor has been submitted to and approved by the Secretary. Such an application shall be submitted in

such form and manner and contain such information as the Secretary may prescribe. Contracts may be entered into under this title without regard to sections 3648 and 3709 of the Revised Statutes (31 U.S.C. 529; 41 U.S.C. 5).

RESEARCH PROGRAMS.

SEC. 1702.[300u–1] (a) The Secretary is authorized to conduct and support by grant or contract (and encourage others to support) research in health information and health promotion, preventive health services, and education in the appropriate use of health care. Applications for grants and contracts under this section shall be subject to appropriate peer review. The Secretary shall also—

(1) provide consultation and technical assistance to persons who need help in preparing research proposals or in actually conducting research;

(2) determine the best methods of disseminating information concerning personal health behavior, preventive health services and the appropriate use of health care and of affecting behavior so that such information is applied to maintain and improve health, and prevent disease, reduce its risk, or modify its course or severity;

(3) determine and study environmental, occupational, social, and behavioral factors which affect and determine health and ascertain those programs and areas for which educational and preventive measures could be implemented to improve health as it is affected by such factors;

(4) develop (A) methods by which the cost and effectiveness of activities respecting health information and health promotion, preventive health services, and education in the appropriate use of health care, can be measured, including methods for evaluating the effectiveness of various settings for such activities and the various types of persons engaged in such activities, (B) methods for reimbursement or payment for such activities, and (C) models and standards for the conduct of such activities, including models and standards for the education, by providers of institutional health services, of individuals receiving such services respecting the nature of the institutional health services provided the individuals and the symptoms, signs, or diagnoses which led to provision of such services;

(5) develop a method for assessing the cost and effectiveness of specific medical services and procedures under various conditions of use, including the assessment of the sensitivity and specificity of screening and diagnostic procedures; and

(6) enumerate and assess, using methods developed under paragraph (5), preventive health measures and services with respect to their cost and effectiveness under various conditions of use (which measures and services may include blood pressure screening, cholesterol screening and control, smoking cessation programs, substance abuse programs, cancer screening, dietary and nutritional counseling, diabetes screening and education, intraocular pressure screening, and stress management).

(b) The Secretary shall make a periodic survey of the needs, interest, attitudes, knowledge, and behavior of the American public regarding health and health care. The Secretary shall take into consideration the findings of such surveys and the findings of similar surveys conducted by national and community health education organizations, and other organizations and agencies for formulating policy respecting health information and health promotion, preventive health services, and education in the appropriate use of health care.

COMMUNITY PROGRAMS.

SEC. 1703.[300u–2] (a) The Secretary is authorized to conduct and support by grant or contract (and encourage others to support) new and innovative programs in health information and health promotion, preventive health services, and education in the appropriate use of health care, and may specifically—

(1) support demonstration and training programs in such matters which programs (A) are in hospitals, ambulatory care settings, home care settings, schools, day care programs for children, and other appropriate settings representative of broad cross sections of the population, and include public education activities of voluntary health agencies, professional medical societies, and other private nonprofit health organizations, (B) focus on objectives that are measurable, and (C) emphasize the prevention or moderation of illness or accidents that appear controllable through individual knowledge and behavior;

(2) provide consultation and technical assistance to organizations that request help in planning, operating, or evaluating programs in such matters;

(3) develop health information and health promotion materials and teaching programs including (A) model curriculums for the training of educational and health professionals and paraprofessionals in health education by medical, dental, and nursing schools, schools of public health, and other institutions engaged in training of educational or health professionals, (B) model curriculums to be used in elementary and secondary schools and institutions of higher learning, (C) materials and programs for the continuing education of health professionals and paraprofessionals in the health education of their patients, (D) materials for public service use by the printed and broadcast media, and (E) materials and programs to assist providers of health care in providing health education to their patients; and

(4) support demonstration and evaluation programs for individual and group self-help programs designed to assist the participant in using his individual capacities to deal with health problems, including programs concerned with obesity, hypertension, and diabetes.

(b) The Secretary is authorized to make grants to States and other public and nonprofit entities to assist them in meeting the costs of demonstrating and evaluating programs which provide information respecting the costs and quality of health care or information respecting health insurance policies and prepaid health

plans, or information respecting both. After the development of models pursuant to sections 1704(4) and 1704(5) for such information, no grant may be made under this subsection for a program unless the information to be provided under the program is provided in accordance with one of such models applicable to the information.

(c) The Secretary is authorized to support by grant or contract (and to encourage others to support) private nonprofit entities working in health information and health promotion, preventive health services, and education in the appropriate use of health care. The amount of any grant or contract for a fiscal year beginning after September 30, 1978, for an entity may not exceed 25 per centum of the expenses of entity for such fiscal year for health information and health promotion, preventive health services, and education in the appropriate use of health care.

INFORMATION PROGRAMS.

SEC. 1704.[300u–3] The Secretary is authorized to conduct and support by grant or contract (and encourage others to support) such activities as may be required to make information respecting health information and health promotion, preventive health services, and education in the appropriate use of health care available to the consumers of medical care, providers of such care, schools, and others who are or should be informed respecting such matters. Such activities may include at least the following:

(1) The publication of information, pamphlets, and other reports which are specially suited to interest and instruct the health consumer, which information, pamphlets, and other reports shall be updated annually, shall pertain to the individual's ability to improve and safeguard his own health; shall include material, accompanied by suitable illustrations, on child care, family life and human development, disease prevention (particularly prevention of pulmonary disease, cardiovascular disease, and cancer), physical fitness, dental health, environmental health, nutrition, safety and accident prevention, drug abuse and alcoholism, mental health, management of chronic diseases (including diabetes and arthritis), and venereal diseases; and shall be designed to reach populations of different languages and of different social and economic backgrounds.

(2) Securing the cooperation of the communication media, providers of health care, schools, and others in activities designed to promote and encourage the use of health maintaining information and behavior.

(3) The study of health information and promotion in advertising and the making to concerned Federal agencies and others such recommendations respecting such advertising as are appropriate.

(4) The development of models and standards for the publication by States, insurance carriers, prepaid health plans, and others (except individual health practitioners) of information for use by the public respecting the cost and quality of health care, including information to enable the public to make comparisons of the cost and quality of health care.

(5) The development of models and standards for the publication by States, insurance carriers, prepaid health plans, and others of information for use by the public respecting health insurance policies and prepaid health plans, including information on the benefits provided by the various types of such policies and plans, the premium charges for such policies and plans, exclusions from coverage or eligibility for coverage, cost sharing requirements, and the ratio of the amounts paid as benefits to the amounts received as premiums and information to enable the public to make relevant comparisons of the costs and benefits of such policies and plans.

REPORT AND STUDY.

SEC. 1705.[300u–4] (a) The Secretary shall, not later than two years after the date of the enactment of this title and biannually thereafter, submit to the President for transmittal to Congress a report on the status of health information and health promotion, preventive health services, and education in the appropriate use of health care. Each such report shall include—

(1) a statement of the activities carried out under this title since the last report and the extent to which each such activity achieves the purposes of this title;

(2) an assessment of the manpower resources needed to carry out programs relating to health information and health promotion, preventive health services, and education in the appropriate use of health care, and a statement describing the activities currently being carried out under this title designed to prepare teachers and other manpower for such programs;

(3) the goals and strategy formulated pursuant to section 1701(a)(1), the models and standards developed under this title, and the results of the study required by subsection (b) of this section; and

(4) such recommendations as the Secretary considers appropriate for legislation respecting health information and health promotion, preventive health services, and education in the appropriate use of health care, including recommendations for revisions to and extension of this title.

(b) The Secretary shall conduct a study of health education services and preventive health services to determine the coverage of such services under public and private health insurance programs, including the extent and nature of such coverage and the cost sharing requirements required by such programs for coverage of such services.

CENTERS FOR RESEARCH AND DEMONSTRATION OF HEALTH PROMOTION AND DISEASE PREVENTION.

SEC. 1706.[300u–5] (a) The Secretary shall make grants or enter into contracts with academic health centers for the establishment, maintenance, and operation of centers for research and demonstration with respect to health promotion and disease prevention. Centers established, maintained, or operated under this section shall undertake research and demonstration projects in health promotion, disease prevention, and improved methods of appraising

health hazards and risk factors, and shall serve as demonstration sites for the use of new and innovative research in public health techniques to prevent chronic diseases.

(b) Each center established, maintained, or operated under this section shall—

(1) be located in an academic health center with—

(A) a multidisciplinary faculty with expertise in public health and which has working relationships with relevant groups in such fields as medicine, psychology, nursing, social work, education and business;

(B) graduate training programs relevant to disease prevention;

(C) a core faculty in epidemiology, biostatistics, social sciences, behavioral and environmental health sciences, and health administration;

(D) a demonstrated curriculum in disease prevention;

(E) a capability for residency training in public health or preventive medicine; and

(F) such other qualifications as the Secretary may prescribe;

(2) conduct—

(A) health promotion and disease prevention research, including retrospective studies and longitudinal prospective studies in population groups and communities;

(B) demonstration projects for the delivery of services relating to health promotion and disease prevention to defined population groups using, as appropriate, community outreach and organization techniques and other methods of educating and motivating communities; and

(C) evaluation studies on the efficacy of demonstration projects conducted under subparagraph (B) of this paragraph.

The design of any evaluation study conducted under subparagraph (C) shall be established prior to the commencement of the demonstration project under subparagraph (B) for which the evaluation will be conducted.

(c)(1) In making grants and entering into contracts under this section, the Secretary shall provide for an equitable geographical distribution of centers established, maintained, and operated under this section and for the distribution of such centers among areas containing a wide range of population groups which exhibit incidences of diseases which are most amenable to preventive intervention.

(2) The Secretary, through the Director of the Centers for Disease Control and Prevention and in consultation with the Director of the National Institutes of Health, shall establish procedures for the appropriate peer review of applications for grants and contracts under this section by peer review groups composed principally of non-Federal experts.

(d) For purposes of this section, the term "academic health center" means a school of medicine, a school of osteopathy, or a school of public health, as such terms are defined in section 701(4).

(e) For the purpose of carrying out this section, there are authorized to be appropriated $10,000,000 for fiscal year 1992, and

such sums as may be necessary for each of the fiscal years 1993 through 2003.

OFFICE OF MINORITY HEALTH.

SEC. 1707.[300u–6] (a) IN GENERAL.—There is established an Office of Minority Health. The Office of Minority Health as existing on the date of enactment of the Patient Protection and Affordable Care Act shall be transferred to the Office of the Secretary in such manner that there is established in the Office of the Secretary, the Office of Minority Health, which shall be headed by the Deputy Assistant Secretary for Minority Health who shall report directly to the Secretary, and shall retain and strengthen authorities (as in existence on such date of enactment) for the purpose of improving minority health and the quality of health care minorities receive, and eliminating racial and ethnic disparities. In carrying out this subsection, the Secretary, acting through the Deputy Assistant Secretary, shall award grants, contracts, enter into memoranda of understanding, cooperative, interagency, intra-agency and other agreements with public and nonprofit private entities, agencies, as well as Departmental and Cabinet agencies and organizations, and with organizations that are indigenous human resource providers in communities of color to assure improved health status of racial and ethnic minorities, and shall develop measures to evaluate the effectiveness of activities aimed at reducing health disparities and supporting the local community. Such measures shall evaluate community outreach activities, language services, workforce cultural competence, and other areas as determined by the Secretary.

(b) DUTIES.—With respect to improving the health of racial and ethnic minority groups, the Secretary, acting through the Deputy Assistant Secretary for Minority Health (in this section referred to as the "Deputy Assistant Secretary"), shall carry out the following:

(1) Establish short-range and long-range goals and objectives and coordinate all other activities within the Public Health Service that relate to disease prevention, health promotion, service delivery, and research concerning such individuals. The heads of each of the agencies of the Service shall consult with the Deputy Assistant Secretary to ensure the coordination of such activities.

(2) Enter into interagency agreements with other agencies of the Public Health Service.

(3) Support research, demonstrations and evaluations to test new and innovative models.

(4) Increase knowledge and understanding of health risk factors.

(5) Develop mechanisms that support better information dissemination, education, prevention, and service delivery to individuals from disadvantaged backgrounds, including individuals who are members of racial or ethnic minority groups.

(6) Ensure that the National Center for Health Statistics collects data on the health status of each minority group.

(7) With respect to individuals who lack proficiency in speaking the English language, enter into contracts with public and nonprofit private providers of primary health services for

the purpose of increasing the access of the individuals to such services by developing and carrying out programs to provide bilingual or interpretive services.

(8) Support a national minority health resource center to carry out the following:

(A) Facilitate the exchange of information regarding matters relating to health information and health promotion, preventive health services, and education in the appropriate use of health care.

(B) Facilitate access to such information.

(C) Assist in the analysis of issues and problems relating to such matters.

(D) Provide technical assistance with respect to the exchange of such information (including facilitating the development of materials for such technical assistance).

(9) Carry out programs to improve access to health care services for individuals with limited proficiency in speaking the English language. Activities under the preceding sentence shall include developing and evaluating model projects.

(10) Advise in matters related to the development, implementation, and evaluation of health professions education in decreasing disparities in health care outcomes, including cultural competency as a method of eliminating health disparities.

(c) ADVISORY COMMITTEE.—

(1) IN GENERAL.—The Secretary shall establish an advisory committee to be known as the Advisory Committee on Minority Health (in this subsection referred to as the "Committee").

(2) DUTIES.—The Committee shall provide advice to the Deputy Assistant Secretary carrying out this section, including advice on the development of goals and specific program activities under paragraphs (1) through (10) of subsection (b) for each racial and ethnic minority group.

(3) CHAIR.—The chairperson of the Committee shall be selected by the Secretary from among the members of the voting members of the Committee. The term of office of the chairperson shall be 2 years.

(4) COMPOSITION.—

(A) The Committee shall be composed of 12 voting members appointed in accordance with subparagraph (B), and nonvoting, ex officio members designated in subparagraph (C).

(B) The voting members of the Committee shall be appointed by the Secretary from among individuals who are not officers or employees of the Federal Government and who have expertise regarding issues of minority health. The racial and ethnic minority groups shall be equally represented among such members.

(C) The nonvoting, ex officio members of the Committee shall be such officials of the Department of Health and Human Services as the Secretary determines to be appropriate.

(5) TERMS.—Each member of the Committee shall serve for a term of 4 years, except that the Secretary shall initially ap-

point a portion of the members to terms of 1 year, 2 years, and 3 years.

(6) VACANCIES.—If a vacancy occurs on the Committee, a new member shall be appointed by the Secretary within 90 days from the date that the vacancy occurs, and serve for the remainder of the term for which the predecessor of such member was appointed. The vacancy shall not affect the power of the remaining members to execute the duties of the Committee.

(7) COMPENSATION.—Members of the Committee who are officers or employees of the United States shall serve without compensation. Members of the Committee who are not officers or employees of the United States shall receive compensation, for each day (including travel time) they are engaged in the performance of the functions of the Committee. Such compensation may not be in an amount in excess of the daily equivalent of the annual maximum rate of basic pay payable under the General Schedule (under title 5, United States Code) for positions above GS–15.

(d) CERTAIN REQUIREMENTS REGARDING DUTIES.—

(1) RECOMMENDATIONS REGARDING LANGUAGE.—

(A) PROFICIENCY IN SPEAKING ENGLISH.—The Deputy Assistant Secretary shall consult with the Director of the Office of International and Refugee Health, the Director of the Office of Civil Rights, and the Directors of other appropriate departmental entities regarding recommendations for carrying out activities under subsection (b)(9).

(B) HEALTH PROFESSIONS EDUCATION REGARDING HEALTH DISPARITIES.—The Deputy Assistant Secretary shall carry out the duties under subsection (b)(10) in collaboration with appropriate personnel of the Department of Health and Human Services, other Federal agencies, and other offices, centers, and institutions, as appropriate, that have responsibilities under the Minority Health and Health Disparities Research and Education Act of 2000.

(2) EQUITABLE ALLOCATION REGARDING ACTIVITIES.—In carrying out subsection (b), the Secretary shall ensure that services provided under such subsection are equitably allocated among all groups served under this section by the Secretary.

(3) CULTURAL COMPETENCY OF SERVICES.—The Secretary shall ensure that information and services provided pursuant to subsection (b) are provided in the language, educational, and cultural context that is most appropriate for the individuals for whom the information and services are intended.

(e) GRANTS AND CONTRACTS REGARDING DUTIES.—

(1) IN GENERAL.—In carrying out subsection (b), the Secretary acting through the Deputy Assistant Secretary may make awards of grants, cooperative agreements, and contracts to public and nonprofit private entities.

(2) PROCESS FOR MAKING AWARDS.—The Deputy Assistant Secretary shall ensure that awards under paragraph (1) are made, to the extent practical, only on a competitive basis, and that a grant is awarded for a proposal only if the proposal has

been recommended for such an award through a process of peer review.

(3) EVALUATION AND DISSEMINATION.—The Deputy Assistant Secretary, directly or through contracts with public and private entities, shall provide for evaluations of projects carried out with awards made under paragraph (1) during the preceding 2 fiscal years. The report shall be included in the report required under subsection (f) for the fiscal year involved.

(f) REPORTS.—

(1) IN GENERAL.—Not later than February 1 of fiscal year 1999 and of each second year thereafter, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report describing the activities carried out under this section during the preceding 2 fiscal years and evaluating the extent to which such activities have been effective in improving the health of racial and ethnic minority groups. Each such report shall include the biennial reports submitted under sections 201(e)(3) and 201(f)(2) for such years by the heads of the Public Health Service agencies.

(2) AGENCY REPORTS.—Not later than February 1, 1999, and biennially thereafter, the heads of the Public Health Service agencies shall submit to the Deputy Assistant Secretary a report summarizing the minority health activities of each of the respective agencies.

(g) DEFINITION.—For purposes of this section:

(1) The term "racial and ethnic minority group" means American Indians (including Alaska Natives, Eskimos, and Aleuts); Asian Americans; Native Hawaiians and other Pacific Islanders; Blacks; and Hispanics.

(2) The term "Hispanic" means individuals whose origin is Mexican, Puerto Rican, Cuban, Central or South American, or any other Spanish-speaking country.

(h) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of fiscal years 2011 through 2016.

SEC. 1707A.[300u–6a] INDIVIDUAL OFFICES OF MINORITY HEALTH WITHIN THE DEPARTMENT.

(a) IN GENERAL.—The head of each agency specified in subsection (b)(1) shall establish within the agency an office to be known as the Office of Minority Health. The head of each such Office shall be appointed by the head of the agency within which the Office is established, and shall report directly to the head of the agency. The head of such agency shall carry out this section (as this section relates to the agency) acting through such Director.

(b) SPECIFIED AGENCIES.—The agencies referred to in subsection (a) are the Centers for Disease Control and Prevention, the Health Resources and Services Administration, the Substance Abuse and Mental Health Services Administration, the Agency for Healthcare Research and Quality, the Food and Drug Administration, and the Centers for Medicare & Medicaid Services.

(c) DIRECTOR; APPOINTMENT.—Each Office of Minority Health established in an agency listed in subsection (a) shall be headed by

a director, with documented experience and expertise in minority health services research and health disparities elimination.

(d) REFERENCES.—Except as otherwise specified, any reference in Federal law to an Office of Minority Health (in the Department of Health and Human Services) is deemed to be a reference to the Office of Minority Health in the Office of the Secretary.

(e) FUNDING.—

(1) ALLOCATIONS.—Of the amounts appropriated for a specified agency for a fiscal year, the Secretary must designate an appropriate amount of funds for the purpose of carrying out activities under this section through the minority health office of the agency. In reserving an amount under the preceding sentence for a minority health office for a fiscal year, the Secretary shall reduce, by substantially the same percentage, the amount that otherwise would be available for each of the programs of the designated agency involved.

(2) AVAILABILITY OF FUNDS FOR STAFFING.—The purposes for which amounts made available under paragraph may be expended by a minority health office include the costs of employing staff for such office.

OFFICE OF ADOLESCENT HEALTH.

SEC. 1708.[300u–7] (a) IN GENERAL.—There is established an Office of Adolescent Health within the Office of the Assistant Secretary for Health, which office shall be headed by a director appointed by the Secretary. The Secretary shall carry out this section acting through the Director of such Office.

(b) DUTIES.—With respect to adolescent health, the Secretary shall—

(1) coordinate all activities within the Department of Health and Human Services that relate to disease prevention, health promotion, preventive health services, and health information and education with respect to the appropriate use of health care, including coordinating—

(A) the design of programs, support for programs, and the evaluation of programs;

(B) the monitoring of trends;

(C) projects of research (including multidisciplinary projects) on adolescent health; and

(D) the training of health providers who work with adolescents, particularly nurse practitioners, physician assistants, and social workers;

(2) coordinate the activities described in paragraph (1) with similar activities in the private sector; and

(3) support projects, conduct research, and disseminate information relating to preventive medicine, health promotion, and physical fitness and sports medicine.

(c) CERTAIN DEMONSTRATION PROJECTS.—

(1) IN GENERAL.—In carrying out subsection (b)(3), the Secretary may make grants to carry out demonstration projects for the purpose of improving adolescent health, including projects to train health care providers in providing services to adoles-

cents and projects to reduce the incidence of violence among adolescents, particularly among minority males.

(2) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out paragraph (1), there are authorized to be appropriated $5,000,000 for fiscal year 1993, and such sums as may be necessary for each of the fiscal years 1994 through 1997.

(d) INFORMATION CLEARINGHOUSE.—In carrying out subsection (b), the Secretary shall establish and maintain a National Information Clearinghouse on Adolescent Health to collect and disseminate to health professionals and the general public information on adolescent health.

(e) NATIONAL PLAN.—In carrying out subsection (b), the Secretary shall develop a national plan for improving adolescent health. The plan shall be consistent with the applicable objectives established by the Secretary for the health status of the people of the United States for the year 2000, and shall be periodically reviewed, and as appropriate, revised. The plan, and any revisions in the plan, shall be submitted to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate.

(f) ADOLESCENT HEALTH.—For purposes of this section, the term "adolescent health", with respect to adolescents of all ethnic and racial groups, means all diseases, disorders, and conditions (including with respect to mental health)—

(1) unique to adolescents, or more serious or more prevalent in adolescents;

(2) for which the factors of medical risk or types of medical intervention are different for adolescents, or for which it is unknown whether such factors or types are different for adolescents; or

(3) with respect to which there has been insufficient clinical research involving adolescents as subjects or insufficient clinical data on adolescents.

BIENNIAL REPORT REGARDING NUTRITION AND HEALTH.

SEC. 1709.[300u–8] (a) BIENNIAL REPORT.—The Secretary shall require the Surgeon General of the Public Health Service to prepare biennial reports on the relationship between nutrition and health. Such reports may, with respect to such relationship, include any recommendations of the Secretary and the Surgeon General.

(b) SUBMISSION TO CONGRESS.—The Secretary shall ensure that, not later than February 1 of 1995 and of every second year thereafter, a report under subsection (a) is submitted to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate.

EDUCATION REGARDING DES.

SEC. 1710.[300u–9] (a) IN GENERAL.—The Secretary, acting through the heads of the appropriate agencies of the Public Health Service, shall carry out a national program for the education of health professionals and the public with respect to the drug diethylstilbestrol (commonly known as DES). To the extent appropriate, such national program shall use methodologies developed

through the education demonstration program carried out under section 403C. In developing and carrying out the national program, the Secretary shall consult closely with representatives of nonprofit private entities that represent individuals who have been exposed to DES and that have expertise in community-based information campaigns for the public and for health care providers. The implementation of the national program shall begin during fiscal year 1999.

(b) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1999 through 2003. The authorization of appropriations established in the preceding sentence is in addition to any other authorization of appropriation that is available for such purpose.

PUBLIC HEALTH SERVICE ACT

As Amended Through P.L. 112–240, Enacted January 2, 2013

TITLE XVIII—PRESIDENT'S COMMISSION FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH

ESTABLISHMENT OF COMMISSION.

SEC. 1801.[300v] (a) ESTABLISHMENT.—(1) There is established the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research[1] (hereinafter in this title referred to as the "Commission") which shall be composed of eleven members appointed by the President. The members of the Commission shall be appointed as follows:

(A) Three of the members shall be appointed from individuals who are distinguished in biomedical or behavioral research.

(B) Three of the members shall be appointed from individuals who are distinguished in the practice of medicine or otherwise distinguished in the provision of health care.

(C) Five of the members shall be appointed from individuals who are distinguished in one or more of the fields of ethics, theology, law, the natural sciences (other than a biomedical or behavioral science), the social sciences, the humanities, health administration, government, and public affairs.

(2) No individual who is a full-time officer or employee of the United States may be appointed as a member of the Commission. The Secretary of Health, Education, and Welfare, the Secretary of Defense, the Director of Central Intelligence, the Director of the Office of Science and Technology Policy, the Administrator of Veterans' Affairs, and the Director of the National Science Foundation shall each designate an individual to provide liaison with the Commission.

(3) No individual may be appointed to serve as a member of the Commission if the individual has served for two terms of four years each as such a member.

(4) A vacancy in the Commission shall be filled in the manner in which the original appointment was made.

(b) TERMS.—(1) Except as provided in paragraphs (2) and (3), members shall be appointed for terms of four years.

(2) Of the members first appointed—

(A) four shall be appointed for terms of three years, and

(B) three shall be appointed for terms of two years,

[1] Such a Commission was established on December 17, 1979, by Executive Order No. 12184 (44 Fed. Reg. 75091). The Executive Order was revoked on February 25, 1986, by Executive Order No. 12553 (51 Fed. Reg. 7237).

as designated by the President at the time of appointment.

(3) Any member appointed to fill a vacancy occurring before the expiration of the term for which his predecessor was appointed shall be appointed only for the remainder of such term. A member may serve after the expiration of his term until his successor has taken office.

(c) CHAIRMAN.—The Chairman of the Commission shall be appointed by the President, by and with the advice and consent of the Senate, from members of the Commission.

(d) MEETINGS.—(1) Seven members of the Commission shall constitute a quorum for business, but a lesser number may conduct hearings.

(2) The Commission shall meet at the call of the Chairman or at the call of a majority of its members.

(e) COMPENSATION.—(1) Members of the Commission shall each be entitled to receive the daily equivalent of the annual rate of basic pay in effect for grade GS–18 of the General Schedule for each day (including travel time) during which they are engaged in the actual performance of duties vested in the Commission.

(2) While away from their homes or regular places of business in the performance of services for the Commission, members of the Commission shall be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as persons employed intermittently in the Government service are allowed expenses under section 5703 of title 5 of the United States Code.

DUTIES OF THE COMMISSION.

SEC. 1802.[300v–1] (a) STUDIES.—(1) The Commission shall undertake studies of the ethical and legal implications of—

(A) the requirements for informed consent to participation in research projects and to otherwise undergo medical procedures;

(B) the matter of defining death, including the advisability of developing a uniform definition of death;

(C) voluntary testing, counseling, and information and education programs with respect to genetic diseases and conditions, taking into account the essential equality of all human beings, born and unborn;

(D) the differences in the availability of health services as determined by the income or residence of the persons receiving the services;

(E) current procedures and mechanisms designed (i) to safeguard the privacy of human subjects of behavioral and biomedical research, (ii) to ensure the confidentiality of individually identifiable patient records, and (iii) to ensure appropriate access of patients to information continued[2] in such records,[3] and

(F) such other matters relating to medicine or biomedical or behavioral research as the President may designate for study by the Commission.

[2] So in law. Probably should be "contained".
[3] So in law. The comma should probably be a semicolon.

The Commission shall determine the priority and order of the studies required under this paragraph.

(2) The Commission may undertake an investigation or study of any other appropriate matter which relates to medicine or biomedical or behavioral research (including the protection of human subjects of biomedical or behavioral research) and which is consistent with the purposes of this title on its own initiative or at the request of the head of the Federal agency.

(3) In order to avoid duplication of effort, the Commission may, in lieu of, or as part of, any study or investigation required or otherwise conducted under this subsection, use a study or investigation conducted by another entity if the Commission sets forth its reasons for such use.

(4) Upon the completion of each investigation or study undertaken by the Commission under this subsection (including a study or investigation which merely uses another study or investigation), it shall report its findings (including any recommendations for legislation or administrative action) to the President and the Congress and to each Federal agency to which a recommendation in the report applies.

(b) RECOMMENDATIONS TO AGENCIES.—(1) Within 60 days of the date a Federal agency receives a recommendation from the Commission that the agency take any action with respect to its rules, policies, guidelines, or regulations, the agency shall publish such recommendation in the Federal Register and shall provide opportunity for interested persons to submit written data, views, and arguments with respect to adoption of the recommendation.

(2) Within the 180-day period beginning on the date of such publication, the agency shall determine whether the action proposed by such recommendation is appropriate, and, to the extent that it determines that—

(A) such action is not appropriate, the agency shall, within such time period, provide the Commission with, and publish in the Federal Register, a notice of such determination (including an adequate statement of the reasons for the determination), or

(B) such action is appropriate, the agency shall undertake such action as expeditiously as feasible and shall notify the Commission of the determination and the action undertaken.

(c) REPORT ON PROTECTION OF HUMAN SUBJECTS.—The Commission shall biennially report to the President, the Congress, and appropriate Federal agencies on the protection of human subjects of biomedical and behavioral research. Each such report shall include a review of the adequacy and uniformity (1) of the rules, policies, guidelines, and regulations of all Federal agencies regarding the protection of human subjects of biomedical or behavioral research which such agencies conduct or support, and (2) of the implementation of such rules, policies, guidelines, and regulations by such agencies, and may include such recommendations for legislation and administrative action as the Commission deems appropriate.

(d) ANNUAL REPORT.—Not later than December 15 of each year (beginning with 1979) the Commission shall report to the President, the Congress, and appropriate Federal agencies on the activi-

ties of the Commission during the fiscal year ending in such year. Each such report shall include a complete list of all recommendations described in subsection (b)(1) made to Federal agencies by the Commission during the fiscal year and the actions taken, pursant[4] to subsection (b)(2), by the agencies upon such recommendations, and may include such recommendations for legislation and administrative action as the Commission deems appropriate.

(e) PUBLICATIONS.—The Commission may at any time publish and disseminate to the public reports respecting its activities.

(f) DEFINITIONS.—For purposes of this section:

(1) The term "Federal agency" means an authority of the government of the United States, but does not include (A) the Congress, (B) the courts of the United States, and (C) the government of the Commonwealth of Puerto Rico, the government of the District of Columbia, or the government of any territory or possession of the United States.

(2) The term "protection of human subjects" includes the protection of the health, safety, and privacy of individuals.

ADMINISTRATIVE PROVISIONS.

SEC. 1803.[300v–2] (a) HEARINGS.—The Commission may for the purpose of carrying out this title hold such hearings, sit and act at such times and places, take such testimony, and receive such evidence, as the Commission may deem advisable.

(b) STAFF.—(1) The Commission may appoint and fix the pay of such staff personnel as it deems desirable. Such personnel shall be appointed subject to the provisions of title 5, United States Code, governing appointments in the competitive service, and shall be paid in accordance with the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates.

(2) The Commission may procure temporary and intermittent services to the same extent as is authorized by section 3109(b) of title 5 of the United States Code, but at rates for individuals not to exceed the daily equivalent of the annual rate of basis pay in effect for grade GS–18 of the General Schedule.

(3) Upon request of the Commission, the head of any Federal agency is authorized to detail, on a reimbursable basis, any of the personnel of such agency to the Commission to assist it in carrying out its duties under this title.

(c) CONTRACTS.—The Commission, in performing its duties and functions under this title, may enter into contracts with appropriate public or nonprofit private entities. The authority of the Commission to enter into such contracts is effective for any fiscal year only to such extent or in such amounts as are provided in advance in appropriation Acts.

(d) INFORMATION.—(1) The Commission may secure directly from any Federal agency information necessary to enable it to carry out this title. Upon request of the Chairman of the Commission, the head of such agency shall furnish such information to the Commission.

[4] So in law. Probably should be "pursuant".

(2) The Commission shall promptly arrange for such security clearances for its members and appropriate staff as are necessary to obtain access to classified information needed to carry out its duties under this title.

(3) The Commission shall not disclose any information reported to or otherwise obtained by the Commission which is exempt from disclosure under subsection (a) of section 552 of title 5, United States Code, by reason of paragraphs (4) and (6) of subsection (b) of such section.

(e) SUPPORT SERVICES.—The Administrator of General Services shall provide to the Commission on a reimbursable basis such administrative support services as the Commission may request.

AUTHORIZATION OF APPROPRIATIONS; TERMINATION OF COMMISSION.

SEC. 1804.[300v–3] (a) AUTHORIZATIONS.—To carry out this title there are authorized to be appropriated $5,000,000 for the fiscal year ending September 30, 1979, $5,000,000 for the fiscal year ending September 30, 1980, $5,000,000 for the fiscal year ending September 30, 1981, and $5,000,000 for the fiscal year ending September 30, 1982.

(b) FEDERAL ADVISORY COMMITTEE ACT; TERMINATION.—The Commission shall be subject to the Federal Advisory Committee Act, except that, under section 14(a)(1)(B) of such Act, the Commission shall terminate on December 31, 1982.

December 13, 2013

PUBLIC HEALTH SERVICE ACT

As Amended Through P.L. 112–240, Enacted January 2, 2013

TITLE XIX—BLOCK GRANTS

PART A—PREVENTIVE HEALTH AND HEALTH SERVICES BLOCK GRANT

AUTHORIZATION OF APPROPRIATIONS.

SEC. 1901.[300w] (a) For the purpose of allotments under section 1902, there are authorized to be appropriated $205,000,000 for fiscal year 1993, and such sums as may be necessary for each of the fiscal years 1994 through 1998.

(b) Of the amount appropriated for any fiscal year under subsection (a), at least $7,000,000 shall be made available for allotments under section 1902(b).

ALLOTMENTS.

SEC. 1902.[300w–1] (a)(1) From the amounts appropriated under section 1901 for any fiscal year and available for allotment under this subsection, the Secretary shall allot to each State an amount which bears the same ratio to the available amounts for that fiscal year as the amounts provided by the Secretary under the provisions of law listed in paragraph (2) to the State and entities in the State for fiscal year 1981 bore to the total amount appropriated for such provisions of law for fiscal year 1981.

(2) The provisions of law referred to in paragraph (1) are the following provisions of law as in effect on September 30, 1981:

(A) The authority for grants under section 317 for preventive health service programs for the control of rodents.

(B) The authority for grants under section 317 for establishing and maintaining community and school-based fluoridation programs.

(C) The authority for grants under section 317 for preventive health service programs for hypertension.

(D) Sections 401 and 402 of the Health Services and Centers Amendments of 1978.

(E) Section 314(d).

(F) Section 339(a).

(G) Sections 1202, 1203, and 1204.

(b) From the amount required to be made available under section 1901(b) for allotments under this subsection for any fiscal year, the Secretary shall make allotments to each State on the basis of the population of the State.

(c) To the extent that all the funds appropriated under section 1901 for a fiscal year and available for allotment in such fiscal year are not otherwise allotted to States because—

(1) one or more States have not submitted an application or description of activities in accordance with section 1905 for the fiscal year;

(2) one or more States have notified the Secretary that they do not intend to use the full amount of their allotment; or

(3) some State allotments are offset or repaid under section 1906(b)(3);

such excess shall be allotted among each of the remaining States in proportion to the amount otherwise allotted to such States for the fiscal year without regard to this subsection.

(d)(1) If the Secretary—

(A) receives a request from the governing body of an Indian tribe or tribal organization within any State that funds under this part be provided directly by the Secretary to such tribe or organization, and

(B) determines that the members of such tribe or tribal organization would be better served by means of grants made directly by the Secretary under this part,

the Secretary shall reserve from amounts which would otherwise be allotted to such State under subsection (a) for the fiscal year the amount determined under paragraph (2).

(2) The Secretary shall reserve for the purpose of paragraph (1) from amounts that would otherwise be allotted to such State under subsection (a) an amount equal to the amount which bears the same ratio to the State's allotment for the fiscal year involved as the total amount provided or allotted for fiscal year 1981 by the Secretary to such tribe or tribal organization under the provisions of law referred to in subsection (a) bore to the total amount provided or allotted for such fiscal year by the Secretary to the State and entities (including Indian tribes and tribal organizations) in the State under such provisions of law.

(3) The amount reserved by the Secretary on the basis of a determination under this subsection shall be granted to the Indian tribe or tribal organization serving the individuals for whom such a determination has been made.

(4) In order for an Indian tribe or tribal organization to be eligible for a grant for a fiscal year under this subsection, it shall submit to the Secretary a plan for such fiscal year which meets such criteria as the Secretary may prescribe.

(5) The terms "Indian tribe" and "tribal organization" have the same meaning given such terms in section 4(b) and section 4(c) of the Indian Self-Determination and Education Assistance Act.

(e) The Secretary shall conduct a study for the purpose of devising a formula for the equitable distribution of funds available for allotment to the States under this section. In conducting the study, the Secretary shall take into account—

(1) the financial resources of the various States,

(2) the populations of the States, and

(3) any other factor which the Secretary may consider appropriate.

Before June 30, 1982, the Secretary shall submit a report to the Congress respecting the development of a formula and make such recommendations as the Secretary may deem appropriate in order to ensure the most equitable distribution of funds under allotments under this section.

PAYMENTS UNDER ALLOTMENTS TO STATES.

SEC. 1903.[300w–2] (a)(1) For each fiscal year, the Secretary shall make payments, as provided by section 203 of the Intergovernmental Cooperation Act of 1968 (42 U.S.C. 4213), to each State from its allotment under section 1902 (other than any amount reserved under section 1902(d)) from amounts appropriated for that fiscal year.

(2) Any amount paid to a State for a fiscal year and remaining unobligated at the end of such year shall remain available for the next fiscal year to such State for the purposes for which it was made.

(b) The Secretary, at the request of a State, may reduce the amount of payments under subsection (a) by—

(1) the fair market value of any supplies or equipment furnished the State, and

(2) the amount of the pay, allowances, and travel expenses of any officer or employee of the Government when detailed to the State and the amount of any other costs incurred in connection with the detail of such officer or employee,

when the furnishing of supplies or equipment or the detail of an officer or employee is for the convenience of and at the request of the State and for the purpose of conducting activities described in section 1904. The amount by which any payment is so reduced shall be available for payment by the Secretary of the costs incurred in furnishing the supplies or equipment or in detailing the personnel, on which the reduction of the payment is based, and the amount shall be deemed to be part of the payment and shall be deemed to have been paid to the State.

USE OF ALLOTMENTS.

SEC. 1904.[300w–3] (a)(1) Except as provided in subsections (b) and (c), payments made to a State under section 1903 may be used for the following:

(A) Activities consistent with making progress toward achieving the objectives established by the Secretary for the health status of the population of the United States for the year 2000 (in this part referred to as "year 2000 health objectives").

(B) Preventive health service programs for the control of rodents and for community and school-based fluoridation programs.

(C) Feasibility studies and planning for emergency medical services systems and the establishment, expansion, and improvement of such systems. Amounts for such systems may not be used for the costs of the operation of the systems or the purchase of equipment for the systems, except that such amounts may be used for the payment of not more than 50 percent of

the costs of purchasing communications equipment for the systems. Amounts may be expended for feasibility studies or planning for the trauma-care components of such systems only if the studies or planning, respectively, is consistent with the requirements of section 1213(a).

(D) Providing services to victims of sex offenses and for prevention of sex offenses.

(E) The establishment, operation, and coordination of effective and cost-efficient systems to reduce the prevalence of illness due to asthma and asthma-related illnesses, especially among children, by reducing the level of exposure to cockroach allergen or other known asthma triggers through the use of integrated pest management, as applied to cockroaches or other known allergens. Amounts expended for such systems may include the costs of building maintenance and the costs of programs to promote community participation in the carrying out at such sites of integrated pest management, as applied to cockroaches or other known allergens. For purposes of this subparagraph, the term "integrated pest management" means an approach to the management of pests in public facilities that combines biological, cultural, physical, and chemical tools in a way that minimizes economic, health, and environmental risks.

(F) With respect to activities described in any of subparagraphs (A) through (E), related planning, administration, and educational activities.

(G) Monitoring and evaluation of activities carried out under any of subparagraphs (A) through (F).

(2) Except as provided in subsection (b), amounts paid to a State under section 1903 from its allotment under section 1902(b) may only be used for providing services to rape victims and for rape prevention.

(3) The Secretary may provide technical assistance to States in planning and operating activities to be carried out under this part.

(b) A State may not use amounts paid to it under section 1903 to—

(1) provide inpatient services,

(2) make cash payments to intended recipients of health services,

(3) purchase or improve land, purchase, construct, or permanently improve (other than minor remodeling) any building or other facility, or purchase major medical equipment,

(4) satisfy any requirement for the expenditure of non-Federal funds as a condition for the receipt of Federal funds, or

(5) provide financial assistance to any entity other than a public or nonprofit private entity.

Except as provided in subsection (a)(1)(E), the Secretary may waive the limitation contained in paragraph (3) upon the request of a State if the Secretary finds that there are extraordinary circumstances to justify the waiver and that granting the waiver will assist in carrying out this part.

(c) A State may transfer not more than 7 percent of the amount allotted to the State under section 1902(a) for any fiscal year for use by the State under part B of this title and title V of the Social Security Act in such fiscal year as follows: At any time

in the first three quarters of the fiscal year a State may transfer not more than 3 percent of the allotment of the State for the fiscal year for such use, and in the last quarter of a fiscal year a State may transfer for such use not more than the remainder of the amount of its allotment which may be transferred.

(d) Of the amount paid to any State under section 1903, not more than 10 percent paid from each of its allotments under subsections (a) and (b) of section 1902 may be used for administering the funds made available under section 1903. The State will pay from non-Federal sources the remaining costs of administering such funds.

APPLICATION FOR PAYMENTS; STATE PLAN.

SEC. 1905.[300w–4] (a) IN GENERAL.—The Secretary may make payments under section 1903 to a State for a fiscal year only if—

(1) the State submits to the Secretary an application for the payments;

(2) the application contains a State plan in accordance with subsection (b);

(3) the application contains the certification described in subsection (c);

(4) the application contains such assurances as the Secretary may require regarding the compliance of the State with the requirements of this part (including assurances regarding compliance with the agreements described in subsection (c)); and

(5) the application is in such form and is submitted by such date as the Secretary may require.

(b) STATE PLAN.—A State plan required in subsection (a)(2) for a fiscal year is in accordance with this subsection if the plan meets the following conditions:

(1) The plan is developed by the State agency with principal responsibility for public health programs, in consultation with the advisory committee established pursuant to subsection (c)(2).

(2) The plan specifies the activities authorized in section 1904 that are to be carried out with payments made to the State under section 1903, including a specification of the year 2000 health objectives for which the State will expend the payments.

(3) The plan specifies the populations in the State for which such activities are to be carried out.

(4) The plan specifies any populations in the State that have a disparate need for such activities.

(5) With respect to each population specified under paragraph (3), the plan contains a strategy for expending such payments to carry out such activities to make progress toward improving the health status of the population, which strategy includes—

(A) a description of the programs and projects to be carried out;

(B) an estimate of the number of individuals to be served by the programs and projects; and

(C) an estimate of the number of public health personnel needed to carry out the strategy.

(6) The plan specifies the amount of such payments to be expended for each of such activities and, with respect to the activity involved—

(A) the amount to be expended for each population specified under paragraph (3); and

(B) the amount to be expended for each population specified under paragraph (4).

(c) STATE CERTIFICATION.—The certification referred to in subsection (a)(3) for a fiscal year is a certification to the Secretary by the chief executive officer of the State involved as follows:

(1)(A) In the development of the State plan required in subsection (a)(2)—

(i) the chief health officer of the State held public hearings on the plan; and

(ii) proposals for the plan were made public in a manner that facilitated comments from public and private entities (including Federal and other public agencies).

(B) The State agrees that, if any revisions are made in such plan during the fiscal year, the State will, with respect to the revisions, hold hearings and make proposals public in accordance with subparagraph (A), and will submit to the Secretary a description of the revisions.

(2) The State has established an advisory committee in accordance with subsection (d).

(3) The State agrees to expend payments under section 1903 only for the activities authorized in section 1904.

(4) The State agrees to expend such payments in accordance with the State plan submitted under subsection (a)(2) (with any revisions submitted to the Secretary under paragraph (1)(B)), including making expenditures to carry out the strategy contained in the plan pursuant to subsection (b)(5).

(5)(A) The State agrees that, in the case of each population for which such strategy is carried out, the State will measure the extent of progress being made toward improving the health status of the population.

(B) The State agrees that—

(i) the State will collect and report data in accordance with section 1906(a); and

(ii) for purposes of subparagraph (A), progress will be measured through use of each of the applicable uniform data items developed by the Secretary under paragraph (2) of such section, or if no such items are applicable, through use of the uniform criteria developed by the Secretary under paragraph (3) of such section.

(6) With respect to the activities authorized in section 1904, the State agrees to maintain State expenditures for such activities at a level that is not less than the average level of such expenditures maintained by the State for the 2-year period preceding the fiscal year for which the State is applying to receive payments under section 1903.

(7) The State agrees to establish reasonable criteria to evaluate the effective performance of entities that receive funds from such payments and procedures for procedural and substantive independent State review of the failure by the State to provide funds for any such entity.

(8) The State agrees to permit and cooperate with Federal investigations undertaken in accordance with section 1907.

(9) The State has in effect a system to protect from inappropriate disclosure patient and sex offense victim records maintained by the State in connection with an activity funded under this part or by any entity which is receiving payments from the allotment of the State under this part.

(10) The State agrees to provide the officer of the State government responsible for the administration of the State highway safety program with an opportunity to—

(A) participate in the development of any plan by the State relating to emergency medical services, as such plan relates to highway safety; and

(B) review and comment on any proposal by any State agency to use any Federal grant or Federal payment received by the State for the provision of emergency medical services as such proposal relates to highway safety.

(d) STATE ADVISORY COMMITTEE.—

(1) IN GENERAL.—For purposes of subsection (c)(2), an advisory committee is in accordance with this subsection if such committee is known as the State Preventive Health Advisory Committee (in this subsection referred to as the "Committee") and the Committee meets the conditions described in the subsequent paragraphs of this subsection.

(2) DUTIES.—A condition under paragraph (1) for a State is that the duties of the Committee are—

(A) to hold public hearings on the State plan required in subsection (a)(2); and

(B) to make recommendations pursuant to subsection (b)(1) regarding the development and implementation of such plan, including recommendations on—

(i) the conduct of assessments of the public health;

(ii) which of the activities authorized in section 1904 should be carried out in the State;

(iii) the allocation of payments made to the State under section 1903;

(iv) the coordination of activities carried out under such plan with relevant programs of other entities; and

(v) the collection and reporting of data in accordance with section 1906(a).

(3) COMPOSITION.—

(A) A condition under paragraph (1) for a State is that the Committee is composed of such members of the general public, and such officials of the health departments of political subdivisions of the State, as may be necessary to provide adequate representation of the general public and of such health departments.

(B) With respect to compliance with subparagraph (A), the membership of advisory committees established pursuant to subsection (c)(2) may include representatives of community-based organizations (including minority community-based organizations), schools of public health, and entities to which the State involved awards grants or contracts to carry out activities authorized in section 1904.

(4) CHAIR; MEETINGS.—A condition under paragraph (1) for a State is that the State public health officer serves as the chair of the Committee, and that the Committee meets not less than twice each fiscal year.

REPORTS, DATA, AND AUDITS.

SEC. 1906.[300w–5] (a)(1) For purposes of section 1905(c)(5)(B)(i), a State is collecting and reporting data for a fiscal year in accordance with this subsection if the State submits to the Secretary, not later than February 1 of the succeeding fiscal year, a report that—

(A) describes the purposes for which the State expended payments made to the State under section 1903;

(B) pursuant to section 1905(c)(5)(A), describes the extent of progress made by the State for purposes of such section;

(C) meets the conditions described in the subsequent paragraphs of this subsection; and

(D) contains such additional information regarding activities authorized in section 1904, and is submitted in such form, as the Secretary may require.

(2)(A) The Secretary, in consultation with the States, shall develop sets of data for uniformly defining health status for purposes of the year 2000 health objectives (which sets are in this subsection referred to as "uniform data sets"). Each of such sets shall consist of one or more categories of information (in this subsection individually referred to as a "uniform data item"). The Secretary shall develop formats for the uniform collecting and reporting of information on such items.

(B) A condition under paragraph (1)(C) for a fiscal year is that the State involved will, in accordance with the applicable format under subparagraph (A), collect during such year, and include in the report under paragraph (1), the necessary information for one uniform data item from each of the uniform data sets, which items are selected for the State by the Secretary.

(C) In the case of fiscal year 1995 and each subsequent fiscal year, a condition under paragraph (1) for a State is that the State will, in accordance with the applicable format under subparagraph (A), collect during such year, and include in the report under paragraph (1), the necessary information for each of the uniform data sets appropriate to the year 2000 health objectives that the State has, in the State plan submitted under section 1905 for the fiscal year, specified as a purpose for which payments under section 1903 are to be expended.

(3) The Secretary, in consultation with the States, shall establish criteria for the uniform collection and reporting of data on ac-

tivities authorized in section 1904 with respect to which no uniform data items exist.

(4) A condition under paragraph (1) for a fiscal year is that the State involved will make copies of the report submitted under such paragraph for the fiscal year available for public inspection, and will upon request provide a copy of the report to any individual for a charge not exceeding the cost of providing the copy.

(b)(1) Each State shall establish fiscal control and fund accounting procedures as may be necessary to assure the proper disbursal of and accounting for Federal funds paid to the State under section 1903 and funds transferred under section 1904(c) for use under this part.

(2) Each State shall annually audit its expenditures from payments received under section 1903. Such State audits shall be conducted by an entity independent of any agency administering a program funded under this part and, in so far as practical, in accordance with the Comptroller General's standards for auditing governmental organizations, programs, activities, and functions. Within 30 days following the date each audit is completed, the chief executive officer of the State shall transmit a copy of that audit to the Secretary.

(3) Each State shall, after being provided by the Secretary with adequate notice and opportunity for a hearing within the State, repay to the United States amounts found not to have been expended in accordance with the requirements of this part or the certification provided by the State under section 1905. If such repayment is not made, the Secretary shall, after providing the State with adequate notice and opportunity for a hearing within the State, offset such amounts against the amount of any allotment to which the State is or may become entitled under this part.

(4) The State shall make copies of the reports and audits required by this section available for public inspection within the State.

(5) The Comptroller General of the United States shall, from time to time, evaluate the expenditures by States of grants under this part in order to assure that expenditures are consistent with the provisions of this part and the certification provided by the State under section 1905.

(6) Not later than October 1, 1990, the Secretary shall report to the Congress on the activities of the States that have received funds under this part and may include in the report any recommendations for appropriate changes in legislation.

(c) Title XVII of the Omnibus Budget Reconciliation Act of 1981 shall not apply with respect to audits of funds allotted under this part.

WITHHOLDING.

SEC. 1907.[300w–6] (a)(1) The Secretary shall, after adequate notice and an opportunity for a hearing conducted within the affected State, withhold funds from any State which does not use its allotment in accordance with the requirements of this part or the certification provided under section 1905. The Secretary shall withhold such funds until the Secretary finds that the reason for the

withholding has been removed and there is reasonable assurance that it will not recur.

(2) The Secretary may not institute proceedings to withhold funds under paragraph (1) unless the Secretary has conducted an investigation concerning whether the State has used its allotment in accordance with the requirements of this part or the certification provided under section 1905. Investigations required by this paragraph shall be conducted within the affected State by qualified investigators.

(3) The Secretary shall respond in an expeditious manner to complaints of a substantial or serious nature that a State has failed to use funds in accordance with the requirements of this part or certifications provided under section 1905.

(4) The Secretary may not withhold funds under paragraph (1) from a State for a minor failure to comply with the requirements of this part or certifications provided under section 1905.

(b)(1) The Secretary shall conduct in several States in each fiscal year investigations of the use of funds received by the States under this part in order to evaluate compliance with the requirements of this part and certifications provided under section 1905.

(2) The Comptroller General of the United States may conduct investigations of the use of funds received under this part by a State in order to insure compliance with the requirements of this part and certifications provided under section 1905.

(c) Each State, and each entity which has received funds from an allotment made to a State under this part, shall make appropriate books, documents, papers, and records available to the Secretary or the Comptroller General of the United States, or any of their duly authorized representatives, for examination, copying, or mechanical reproduction on or off the premises of the appropriate entity upon a reasonable request therefor.

(d)(1) In conducting any investigation in a State, the Secretary or the Comptroller General of the United States may not make a request for any information not readily available to such State or an entity which has received funds from an allotment made to the State under this part or make an unreasonable request for information to be compiled, collected, or transmitted in any form not readily available.

(2) Paragraph (1) does not apply to the collection, compilation, or transmittal of data in the course of a judicial proceeding.

NONDISCRIMINATION.

SEC. 1908.[300w–7] (a)(1) For the purpose of applying the prohibitions against discrimination on the basis of age under the Age Discrimination Act of 1975, on the basis of handicap under section 504 of the Rehabilitation Act of 1973, on the basis of sex under title IX of the Education Amendments of 1972, or on the basis of race, color, or national origin under title VI of the Civil Rights Act of 1964, programs and activities funded in whole or in part with funds made available under this part are considered to be programs and activities receiving Federal financial assistance.

(2) No person shall on the ground of sex or religion be excluded from participation in, be denied the benefits of, or be subjected to

discrimination under, any program or activity funded in whole or in part with funds made available under this part.

(b) Whenever the Secretary finds that a State, or an entity that has received a payment from an allotment to a State under section 1902, has failed to comply with a provision of law referred to in subsection (a)(1), with subsection (a)(2), or with an applicable regulation (including one prescribed to carry out subsection (a)(2)), the Secretary shall notify the chief executive officer of the State and shall request him to secure compliance. If within a reasonable period of time, not to exceed sixty days, the chief executive officer fails or refuses to secure compliance, the Secretary may—

(1) refer the matter to the Attorney General with a recommendation that an appropriate civil action be instituted,

(2) exercise the powers and functions provided by title VI of the Civil Rights Act of 1964, the Age Discrimination Act of 1975, or section 504 of the Rehabilitation Act of 1973, as may be applicable, or

(3) take such other action as may be provided by law.

(c) When a matter is referred to the Attorney General pursuant to subsection (b)(1), or whenever he has reason to believe that a State or an entity is engaged in a pattern or practice in violation of a provision of law referred to in subsection (a)(1) or in violation of subsection (a)(2), the Attorney General may bring a civil action in any appropriate district court of the United States for such relief as may be appropriate, including injunctive relief.

CRIMINAL PENALTY FOR FALSE STATEMENTS.

SEC. 1909.[300w–8] Whoever—

(1) knowingly and willfully makes or causes to be made any false statement or representation of a material fact in connection with the furnishing of items or services for which payment may be made by a State from funds allotted to the State under this part, or

(2) having knowledge of the occurrence of any event affecting his initial or continued right to any such payment conceals or fails to disclose such event with an intent fraudulently to secure such payment either in a greater amount than is due or when no such payment is authorized,

shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

EMERGENCY MEDICAL SERVICES FOR CHILDREN.

SEC. 1910.[300w–9] (a) For activities in addition to the activities which may be carried out by States under section 1904(a)(1)(F), the Secretary may make grants to States or accredited schools of medicine in States to support a program of demonstration projects for the expansion and improvement of emergency medical services for children who need treatment for trauma or critical care. Any grant made under this subsection shall be for not more than a 4-year period (with an optional 5th year based on performance), subject to annual evaluation by the Secretary. Only 3 grants under this subsection may be made in a State (to a State or to a school of medicine in such State) in any fiscal year.

(b) The Secretary may renew a grant made under subsection (a) for one additional one-year period only if the Secretary determines that renewal of such grant will provide significant benefits through the collection, analysis, and dissemination of information or data which will be useful to States in which grants under such subsection have not been made.

(c) For purposes of this section—

(1) the term "school of medicine" has the same meaning as in section 701(4); and

(2) the term "accredited" has the same meaning as in section 701(5).

(d) To carry out this section, there are authorized to be appropriated $2,000,000 for fiscal year 1985 and for each of the two succeeding fiscal years, $3,000,000 for fiscal year 1989, $4,000,000 for fiscal year 1990, $5,000,000 for each of the fiscal years 1991 and 1992, such sums as may be necessary for each of the fiscal years 1993 through 2005, $25,000,000 for fiscal year 2010, $26,250,000 for fiscal year 2011, $27,562,500 for fiscal year 2012, $28,940,625 for fiscal year 2013, and $30,387,656 for fiscal year 2014.

PART B—BLOCK GRANTS REGARDING MENTAL HEALTH AND SUBSTANCE ABUSE

Subpart I—Block Grants for Community Mental Health Services

SEC. 1911.[300x] FORMULA GRANTS TO STATES.

(a) IN GENERAL.—For the purpose described in subsection (b), the Secretary, acting through the Director of the Center for Mental Health Services, shall make an allotment each fiscal year for each State in an amount determined in accordance with section 1918. The Secretary shall make a grant to the State of the allotment made for the State for the fiscal year if the State submits to the Secretary an application in accordance with section 1917.

(b) PURPOSE OF GRANTS.—A funding agreement for a grant under subsection (a) is that, subject to section 1916, the State involved will expend the grant only for the purpose of—

(1) carrying out the plan submitted under section 1912(a) by the State for the fiscal year involved;

(2) evaluating programs and services carried out under the plan; and

(3) planning, administration, and educational activities related to providing services under the plan.

SEC. 1912.[300x–1] STATE PLAN FOR COMPREHENSIVE COMMUNITY MENTAL HEALTH SERVICES FOR CERTAIN INDIVIDUALS.

(a) IN GENERAL.—The Secretary may make a grant under section 1911 only if—

(1) the State involved submits to the Secretary a plan for providing comprehensive community mental health services to adults with a serious mental illness and to children with a serious emotional disturbance;

(2) the plan meets the criteria specified in subsection (b); and

(3) the plan is approved by the Secretary.

(b) CRITERIA FOR PLAN.—With respect to the provision of comprehensive community mental health services to individuals who are either adults with a serious mental illness or children with a serious emotional disturbance, the criteria referred to in subsection (a) regarding a plan are as follows:

(1) COMPREHENSIVE COMMUNITY-BASED MENTAL HEALTH SYSTEMS.—The plan provides for an organized community-based system of care for individuals with mental illness and describes available services and resources in a comprehensive system of care, including services for dually diagnosed individuals. The description of the system of care shall include health and mental health services, rehabilitation services, employment services, housing services, educational services, substance abuse services, medical and dental care, and other support services to be provided to individuals with Federal, State and local public and private resources to enable such individuals to function outside of inpatient or residential institutions to the maximum extent of their capabilities, including services to be provided by local school systems under the Individuals with Disabilities Education Act. The plan shall include a separate description of case management services and provide for activities leading to reduction of hospitalization.

(2) MENTAL HEALTH SYSTEM DATA AND EPIDEMIOLOGY.—The plan contains an estimate of the incidence and prevalence in the State of serious mental illness among adults and serious emotional disturbance among children and presents quantitative targets to be achieved in the implementation of the system described in paragraph (1).

(3) CHILDREN'S SERVICES.—In the case of children with serious emotional disturbance, the plan—

(A) subject to subparagraph (B), provides for a system of integrated social services, educational services, juvenile services, and substance abuse services that, together with health and mental health services, will be provided in order for such children to receive care appropriate for their multiple needs (such system to include services provided under the Individuals with Disabilities Education Act);

(B) provides that the grant under section 1911 for the fiscal year involved will not be expended to provide any service under such system other than comprehensive community mental health services; and

(C) provides for the establishment of a defined geographic area for the provision of the services of such system.

(4) TARGETED SERVICES TO RURAL AND HOMELESS POPULATIONS.—The plan describes the State's outreach to and services for individuals who are homeless and how community-based services will be provided to individuals residing in rural areas.

(5) MANAGEMENT SYSTEMS.—The plan describes the financial resources, staffing and training for mental health providers that is necessary to implement the plan, and provides for the training of providers of emergency health services re-

garding mental health. The plan further describes the manner in which the State intends to expend the grant under section 1911 for the fiscal year involved.

Except as provided for in paragraph (3), the State plan shall contain the information required under this subsection with respect to both adults with serious mental illness and children with serious emotional disturbance.

(c) DEFINITIONS REGARDING MENTAL ILLNESS AND EMOTIONAL DISTURBANCE; METHODS FOR ESTIMATE OF INCIDENCE AND PREVALENCE.—

(1) ESTABLISHMENT BY SECRETARY OF DEFINITIONS; DISSEMINATION.—For purposes of this subpart, the Secretary shall establish definitions for the terms "adults with a serious mental illness" and "children with a serious emotional disturbance". The Secretary shall disseminate the definitions to the States.

(2) STANDARDIZED METHODS.—The Secretary shall establish standardized methods for making the estimates required in subsection (b)(11) with respect to a State. A funding agreement for a grant under section 1911 for the State is that the State will utilize such methods in making the estimates.

(3) DATE CERTAIN FOR COMPLIANCE BY SECRETARY.—Not later than 90 days after the date of the enactment of the ADAMHA Reorganization Act[1], the Secretary shall establish the definitions described in paragraph (1), shall begin dissemination of the definitions to the States, and shall establish the standardized methods described in paragraph (2).

(d) REQUIREMENT OF IMPLEMENTATION OF PLAN.—

(1) COMPLETE IMPLEMENTATION.—Except as provided in paragraph (2), in making a grant under section 1911 to a State for a fiscal year, the Secretary shall make a determination of the extent to which the State has implemented the plan required in subsection (a). If the Secretary determines that a State has not completely implemented the plan, the Secretary shall reduce the amount of the allotment under section 1911 for the State for the fiscal year involved by an amount equal to 10 percent of the amount determined under section 1918 for the State for the fiscal year.

(2) SUBSTANTIAL IMPLEMENTATION AND GOOD FAITH EFFORT REGARDING FISCAL YEAR 1993.—

(A) In making a grant under section 1911 to a State for fiscal year 1993, the Secretary shall make a determination of the extent to which the State has implemented the plan required in subsection (a). If the Secretary determines that the State has not substantially implemented the plan, the Secretary shall, subject to subparagraph (B), reduce the amount of the allotment under section 1911 for the State for such fiscal year by an amount equal to 10 percent of the amount determined under section 1918 for the State for the fiscal year.

(B) In carrying out subparagraph (A), if the Secretary determines that the State is making a good faith effort to

[1] Enacted July 10, 1992.

implement the plan required in subsection (a), the Secretary may make a reduction under such subparagraph in an amount that is less than the amount specified in such subparagraph, except that the reduction may not be made in an amount that is less than 5 percent of the amount determined under section 1918 for the State for fiscal year 1993.

SEC. 1913.[300x–2] CERTAIN AGREEMENTS.

(a) ALLOCATION FOR SYSTEMS OF INTEGRATED SERVICES FOR CHILDREN.—

(1) IN GENERAL.—With respect to children with a serious emotional disturbance, a funding agreement for a grant under section 1911 is that—

(A) in the case of a grant for fiscal year 1993, the State involved will expend not less than 10 percent of the grant to increase (relative to fiscal year 1992) funding for the system of integrated services described in section 1912(b)(9);

(B) in the case of a grant for fiscal year 1994, the State will expend not less than 10 percent of the grant to increase (relative to fiscal year 1993) funding for such system; and

(C) in the case of a grant for any subsequent fiscal year, the State will expend for such system not less than an amount equal to the amount expended by the State for fiscal year 1994.

(2) WAIVER.—

(A) Upon the request of a State, the Secretary may provide to the State a waiver of all or part of the requirement established in paragraph (1) if the Secretary determines that the State is providing an adequate level of comprehensive community mental health services for children with a serious emotional distrubance[2], as indicated by a comparison of the number of such children for which such services are sought with the availability in the State of the services.

(B) The Secretary shall approve or deny a request for a waiver under subparagraph (A) not later than 120 days after the date on which the request is made.

(C) Any waiver provided by the Secretary under subparagraph (A) shall be applicable only to the fiscal year involved.

(b) PROVIDERS OF SERVICES.—A funding agreement for a grant under section 1911 for a State is that, with respect to the plan submitted under section 1912(a) for the fiscal year involved—

(1) services under the plan will be provided only through appropriate, qualified community programs (which may include community mental health centers, child mental-health programs, psychosocial rehabilitation programs, mental health peer-support programs, and mental-health primary consumer-directed programs); and

[2] So in law. See section 201 of Public Law 102–321 (106 Stat. 381). Probably should be "disturbance".

(2) services under the plan will be provided through community mental health centers only if the centers meet the criteria specified in subsection (c).

(c) CRITERIA FOR MENTAL HEALTH CENTERS.—The criteria referred to in subsection (b)(2) regarding community mental health centers are as follows:

(1) With respect to mental health services, the centers provide services as follows:

(A) Services principally to individuals residing in a defined geographic area (hereafter in this subsection referred to as a "service area").

(B) Outpatient services, including specialized outpatient services for children, the elderly, individuals with a serious mental illness, and residents of the service areas of the centers who have been discharged from inpatient treatment at a mental health facility.

(C) 24-hour-a-day emergency care services.

(D) Day treatment or other partial hospitalization services, or psychosocial rehabilitation services.

(E) Screening for patients being considered for admission to State mental health facilities to determine the appropriateness of such admission.

(2) The mental health services of the centers are provided, within the limits of the capacities of the centers, to any individual residing or employed in the service area of the center regardless of ability to pay for such services.

(3) The mental health services of the centers are available and accessible promptly, as appropriate and in a manner which preserves human dignity and assures continuity and high quality care.

SEC. 1914.[300x–3] STATE MENTAL HEALTH PLANNING COUNCIL.

(a) IN GENERAL.—A funding agreement for a grant under section 1911 is that the State involved will establish and maintain a State mental health planning council in accordance with the conditions described in this section.

(b) DUTIES.—A condition under subsection (a) for a Council is that the duties of the Council are—

(1) to review plans provided to the Council pursuant to section 1915(a) by the State involved and to submit to the State any recommendations of the Council for modifications to the plans;

(2) to serve as an advocate for adults with a serious mental illness, children with a severe emotional disturbance, and other individuals with mental illnesses or emotional problems; and

(3) to monitor, review, and evaluate, not less than once each year, the allocation and adequacy of mental health services within the State.

(c) MEMBERSHIP.—

(1) IN GENERAL.—A condition under subsection (a) for a Council is that the Council be composed of residents of the State, including representatives of—

(A) the principal State agencies with respect to—

(i) mental health, education, vocational rehabilitation, criminal justice, housing, and social services; and

(ii) the development of the plan submitted pursuant to title XIX of the Social Security Act;

(B) public and private entities concerned with the need, planning, operation, funding, and use of mental health services and related support services;

(C) adults with serious mental illnesses who are receiving (or have received) mental health services; and

(D) the families of such adults or families of children with emotional disturbance.

(2) CERTAIN REQUIREMENTS.—A condition under subsection (a) for a Council is that—

(A) with respect to the membership of the Council, the ratio of parents of children with a serious emotional disturbance to other members of the Council is sufficient to provide adequate representation of such children in the deliberations of the Council; and

(B) not less than 50 percent of the members of the Council are individuals who are not State employees or providers of mental health services.

(d) DEFINITION.—For purposes of this section, the term "Council" means a State mental health planning council.

SEC. 1915.[300x–4] ADDITIONAL PROVISIONS.

(a) REVIEW OF STATE PLAN BY MENTAL HEALTH PLANNING COUNCIL.—The Secretary may make a grant under section 1911 to a State only if—

(1) the plan submitted under section 1912(a) with respect to the grant and the report of the State under section 1942(a) concerning the preceding fiscal year has been reviewed by the State mental health planning council under section 1914; and

(2) the State submits to the Secretary any recommendations received by the State from such council for modifications to the plan (without regard to whether the State has made the recommended modifications) and any comments concerning the annual report.

(b) MAINTENANCE OF EFFORT REGARDING STATE EXPENDITURES FOR MENTAL HEALTH.—

(1) IN GENERAL.—A funding agreement for a grant under section 1911 is that the State involved will maintain State expenditures for community mental health services at a level that is not less than the average level of such expenditures maintained by the State for the 2-year period preceding the fiscal year for which the State is applying for the grant.

(2) EXCLUSION OF CERTAIN FUNDS.—The Secretary may exclude from the aggregate State expenditures under subsection (a), funds appropriated to the principle agency for authorized activities which are of a non-recurring nature and for a specific purpose.

(3) WAIVER.—The Secretary may, upon the request of a State, waive the requirement established in paragraph (1) if the Secretary determines that extraordinary economic conditions in the State justify the waiver.

(4) NONCOMPLIANCE BY STATE.—

(A) In making a grant under section 1911 to a State for a fiscal year, the Secretary shall make a determination of whether, for the previous fiscal year, the State maintained material compliance with the agreement made under paragraph (1). If the Secretary determines that a State has failed to maintain such compliance, the Secretary shall reduce the amount of the allotment under section 1911 for the State for the fiscal year for which the grant is being made by an amount equal to the amount constituting such failure for the previous fiscal year.

(B) The Secretary may make a grant under section 1911 for a fiscal year only if the State involved submits to the Secretary information sufficient for the Secretary to make the determination required in subparagraph (A).

SEC. 1916.[300x–5] RESTRICTIONS ON USE OF PAYMENTS.

(a) IN GENERAL.—A funding agreement for a grant under section 1911 is that the State involved will not expend the grant—

(1) to provide inpatient services;

(2) to make cash payments to intended recipients of health services;

(3) to purchase or improve land, purchase, construct, or permanently improve (other than minor remodeling) any building or other facility, or purchase major medical equipment;

(4) to satisfy any requirement for the expenditure of non-Federal funds as a condition for the receipt of Federal funds; or

(5) to provide financial assistance to any entity other than a public or nonprofit private entity.

(b) LIMITATION ON ADMINISTRATIVE EXPENSES.—A funding agreement for a grant under section 1911 is that the State involved will not expend more than 5 percent of the grant for administrative expenses with respect to the grant.

SEC. 1917.[300x–6] APPLICATION FOR GRANT.

(a) IN GENERAL.—For purposes of section 1911, an application for a grant under such section for a fiscal year in accordance with[3] this section if, subject to subsection (b)—

(1) the plan is received by the Secretary not later than September 1 of the fiscal year prior to the fiscal year for which a State is seeking funds, and the report from the previous fiscal year as required under section 1941 is received by December 1 of the fiscal year of the grant;

(2) the application contains each funding agreement that is described in this subpart or subpart III for such a grant (other than any such agreement that is not applicable to the State);

(3) the agreements are made through certification from the chief executive officer of the State;

(4) with respect to such agreements, the application provides assurances of compliance satisfactory to the Secretary;

[3] So in law. See section 201 of Public Law 102–321 (106 Stat. 384). Probably should be "is in accordance with".

(5) the application contains the plan required in section 1912(a), the information required in section 1915(b)(3)(B), and the report required in section 1942(a);

(6) the application contains recommendations in compliance with section 1915(a), or if no such recommendations are received by the State, the application otherwise demonstrates compliance with such section; and

(7) the application (including the plan under section 1912(a)) is otherwise in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this subpart.

(b) WAIVERS REGARDING CERTAIN TERRITORIES.—In the case of any territory of the United States except Puerto Rico, the Secretary may waive such provisions of this subpart and subpart III as the Secretary determines to be appropriate, other than the provisions of section 1916.

SEC. 1918.[300x–7] DETERMINATION OF AMOUNT OF ALLOTMENT.

(a) STATES.—

(1) DETERMINATION UNDER FORMULA.—Subject to subsection (b), the Secretary shall determine the amount of the allotment required in section 1911 for a State for a fiscal year in accordance with the following formula:

$$A \quad \left(\frac{X}{U} \right)$$

(2) DETERMINATION OF TERM "A".—For purposes of paragraph (1), the term "A" means the difference between—

(A) the amount appropriated under section 1920(a) for allotments under section 1911 for the fiscal year involved; and

(B) an amount equal to 1.5 percent of the amount referred to in subparagraph (A).

(3) DETERMINATION OF TERM "U".—For purposes of paragraph (1), the term "U" means the sum of the respective terms "X" determined for the States under paragraph (4).

(4) DETERMINATION OF TERM "X".—For purposes of paragraph (1), the term "X" means the product of—

(A) an amount equal to the product of—

(i) the term "P", as determined for the State involved under paragraph (5); and

(ii) the factor determined under paragraph (8) for the State; and

(B) the greater of—

(i) 0.4; and

(ii) an amount equal to an amount determined for the State in accordance with the following formula:

$$1 - .35 \quad \left(\frac{R\%}{P\%} \right)$$

(5) DETERMINATION OF TERM "P".—

(A) For purposes of paragraph (4), the term "P" means the sum of—

(i) an amount equal to the product of 0.107 and the number of individuals in the State who are between 18 and 24 years of age (inclusive);

(ii) an amount equal to the product of 0.166 and the number of individuals in the State who are between 25 and 44 years of age (inclusive);

(iii) an amount equal to the product of 0.099 and the number of individuals in the State who are between 45 and 64 years of age (inclusive); and

(iv) an amount equal to the product of 0.082 and the number of individuals in the State who are 65 years of age or older.

(B) With respect to data on population that is necessary for purposes of making a determination under subparagraph (A), the Secretary shall use the most recent data that is available from the Secretary of Commerce pursuant to the decennial census and pursuant to reasonable estimates by such Secretary of changes occurring in the data in the ensuing period.

(6) DETERMINATION OF TERM "R%".—

(A) For purposes of paragraph (4), the term "R%", except as provided in subparagraph (D), means the percentage constituted by the ratio of the amount determined under subparagraph (B) for the State involved to the amount determined under subparagraph (C).

(B) The amount determined under this subparagraph for the State involved is the quotient of—

(i) the most recent 3-year arithmetic mean of the total taxable resources of the State, as determined by the Secretary of the Treasury; divided by

(ii) the factor determined under paragraph (8) for the State.

(C) The amount determined under this subparagraph is the sum of the respective amounts determined for the States under subparagraph (B) (including the District of Columbia).

(D)(i) In the case of the District of Columbia, for purposes of paragraph (4), the term "R%" means the percentage constituted by the ratio of the amount determined under clause (ii) for such District to the amount determined under clause (iii).

(ii) The amount determined under this clause for the District of Columbia is the quotient of—

(I) the most recent 3-year arithmetic mean of total personal income in such District, as determined by the Secretary of Commerce; divided by

(II) the factor determined under paragraph (8) for the District.

(iii) The amount determined under this clause is the sum of the respective amounts determined for the States (including the District of Columbia) by making, for each

State, the same determination as is described in clause (ii) for the District of Columbia.

(7) DETERMINATION OF TERM "P%".—For purposes of paragraph (4), the term "P%" means the percentage constituted by the ratio of the term "P" determined under paragraph (5) for the State involved to the sum of the respective terms "P" determined for the States.

(8) DETERMINATION OF CERTAIN FACTOR.—

(A) The factor determined under this paragraph for the State involved is a factor whose purpose is to adjust the amount determined under clause (i) of paragraph (4)(A), and the amounts determined under each of subparagraphs (B)(i) and (D)(ii)(I) of paragraph (6), to reflect the differences that exist between the State and other States in the costs of providing comprehensive community mental health services to adults with a serious mental illness and to children with a serious emotional disturbance.

(B) Subject to subparagraph (C), the factor determined under this paragraph and in effect for the fiscal year involved shall be determined according to the methodology described in the report entitled "Adjusting the Alcohol, Drug Abuse and Mental Health Services Block Grant Allocations for Poverty Populations and Cost of Service", dated March 30, 1990, and prepared by Health Economics Research, a corporation, pursuant to a contract with the National Institute on Drug Abuse.

(C) The factor determined under this paragraph for the State involved may not for any fiscal year be greater than 1.1 or less than 0.9.

(D)(i) Not later than October 1, 1992, the Secretary, after consultation with the Comptroller General, shall in accordance with this section make a determination for each State of the factor that is to be in effect for the State under this paragraph. The factor so determined shall remain in effect through fiscal year 1994, and shall be recalculated every third fiscal year thereafter.

(ii) After consultation with the Comptroller General, the Secretary shall, through publication in the Federal Register, periodically make such refinements in the methodology referred to in subparagraph (B) as are consistent with the purpose described in subparagraph (A).

(b) MINIMUM ALLOTMENTS FOR STATES.—With respect to fiscal year 2000, and subsequent fiscal years, the amount of the allotment of a State under section 1911 shall not be less than the amount the State received under such section for fiscal year 1998.

(c) TERRITORIES.—

(1) DETERMINATION UNDER FORMULA.—Subject to paragraphs (2) and (4), the amount of an allotment under section 1911 for a territory of the United States for a fiscal year shall be the product of—

(A) an amount equal to the amounts reserved under paragraph (3) for the fiscal year; and

(B) a percentage equal to the quotient of—

(i) the civilian population of the territory, as indicated by the most recently available data; divided by

(ii) the aggregate civilian population of the territories of the United States, as indicated by such data.

(2) MINIMUM ALLOTMENT FOR TERRITORIES.—The amount of an allotment under section 1911 for a territory of the United States for a fiscal year shall be the greater of—

(A) the amount determined under paragraph (1) for the territory for the fiscal year;

(B) $50,000; and

(C) with respect to fiscal years 1993 and 1994, an amount equal to 20.6 percent of the amount received by the territory from allotments made pursuant to this part for fiscal year 1992.

(3) RESERVATION OF AMOUNTS.—The Secretary shall each fiscal year reserve for the territories of the United States 1.5 percent of the amounts appropriated under section 1920(a) for allotments under section 1911 for the fiscal year.

(4) AVAILABILITY OF DATA ON POPULATION.—With respect to data on the civilian population of the territories of the United States, if the Secretary determines for a fiscal year that recent such data for purposes of paragraph (1)(B) do not exist regarding a territory, the Secretary shall for such purposes estimate the civilian population of the territory by modifying the data on the territory to reflect the average extent of change occurring during the ensuing period in the population of all territories with respect to which recent such data do exist.

(5) APPLICABILITY OF CERTAIN PROVISIONS.—For purposes of subsection (a), the term "State" does not include the territories of the United States.

SEC. 1919.[300x–8] DEFINITIONS.

For purposes of this subpart:

(1) The terms "adults with a serious mental illness" and "children with a serious emotional disturbance" have the meanings given such terms under section 1912(c)(1).

(2) The term "funding agreement", with respect to a grant under section 1911 to a State, means that the Secretary may make such a grant only if the State makes the agreement involved.

SEC. 1920.[300x–9] FUNDING.

(a) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this subpart, and subpart III and section 505 with respect to mental health, there are authorized to be appropriated $450,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 and 2003.

(b) ALLOCATIONS FOR TECHNICAL ASSISTANCE, DATA COLLECTION, AND PROGRAM EVALUATION.—

(1) IN GENERAL.—For the purpose of carrying out section 1948(a) with respect to mental health and the purposes specified in paragraphs (2) and (3), the Secretary shall obligate 5 percent of the amounts appropriated under subsection (a) for a fiscal year.

(2) DATA COLLECTION.—The purpose specified in this paragraph is carrying out sections 505 and 1971 with respect to mental health.

(3) PROGRAM EVALUATION.—The purpose specified in this paragraph is the conduct of evaluations of prevention and treatment programs and services with respect to mental health to determine methods for improving the availability and quality of such programs and services.

Subpart II—Block Grants for Prevention and Treatment of Substance Abuse

SEC. 1921.[300x–21] FORMULA GRANTS TO STATES.

(a) IN GENERAL.—For the purpose described in subsection (b), the Secretary, acting through the Center for Substance Abuse Treatment, shall make an allotment each fiscal year for each State in an amount determined in accordance with section 1933. The Secretary shall make a grant to the State of the allotment made for the State for the fiscal year if the State submits to the Secretary an application in accordance with section 1932.

(b) AUTHORIZED ACTIVITIES.—A funding agreement for a grant under subsection (a) is that, subject to section 1931, the State involved will expend the grant only for the purpose of planning, carrying out, and evaluating activities to prevent and treat substance abuse and for related activities authorized in section 1924.

SEC. 1922.[300x–22] CERTAIN ALLOCATIONS.

(a) ALLOCATION REGARDING PRIMARY PREVENTION PROGRAMS.—A funding agreement for a grant under section 1921 is that, in expending the grant, the State involved—

(1) will expend not less than 20 percent for programs for individuals who do not require treatment for substance abuse, which programs—

(A) educate and counsel the individuals on such abuse; and

(B) provide for activities to reduce the risk of such abuse by the individuals;

(2) will, in carrying out paragraph (1)—

(A) give priority to programs for populations that are at risk of developing a pattern of such abuse; and

(B) ensure that programs receiving priority under subparagraph (A) develop community-based strategies for the prevention of such abuse, including strategies to discourage the use of alcoholic beverages and tobacco products by individuals to whom it is unlawful to sell or distribute such beverages or products.

(b)[4] ALLOCATIONS REGARDING WOMEN.—

[4] Paragraph (2)(A) of section 3303(f) of Public Law 106–310 (114 Stat. 1211) provides as follows:

(2) CONFORMING AMENDMENTS.—Effective upon the publication of the regulations developed in accordance with section 1932(e)(1) of the Public Health Service Act (42 U.S.C. 300x–32(d))—

(A) section 1922(c) of the Public Health Service Act (42 U.S.C. 300x–22(c)) is amended by—

Continued

(1) IN GENERAL.—Subject to paragraph (2), a funding agreement for a grant under section 1921 for a fiscal year is that—

(A) in the case of a grant for fiscal year 1993, the State involved will expend not less than 5 percent of the grant to increase (relative to fiscal year 1992) the availability of treatment services designed for pregnant women and women with dependent children (either by establishing new programs or expanding the capacity of existing programs);

(B) in the case of a grant for fiscal year 1994, the State will expend not less than 5 percent of the grant to so increase (relative to fiscal year 1993) the availability of such services for such women; and

(C) in the case of a grant for any subsequent fiscal year, the State will expend for such services for such women not less than an amount equal to the amount expended by the State for fiscal year 1994.

(2) WAIVER.—

(A) Upon the request of a State, the Secretary may provide to the State a waiver of all or part of the requirement established in paragraph (1) if the Secretary determines that the State is providing an adequate level of treatments services for women described in such paragraph, as indicated by a comparison of the number of such women seeking the services with the availability in the State of the services.

(B) The Secretary shall approve or deny a request for a waiver under subparagraph (A) not later than 120 days after the date on which the request is made.

(C) Any waiver provided by the Secretary under subparagraph (A) shall be applicable only to the fiscal year involved.

(3) CHILDCARE AND PRENATAL CARE.—A funding agreement for a grant under section 1921 for a State is that each entity providing treatment services with amounts reserved under paragraph (1) by the State will, directly or through arrangements with other public or nonprofit private entities, make available prenatal care to women receiving such services and, while the women are receiving the services, childcare.

SEC. 1923.[300x–23] INTRAVENOUS SUBSTANCE ABUSE.

(a) CAPACITY OF TREATMENT PROGRAMS.—

(1) NOTIFICATION OF REACHING CAPACITY.—A funding agreement for a grant under section 1921 is that the State involved will, in the case of programs of treatment for intravenous drug abuse, require that any such program receiving amounts from the grant, upon reaching 90 percent of its capacity to admit individuals to the program, provide to the State a notification of such fact.

(i) striking paragraph (2); and

(ii) redesignating paragraph (3) as paragraph (2); and

The reference to section 1922(c) probably should be a reference to section 1922(b), as amended by section 3303(a) of such Public Law.

(2) PROVISION OF TREATMENT.—A funding agreement for a grant under section 1921 is that the State involved will, with respect to notifications under paragraph (1), ensure that each individual who requests and is in need of treatment for intravenous drug abuse is admitted to a program of such treatment not later than—

(A) 14 days after making the request for admission to such a program; or

(B) 120 days after the date of such request, if no such program has the capacity to admit the individual on the date of such request and if interim services are made available to the individual not later than 48 hours after such request.

(b) OUTREACH REGARDING INTRAVENOUS SUBSTANCE ABUSE.—A funding agreement for a grant under section 1921 is that the State involved, in providing amounts from the grant to any entity for treatment services for intravenous drug abuse, will require the entity to carry out activities to encourage individuals in need of such treatment to undergo treatment.

SEC. 1924.[300x–24] REQUIREMENTS REGARDING TUBERCULOSIS AND HUMAN IMMUNODEFICIENCY VIRUS.

(a) TUBERCULOSIS.—

(1) IN GENERAL.—A funding agreement for a grant under section 1921 is that the State involved will require that any entity receiving amounts from the grant for operating a program of treatment for substance abuse—

(A) will, directly or through arrangements with other public or nonprofit private entities, routinely make available tuberculosis services to each individual receiving treatment for such abuse; and

(B) in the case of an individual in need of such treatment who is denied admission to the program on the basis of the lack of the capacity of the program to admit the individual, will refer the individual to another provider of tuberculosis services.

(2) TUBERCULOSIS SERVICES.—For purposes of paragraph (1), the term "tuberculosis services", with respect to an individual, means—

(A) counseling the individual with respect to tuberculosis;

(B) testing to determine whether the individual has contracted such disease and testing to determine the form of treatment for the disease that is appropriate for the individual; and

(C) providing such treatment to the individual.

(b) HUMAN IMMUNODEFICIENCY VIRUS.—

(1) REQUIREMENT FOR CERTAIN STATES.—In the case of a State described in paragraph (2), a funding agreement for a grant under section 1921 is that—

(A) with respect to individuals undergoing treatment for substance abuse, the State will, subject to paragraph (3), carry out 1 or more projects to make available to the individuals early intervention services for HIV disease at

the sites at which the individuals are undergoing such treatment;

(B) for the purpose of providing such early intervention services through such projects, the State will make available from the grant the percentage that is applicable for the State under paragraph (4); and

(C) the State will, subject to paragraph (5), carry out such projects only in geographic areas of the State that have the greatest need for the projects.

(2) DESIGNATED STATES.—For purposes of this subsection, a State described in this paragraph is any State whose rate of cases of acquired immune deficiency syndrome is 10 or more such cases per 100,000 individuals (as indicated by the number of such cases reported to and confirmed by the Director of the Centers for Disease Control for the most recent calendar year for which such data are available).

(3) USE OF EXISTING PROGRAMS REGARDING SUBSTANCE ABUSE.—With respect to programs that provide treatment services for substance abuse, a funding agreement for a grant under section 1921 for a designated State is that each such program participating in a project under paragraph (1) will be a program that began operation prior to the fiscal year for which the State is applying to receive the grant. A program that so began operation may participate in a project under paragraph (1) without regard to whether the program has been providing early intervention services for HIV disease.

(4) APPLICABLE PERCENTAGE REGARDING EXPENDITURES FOR SERVICES.—

(A)(i) For purposes of paragraph (1)(B), the percentage that is applicable under this paragraph for a designated State is, subject to subparagraph (B), the percentage by which the amount of the grant under section 1921 for the State for the fiscal year involved is an increase over the amount specified in clause (ii).

(ii) The amount specified in this clause is the amount that was reserved by the designated State involved from the allotment of the State under section 1912A for fiscal year 1991 in compliance with section 1916(c)(6)(A)(ii) (as such sections were in effect for such fiscal year).

(B) If the percentage determined under subparagraph (A) for a designated State for a fiscal year is less than 2 percent (including a negative percentage, in the case of a State for which there is no increase for purposes of such subparagraph), the percentage applicable under this paragraph for the State is 2 percent. If the percentage so determined is 2 percent or more, the percentage applicable under this paragraph for the State is the percentage determined under subparagraph (A), subject to not exceeding 5 percent.

(5) REQUIREMENT REGARDING RURAL AREAS.—

(A) A funding agreement for a grant under section 1921 for a designated State is that, if the State will carry out 2 or more projects under paragraph (1), the State will

carry out 1 such project in a rural area of the State, subject to subparagraph (B).

(B) The Secretary shall waive the requirement established in subparagraph (A) if the State involved certifies to the Secretary that—

(i) there is insufficient demand in the State to carry out a project under paragraph (1) in any rural area of the State; or

(ii) there are no rural areas in the State.

(6) MANNER OF PROVIDING SERVICES.—With respect to the provision of early intervention services for HIV disease to an individual, a funding agreement for a grant under section 1921 for a designated State is that—

(A) such services will be undertaken voluntarily by, and with the informed consent of, the individual; and

(B) undergoing such services will not be required as a condition of receiving treatment services for substance abuse or any other services.

(7) DEFINITIONS.—For purposes of this subsection:

(A) The term "designated State" means a State described in paragraph (2).

(B) The term "early intervention services", with respect to HIV disease, means—

(i) appropriate pretest counseling;

(ii) testing individuals with respect to such disease, including tests to confirm the presence of the disease, tests to diagnose the extent of the deficiency in the immune system, and tests to provide information on appropriate therapeutic measures for preventing and treating the deterioration of the immune system and for preventing and treating conditions arising from the disease;

(iii) appropriate post-test counseling; and

(iv) providing the therapeutic measures described in clause (ii).

(C) The term "HIV disease" means infection with the etiologic agent for acquired immune deficiency syndrome.

(c) EXPENDITURE OF GRANT FOR COMPLIANCE WITH AGREEMENTS.—

(1) IN GENERAL.—A grant under section 1921 may be expended for purposes of compliance with the agreements required in this section, subject to paragraph (2).

(2) LIMITATION.—A funding agreement for a grant under section 1921 for a State is that the grant will not be expended to make payment for any service provided for purposes of compliance with this section to the extent that payment has been made, or can reasonably be expected to be made, with respect to such service—

(A) under any State compensation program, under any insurance policy, or under any Federal or State health benefits program (including the program established in title XVIII of the Social Security Act and the program established in title XIX of such Act); or

(B) by an entity that provides health services on a prepaid basis.

(d) MAINTENANCE OF EFFORT.—With respect to services provided for by a State for purposes of compliance with this section, a funding agreement for a grant under section 1921 is that the State will maintain expenditures of non-Federal amounts for such services at a level that is not less than average level of such expenditures maintained by the State for 2-year period preceding the first fiscal year for which the State receives such a grant.

(e) APPLICABILITY OF CERTAIN PROVISION.—Section 1931 applies to this section (and to each other provision of this subpart).

SEC. 1925.[300x–25] GROUP HOMES FOR RECOVERING SUBSTANCE ABUSERS.

(a) STATE REVOLVING FUNDS FOR ESTABLISHMENT OF HOMES.—A State, using funds available under section 1921, may establish and maintain the ongoing operation of a revolving fund in accordance with this section to support group homes for recovering substance abusers as follows:

(1) The purpose of the fund is to make loans for the costs of establishing programs for the provision of housing in which individuals recovering from alcohol or drug abuse may reside in groups of not less than 6 individuals. The fund is established directly by the State or through the provision of a grant or contract to a nonprofit private entity.

(2) The programs are carried out in accordance with guidelines issued under subsection (b).

(3) Not less than $100,000 is available for the fund.

(4) Loans made from the revolving fund do not exceed $4,000 and each such loan is repaid to the revolving fund by the residents of the housing involved not later than 2 years after the date on which the loan is made.

(5) Each such loan is repaid by such residents through monthly installments, and a reasonable penalty is assessed for each failure to pay such periodic installments by the date specified in the loan agreement involved.

(6) Such loans are made only to nonprofit private entities agreeing that, in the operation of the program established pursuant to the loan—

(A) the use of alcohol or any illegal drug in the housing provided by the program will be prohibited;

(B) any resident of the housing who violates such prohibition will be expelled from the housing;

(C) the costs of the housing, including fees for rent and utilities, will be paid by the residents of the housing; and

(D) the residents of the housing will, through a majority vote of the residents, otherwise establish policies governing residence in the housing, including the manner in which applications for residence in the housing are approved.

(b) ISSUANCE BY SECRETARY OF GUIDELINES.—The Secretary shall ensure that there are in effect guidelines under this subpart for the operation of programs described in subsection (a).

(c) APPLICABILITY TO TERRITORIES.—The requirements established in subsection (a) shall not apply to any territory of the United States other than the Commonwealth of Puerto Rico.

SEC. 1926.[300x–26] STATE LAW REGARDING SALE OF TOBACCO PRODUCTS TO INDIVIDUALS UNDER AGE OF 18.

(a) RELEVANT LAW.—

(1) IN GENERAL.—Subject to paragraph (2), for fiscal year 1994 and subsequent fiscal years, the Secretary may make a grant under section 1921 only if the State involved has in effect a law providing that it is unlawful for any manufacturer, retailer, or distributor of tobacco products to sell or distribute any such product to any individual under the age of 18.

(2) DELAYED APPLICABILITY FOR CERTAIN STATES.—In the case of a State whose legislature does not convene a regular session in fiscal year 1993, and in the case of a State whose legislature does not convene a regular session in fiscal year 1994, the requirement described in paragraph (1) as a condition of a receipt of a grant under section 1921 shall apply only for fiscal year 1995 and subsequent fiscal years.

(b) ENFORCEMENT.—

(1) IN GENERAL.—For the first applicable fiscal year and for subsequent fiscal years, a funding agreement for a grant under section 1921 is that the State involved will enforce the law described in subsection (a) in a manner that can reasonably be expected to reduce the extent to which tobacco products are available to individuals under the age of 18.

(2) ACTIVITIES AND REPORTS REGARDING ENFORCEMENT.—For the first applicable fiscal year and for subsequent fiscal years, a funding agreement for a grant under section 1921 is that the State involved will—

(A) annually conduct random, unannounced inspections to ensure compliance with the law described in subsection (a); and

(B) annually submit to the Secretary a report describing—

(i) the activities carried out by the State to enforce such law during the fiscal year preceding the fiscal year for which the State is seeking the grant;

(ii) the extent of success the State has achieved in reducing the availability of tobacco products to individuals under the age of 18; and

(iii) the strategies to be utilized by the State for enforcing such law during the fiscal year for which the grant is sought.

(c) NONCOMPLIANCE OF STATE.—Before making a grant under section 1921 to a State for the first applicable fiscal year or any subsequent fiscal year, the Secretary shall make a determination of whether the State has maintained compliance with subsections (a) and (b). If, after notice to the State and an opportunity for a hearing, the Secretary determines that the State is not in compliance with such subsections, the Secretary shall reduce the amount of the allotment under such section for the State for the fiscal year involved by an amount equal to—

(1) in the case of the first applicable fiscal year, 10 percent of the amount determined under section 1933 for the State for the fiscal year;

(2) in the case of the first fiscal year following such applicable fiscal year, 20 percent of the amount determined under section 1933 for the State for the fiscal year;

(3) in the case of the second such fiscal year, 30 percent of the amount determined under section 1933 for the State for the fiscal year; and

(4) in the case of the third such fiscal year or any subsequent fiscal year, 40 percent of the amount determined under section 1933 for the State for the fiscal year.

(d) DEFINITION.—For purposes of this section, the term "first applicable fiscal year" means—

(1) fiscal year 1995, in the case of any State described in subsection (a)(2); and

(2) fiscal year 1994, in the case of any other State.

SEC. 1927.[300x–27] TREATMENT SERVICES FOR PREGNANT WOMEN.

(a) IN GENERAL.—A funding agreement for a grant under section 1921 is that the State involved—

(1) will ensure that each pregnant woman in the State who seeks or is referred for and would benefit from such services is given preference in admissions to treatment facilities receiving funds pursuant to the grant; and

(2) will, in carrying out paragraph (1), publicize the availability to such women of services from the facilities and the fact that the women receive such preference.

(b) REFERRALS REGARDING STATES.—A funding agreement for a grant under section 1921 is that, in carrying out subsection (a)(1)—

(1) the State involved will require that, in the event that a treatment facility has insufficient capacity to provide treatment services to any woman described in such subsection who seeks the services from the facility, the facility refer the woman to the State; and

(2) the State, in the case of each woman for whom a referral under paragraph (1) is made to the State—

(A) will refer the woman to a treatment facility that has the capacity to provide treatment services to the woman; or

(B) will, if no treatment facility has the capacity to admit the woman, make interim services available to the woman not later than 48 hours after the women[5] seeks the treatment services.

SEC. 1928.[300x–28] ADDITIONAL AGREEMENTS.

(a) IMPROVEMENT OF PROCESS FOR APPROPRIATE REFERRALS FOR TREATMENT.—With respect to individuals seeking treatment services, a funding agreement for a grant under section 1921 is that the State involved will improve (relative to fiscal year 1992) the process in the State for referring the individuals to treatment

[5] So in law. See section 202 of Public Law 102–321 (106 Stat. 396). Probably should be "woman".

facilities that can provide to the individuals the treatment modality that is most appropriate for the individuals.

(b) CONTINUING EDUCATION.—With respect to any facility for treatment services or prevention actitivities[6] that is receiving amounts from a grant under section 1921, a funding agreement for a State for a grant under such section is that continuing education in such services or activities (or both, as the case may be) will be made available to employees of the facility who provide the services or activities.

(c) COORDINATION OF VARIOUS ACTIVITIES AND SERVICES.—A funding agreement for a grant under section 1921 is that the State involved will coordinate prevention and treatment activities with the provision of other appropriate services (including health, social, correctional and criminal justice, educational, vocational rehabilitation, and employment services).

(d)[7] WAIVER OF REQUIREMENT.—

(1) IN GENERAL.—Upon the request of a State, the Secretary may provide to a State a waiver of any or all of the requirements established in this section if the Secretary determines that, with respect to services for the prevention and treatment of substance abuse, the requirement involved is unnecessary for maintaining quality in the provision of such services in the State.

(2) DATE CERTAIN FOR ACTING UPON REQUEST.—The Secretary shall approve or deny a request for a waiver under paragraph (1) not later than 120 days after the date on which the request is made.

(3) APPLICABILITY OF WAIVER.—Any waiver provided by the Secretary under paragraph (1) shall be applicable only to the fiscal year involved.

SEC. 1929.[300x–29] SUBMISSION TO SECRETARY OF STATEWIDE ASSESSMENT OF NEEDS.

The Secretary may make a grant under section 1921 only if the State submits to the Secretary an assessment of the need in the State for authorized activities (which assessment is conducted in accordance with criteria issued by the Secretary), both by locality and by the State in general, which assessment includes a description of—

(1) the incidence and prevalence in the State of drug abuse and the incidence and prevalence in the State of alcohol abuse and alcoholism;

(2) current prevention and treatment activities in the State;

(3) the need of the State for technical assistance to carry out such activities;

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[6] So in law. See section 202 of Public Law 102–321 (106 Stat. 396). Probably should be "activities".

[7] Paragraph (2)(B) of section 3303(f) of Public Law 106–310 (114 Stat. 1211) provides as follows:

(2) CONFORMING AMENDMENTS.—Effective upon the publication of the regulations developed in accordance with section 1932(e)(1) of the Public Health Service Act (42 U.S.C. 300x–32(d))—

(A) * * *

(B) section 1928(d) of the Public Health Service Act (42 U.S.C. 300x–28(d)) is repealed.

(4) efforts by the State to improve such activities; and

(5) the extent to which the availability of such activities is insufficient to meet the need for the activities, the interim services to be made available under sections 1923(a) and 1927(b), and the manner in which such services are to be so available.

SEC. 1930.[300x–30] MAINTENANCE OF EFFORT REGARDING STATE EXPENDITURES.

(a) IN GENERAL.—With respect to the principal agency of a State for carrying out authorized activities, a funding agreement for a grant under section 1921 for the State for a fiscal year is that such agency will for such year maintain aggregate State expenditures for authorized activities at a level that is not less than the average level of such expenditures maintained by the State for the 2-year period preceding the fiscal year for which the State is applying for the grant.

(b) EXCLUSION OF CERTAIN FUNDS.—The Secretary may exclude from the aggregate State expenditures under subsection (a), funds appropriated to the principle agency for authorized activities which are of a non-recurring nature and for a specific purpose.

(c) WAIVER.—

(1) IN GENERAL.—Upon the request of a State, the Secretary may waive all or part of the requirement established in subsection (a) if the Secretary determines that extraordinary economic conditions in the State justify the waiver.

(2) DATE CERTAIN FOR ACTING UPON REQUEST.—The Secretary shall approve or deny a request for a waiver under paragraph (1) not later than 120 days after the date on which the request is made.

(3) APPLICABILITY OF WAIVER.—Any waiver provided by the Secretary under paragraph (1) shall be applicable only to the fiscal year involved.

(d) NONCOMPLIANCE BY STATE.—

(1) IN GENERAL.—In making a grant under section 1921 to a State for a fiscal year, the Secretary shall make a determination of whether, for the previous fiscal year, the State maintained material compliance with any agreement made under subsection (a). If the Secretary determines that a State has failed to maintain such compliance, the Secretary shall reduce the amount of the allotment under section 1921 for the State for the fiscal year for which the grant is being made by an amount equal to the amount constituting such failure for the previous fiscal year.

(2) SUBMISSION OF INFORMATION TO SECRETARY.—The Secretary may make a grant under section 1921 for a fiscal year only if the State involved submits to the Secretary information sufficient for the Secretary to make the determination required in paragraph (1).

SEC. 1931.[300x–31] RESTRICTIONS ON EXPENDITURE OF GRANT.

(a) IN GENERAL.—

(1) CERTAIN RESTRICTIONS.—A funding agreement for a grant under section 1921 is that the State involved will not expend the grant—

(A) to provide inpatient hospital services, except as provided in subsection (b);

(B) to make cash payments to intended recipients of health services;

(C) to purchase or improve land, purchase, construct, or permanently improve (other than minor remodeling) any building or other facility, or purchase major medical equipment;

(D) to satisfy any requirement for the expenditure of non-Federal funds as a condition for the receipt of Federal funds;

(E) to provide financial assistance to any entity other than a public or nonprofit private entity; or

(F) to carry out any program prohibited by section 256(b) of the Health Omnibus Programs Extension of 1988 (42 U.S.C. 300ee–5).

(2) LIMITATION ON ADMINISTRATIVE EXPENSES.—A funding agreement for a grant under section 1921 is that the State involved will not expend more than 5 percent of the grant to pay the costs of administering the grant.

(3) LIMITATION REGARDING PENAL AND CORRECTIONAL INSTITUTIONS.—A funding agreement for a State for a grant under section 1921 is that, in expending the grant for the purpose of providing treatment services in penal or correctional institutions of the State, the State will not expend more than an amount equal to the amount expended for such purpose by the State from the grant made under section 1912A to the State for fiscal year 1991 (as section 1912A was in effect for such fiscal year).

(b) EXCEPTION REGARDING INPATIENT HOSPITAL SERVICES.—

(1) MEDICAL NECESSITY AS PRECONDITION.—With respect to compliance with the agreement made under subsection (a), a State may expend a grant under section 1921 to provide inpatient hospital services as treatment for substance abuse only if it has been determined, in accordance with guidelines issued by the Secretary, that such treatment is a medical necessity for the individual involved, and that the individual cannot be effectively treated in a community-based, nonhospital, residential program of treatment.

(2) RATE OF PAYMENT.—In the case of an individual for whom a grant under section 1921 is expended to provide inpatient hospital services described in paragraph (1), a funding agreement for the grant for the State involved is that the daily rate of payment provided to the hospital for providing the services to the individual will not exceed the comparable daily rate provided for community-based, nonhospital, residential programs of treatment for substance abuse.

(c) WAIVER REGARDING CONSTRUCTION OF FACILITIES.—

(1) IN GENERAL.—The Secretary may provide to any State a waiver of the restriction established in subsection (a)(1)(C) for the purpose of authorizing the State to expend a grant under section 1921 for the construction of a new facility or rehabilitation of an existing facility, but not for land acquisition.

(2) STANDARD REGARDING NEED FOR WAIVER.—The Secretary may approve a waiver under paragraph (1) only if the State demonstrates to the Secretary that adequate treatment cannot be provided through the use of existing facilities and that alternative facilities in existing suitable buildings are not available.

(3) AMOUNT.—In granting a waiver under paragraph (1), the Secretary shall allow the use of a specified amount of funds to construct or rehabilitate a specified number of beds for residential treatment and a specified number of slots for outpatient treatment, based on reasonable estimates by the State of the costs of construction or rehabilitation. In considering waiver applications, the Secretary shall ensure that the State has carefully designed a program that will minimize the costs of additional beds.

(4) MATCHING FUNDS.—The Secretary may grant a waiver under paragraph (1) only if the State agrees, with respect to the costs to be incurred by the State in carrying out the purpose of the waiver, to make available non-Federal contributions in cash toward such costs in an amount equal to not less than $1 for each $1 of Federal funds provided under section 1921.

(5) DATE CERTAIN FOR ACTING UPON REQUEST.—The Secretary shall act upon a request for a waiver under paragraph (1) not later than 120 days after the date on which the request is made.

SEC. 1932.[300x–32] APPLICATION FOR GRANT; APPROVAL OF STATE PLAN.

(a) IN GENERAL.—For purposes of section 1921, an application for a grant under such section for a fiscal year is in accordance with this section if, subject to subsections (c) and (d)(2)—

(1) the application is received by the Secretary not later than October 1 of the fiscal year for which the State is seeking funds;

(2) the application contains each funding agreement that is described in this subpart or subpart III for such a grant (other than any such agreement that is not applicable to the State);

(3) the agreements are made through certification from the chief executive officer of the State;

(4) with respect to such agreements, the application provides assurances of compliance satisfactory to the Secretary;

(5) the application contains the information required in section 1929, the information required in section 1930(c)(2), and the report required in section 1942(a);

(6)(A) the application contains a plan in accordance with subsection (b) and the plan is approved by the Secretary; and

(B) the State provides assurances satisfactory to the Secretary that the State complied with the provisions of the plan under subparagraph (A) that was approved by the Secretary for the most recent fiscal year for which the State received a grant under section 1921; and

(7) the application (including the plan under paragraph (6)) is otherwise in such form, is made in such manner, and

contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this subpart.

(b) STATE PLAN.—

(1) IN GENERAL.—A plan submitted by a State under subsection (a)(6) is in accordance with this subsection if the plan contains detailed provisions for complying with each funding agreement for a grant under section 1921 that is applicable to the State, including a description of the manner in which the State intends to expend the grant.

(2) AUTHORITY OF SECRETARY REGARDING MODIFICATIONS.—As a condition of making a grant under section 1921 to a State for a fiscal year, the Secretary may require that the State modify any provision of the plan submitted by the State under subsection (a)(6) (including provisions on priorities in carrying out authorized activities). If the Secretary approves the plan and makes the grant to the State for the fiscal year, the Secretary may not during such year require the State to modify the plan.

(3) AUTHORITY OF CENTER FOR SUBSTANCE ABUSE PREVENTION.—With respect to plans submitted by the States under subsection (a)(6), the Secretary, acting through the Director of the Center for Substance Abuse Prevention, shall review and approve or disapprove the provisions of the plans that relate to prevention activities.

(c) WAIVERS REGARDING CERTAIN TERRITORIES.—In the case of any territory of the United States except Puerto Rico, the Secretary may waive such provisions of this subpart and subpart III as the Secretary determines to be appropriate, other than the provisions of section 1931.

(d) ISSUANCE OF REGULATIONS; PRECONDITION TO MAKING GRANTS.—

(1) REGULATIONS.—Not later than August 25, 1992, the Secretary, acting as appropriate through the Director of the Center for Treatment Improvement or the Director of the Center for Substance Abuse Prevention, shall by regulation establish standards specifying the circumstances in which the Secretary will consider an application for a grant under section 1921 to be in accordance with this section.

(2) ISSUANCE AS PRECONDITION TO MAKING GRANTS.—The Secretary may not make payments under any grant under section 1921 for fiscal year 1993 on or after January 1, 1993, unless the Secretary has issued standards under paragraph (1).

(e) WAIVER AUTHORITY FOR CERTAIN REQUIREMENTS.—

(1) IN GENERAL.—Upon the request of a State, the Secretary may waive the requirements of all or part of the sections described in paragraph (2) using objective criteria established by the Secretary by regulation after consultation with the States and other interested parties including consumers and providers.

(2) SECTIONS.—The sections described in paragraph (1) are sections 1922(c), 1923, 1924 and 1928.

(3) DATE CERTAIN FOR ACTING UPON REQUEST.—The Secretary shall approve or deny a request for a waiver under paragraph (1) and inform the State of that decision not later than

120 days after the date on which the request and all the information needed to support the request are submitted.

(4) ANNUAL REPORTING REQUIREMENT.—The Secretary shall annually report to the general public on the States that receive a waiver under this subsection.

SEC. 1933.[300x–33] DETERMINATION OF AMOUNT OF ALLOTMENT.

(a) STATES.—

(1) IN GENERAL.—Subject to subsection (b), the Secretary shall determine the amount of the allotment required in section 1921 for a State for a fiscal year as follows:

(A) The formula established in paragraph (1) of section 1918(a) shall apply to this subsection to the same extent and in the same manner as the formula applies for purposes of section 1918(a), except that, in the application of such formula for purposes of this subsection, the modifications described in subparagraph (B) shall apply.

(B) For purposes of subparagraph (A), the modifications described in this subparagraph are as follows:

(i) The amount specified in paragraph (2)(A) of section 1918(a) is deemed to be the amount appropriated under section 1935(a) for allotments under section 1921 for the fiscal year involved.

(ii) The term "P" is deemed to have the meaning given in paragraph (2) of this subsection. Section 1918(a)(5)(B) applies to the data used in determining such term for the States.

(iii) The factor determined under paragraph (8) of section 1918(a) is deemed to have the purpose of reflecting the differences that exist between the State involved and other States in the costs of providing authorized services.

(2) DETERMINATION OF TERM "P".—For purposes of this subsection, the term "P" means the percentage that is the arithmetic mean of the percentage determined under subparagraph (A) and the percentage determined under subparagraph (B), as follows:

(A) The percentage constituted by the ratio of—

(i) an amount equal to the sum of the total number of individuals who reside in the State involved and are between 18 and 24 years of age (inclusive) and the number of individuals in the State who reside in urbanized areas of the State and are between such years of age; to

(ii) an amount equal to the total of the respective sums determined for the States under clause (i).

(B) The percentage constituted by the ratio of—

(i) the total number of individuals in the State who are between 25 and 64 years of age (inclusive); to

(ii) an amount equal to the sum of the respective amounts determined for the States under clause (i).

(b) MINIMUM ALLOTMENTS FOR STATES.—

(1) IN GENERAL.—With respect to fiscal year 2000, and each subsequent fiscal year, the amount of the allotment of a

State under section 1921 shall not be less than the amount the State received under such section for the previous fiscal year increased by an amount equal to 30.65 percent of the percentage by which the aggregate amount allotted to all States for such fiscal year exceeds the aggregate amount allotted to all States for the previous fiscal year.

(2) LIMITATIONS.—

(A) IN GENERAL.—Except as provided in subparagraph (B), a State shall not receive an allotment under section 1921 for a fiscal year in an amount that is less than an amount equal to 0.375 percent of the amount appropriated under section 1935(a) for such fiscal year.

(B) EXCEPTION.—In applying subparagraph (A), the Secretary shall ensure that no State receives an increase in its allotment under section 1921 for a fiscal year (as compared to the amount allotted to the State in the prior fiscal year) that is in excess of an amount equal to 300 percent of the percentage by which the amount appropriated under section 1935(a) for such fiscal year exceeds the amount appropriated for the prior fiscal year.

(3) DECREASE IN OR EQUAL APPROPRIATIONS.—If the amount appropriated under section 1935(a) for a fiscal year is equal to or less than the amount appropriated under such section for the prior fiscal year, the amount of the State allotment under section 1921 shall be equal to the amount that the State received under section 1921 in the prior fiscal year decreased by the percentage by which the amount appropriated for such fiscal year is less than the amount appropriated or such section for the prior fiscal year.

(c) TERRITORIES.—

(1) DETERMINATION UNDER FORMULA.—Subject to paragraphs (2) and (4), the amount of an allotment under section 1921 for a territory of the United States for a fiscal year shall be the product of—

(A) an amount equal to the amounts reserved under paragraph (3) for the fiscal year; and

(B) a percentage equal to the quotient of—

(i) the civilian population of the territory, as indicated by the most recently available data; divided by

(ii) the aggregate civilian population of the territories of the United States, as indicated by such data.

(2) MINIMUM ALLOTMENT FOR TERRITORIES.—The amount of an allotment under section 1921 for a territory of the United States for a fiscal year shall be the greater of—

(A) the amount determined under paragraph (1) for the territory for the fiscal year;

(B) $50,000; and

(C) with respect to fiscal years 1993 and 1994, an amount equal to 79.4 percent of the amount received by the territory from allotments made pursuant to this part for fiscal year 1992.

(3) RESERVATION OF AMOUNTS.—The Secretary shall each fiscal year reserve for the territories of the United States 1.5

percent of the amounts appropriated under section 1935(a) for allotments under section 1921 for the fiscal year.

(4) AVAILABILITY OF DATA ON POPULATION.—With respect to data on the civilian population of the territories of the United States, if the Secretary determines for a fiscal year that recent such data for purposes of paragraph (1)(B) do not exist regarding a territory, the Secretary shall for such purposes estimate the civilian population of the territory by modifying the data on the territory to reflect the average extent of change occurring during the ensuing period in the population of all territories with respect to which recent such data do exist.

(5) APPLICABILITY OF CERTAIN PROVISIONS.—For purposes of subsections (a) and (b), the term "State" does not include the territories of the United States.

(d) INDIAN TRIBES AND TRIBAL ORGANIZATIONS.—

(1) IN GENERAL.—If the Secretary—

(A) receives a request from the governing body of an Indian tribe or tribal organization within any State that funds under this subpart be provided directly by the Secretary to such tribe or organization; and

(B) makes a determination that the members of such tribe or tribal organization would be better served by means of grants made directly by the Secretary under this;[8]

the Secretary shall reserve from the allotment under section 1921 for the State for the fiscal year involved an amount that bears the same ratio to the allotment as the amount provided under this subpart to the tribe or tribal organization for fiscal year 1991 for activities relating to the prevention and treatment of the abuse of alcohol and other drugs bore to the amount of the portion of the allotment under this subpart for the State for such fiscal year that was expended for such activities.

(2) TRIBE OR TRIBAL ORGANIZATION AS GRANTEE.—The amount reserved by the Secretary on the basis of a determination under this paragraph[9] shall be granted to the Indian tribe or tribal organization serving the individuals for whom such a determination has been made.

(3) APPLICATION.—In order for an Indian tribe or tribal organization to be eligible for a grant for a fiscal year under this paragraph, it shall submit to the Secretary a plan for such fiscal year that meets such criteria as the Secretary may prescribe.

(4) DEFINITION.—The terms "Indian tribe" and "tribal organization" have the same meaning given such terms in subsections (b) and (c) of section 4 of the Indian Self-Determination and Education Assistance Act.

SEC. 1934.[300x–34] DEFINITIONS.

For purposes of this subpart:

[8] So in law. See section 102 of Public Law 102–321 (106 Stat. 402). Probably should be "under this subpart".

[9] So in law. See section 102 of Public Law 102–321 (106 Stat. 402). Probably should be "subsection".

(1) The term "authorized activities", subject to section 1931, means the activities described in section 1921(b).

(2) The term "funding agreement", with respect to a grant under section 1921 to a State, means that the Secretary may make such a grant only if the State makes the agreement involved.

(3) The term "prevention activities", subject to section 1931, means activities to prevent substance abuse.

(4) The term "substance abuse" means the abuse of alcohol or other drugs.

(5) The term "treatment activities" means treatment services and, subject to section 1931, authorized activities that are related to treatment services.

(6) The term "treatment facility" means an entity that provides treatment services.

(7) The term "treatment services", subject to section 1931, means treatment for substance abuse.

SEC. 1935.[300x–35] FUNDING.

(a) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this subpart, subpart III and section 505 with respect to substance abuse, and section 515(d), there are authorized to be appropriated $2,000,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 and 2003.

(b) ALLOCATIONS FOR TECHNICAL ASSISTANCE, NATIONAL DATA BASE, DATA COLLECTION, AND PROGRAM EVALUATIONS.—

(1) IN GENERAL.—

(A) For the purpose of carrying out section 1948(a) with respect to substance abuse, section 515(d), and the purposes specified in subparagraphs (B) and (C), the Secretary shall obligate 5 percent of the amounts appropriated under subsection (a) each fiscal year.

(B) The purpose specified in this subparagraph is the collection of data in this paragraph[10] is carrying out sections 505 and 1971 with respect to substance abuse.

(C) The purpose specified in this subparagraph is the conduct of evaluations of authorized activities to determine methods for improving the availability and quality of such activities.

(2) ACTIVITIES OF CENTER FOR SUBSTANCE ABUSE PREVENTION.—Of the amounts reserved under paragraph (1) for a fiscal year, the Secretary, acting through the Director of the Center for Substance Abuse Prevention, shall obligate 20 percent for carrying out paragraph (1)(C), section 1948(a) with respect to prevention activities, and section 515(d).

(3) CORE DATA SET.—A State that receives a new grant, contract, or cooperative agreement from amounts available to the Secretary under paragraph (1), for the purposes of improving the data collection, analysis and reporting capabilities of the State, shall be required, as a condition of receipt of funds, to collect, analyze, and report to the Secretary for each fiscal

[10] So in law. See section 202 of Public Law 102–321 (106 Stat. 403). The words "the collection of data in this paragraph" probably should not appear.

year subsequent to receiving such funds a core data set to be determined by the Secretary in conjunction with the States.

Subpart III—General Provisions

SEC. 1941.[300x–51] OPPORTUNITY FOR PUBLIC COMMENT ON STATE PLANS.

A funding agreement for a grant under section 1911 or 1921 is that the State involved will make the plan required in section 1912, and the plan required in section 1932, respectively, public within the State in such manner as to facilitate comment from any person (including any Federal or other public agency) during the development of the plan (including any revisions) and after the submission of the plan to the Secretary.

SEC. 1942.[300x–52] REQUIREMENT OF REPORTS AND AUDITS BY STATES.

(a) REPORT.—A funding agreement for a grant under section 1911 or 1921 is that the State involved will submit to the Secretary a report in such form and containing such information as the Secretary determines (after consultation with the States) to be necessary for securing a record and a description of—

(1) the purposes for which the grant received by the State for the preceding fiscal year under the program involved were expended and a description of the activities of the State under the program; and

(2) the recipients of amounts provided in the grant.

(b) AUDITS.—A funding agreement for a grant under section 1911 or 1921 is that the State will, with respect to the grant, comply with chapter 75 of title 31, United States Code.

(c) AVAILABILITY TO PUBLIC.—A funding agreement for a grant under section 1911 or 1921 is that the State involved will—

(1) make copies of the reports and audits described in this section available for public inspection within the State; and

(2) provide copies of the report under subsection (a), upon request, to any interested person (including any public agency).

SEC. 1943.[300x–53] ADDITIONAL REQUIREMENTS.

(a) IN GENERAL.—A funding agreement for a grant under section 1911 or 1921 is that the State involved will—

(1)(A) for the fiscal year for which the grant involved is provided, provide for independent peer review to assess the quality, appropriateness, and efficacy of treatment services provided in the State to individuals under the program involved; and

(B) ensure that, in the conduct of such peer review, not fewer than 5 percent of the entities providing services in the State under such program are reviewed (which 5 percent is representative of the total population of such entities);

(2) permit and cooperate with Federal investigations undertaken in accordance with section 1945; and

(3) provide to the Secretary any data required by the Secretary pursuant to section 505 and will cooperate with the Secretary in the development of uniform criteria for the collection of data pursuant to such section.

(b) PATIENT RECORDS.—The Secretary may make a grant under section 1911 or 1921 only if the State involved has in effect a system to protect from inappropriate disclosure patient records maintained by the State in connection with an activity funded under the program involved or by any entity which is receiving amounts from the grant.

SEC. 1944.[300x–54] DISPOSITION OF CERTAIN FUNDS APPROPRIATED FOR ALLOTMENTS.

(a) IN GENERAL.—Amounts described in subsection (b) and available for a fiscal year pursuant to section 1911 or 1921, as the case may be, shall be allotted by the Secretary and paid to the States receiving a grant under the program involved, other than any State referred to in subsection (b) with respect to such program. Such amounts shall be allotted in a manner equivalent to the manner in which the allotment under the program involved was determined.

(b) SPECIFICATION OF AMOUNTS.—The amounts referred to in subsection (a) are any amounts that—

(1) are not paid to States under the program involved as a result of—

(A) the failure of any State to submit an application in accordance with the program;

(B) the failure of any State to prepare such application in compliance with the program; or

(C) any State informing the Secretary that the State does not intend to expend the full amount of the allotment made to the State under the program;

(2) are terminated, repaid, or offset under section 1945;

(3) in the case of the program established in section 1911, are available as a result of reductions in allotments under such section pursuant to section 1912(d) or 1915(b); or

(4) in the case of the program established in section 1921, are available as a result of reductions in allotments under such section pursuant to section 1926 or 1930.

SEC. 1945.[300x–55] FAILURE TO COMPLY WITH AGREEMENTS.

(a) SUSPENSION OR TERMINATION OF PAYMENTS.—Subject to subsection (e), if the Secretary determines that a State has materially failed to comply with the agreements or other conditions required for the receipt of a grant under the program involved, the Secretary may in whole or in part suspend payments under the grant, terminate the grant for cause, or employ such other remedies (including the remedies provided for in subsections (b) and (c)) as may be legally available and appropriate in the circumstances involved.

(b) REPAYMENT OF PAYMENTS.—

(1) IN GENERAL.—Subject to subsection (e), the Secretary may require a State to repay with interest any payments received by the State under section 1911 or 1921 that the Secretary determines were not expended by the State in accordance with the agreements required under the program involved.

(2) OFFSET AGAINST PAYMENTS.—If a State fails to make a repayment required in paragraph (1), the Secretary may offset

the amount of the repayment against the amount of any payment due to be paid to the State under the program involved.

(c) WITHHOLDING OF PAYMENTS.—

(1) IN GENERAL.—Subject to subsections (e) and (g)(3), the Secretary may withhold payments due under section 1911 or 1921 if the Secretary determines that the State involved is not expending amounts received under the program involved in accordance with the agreements required under the program.

(2) TERMINATION OF WITHHOLDING.—The Secretary shall cease withholding payments from a State under paragraph (1) if the Secretary determines that there are reasonable assurances that the State will expend amounts received under the program involved in accordance with the agreements required under the program.

(d) APPLICABILITY OF REMEDIES TO CERTAIN VIOLATIONS.—

(1) IN GENERAL.—With respect to agreements or other conditions for receiving a grant under the program involved, in the case of the failure of a State to maintain material compliance with a condition referred to in paragraph (2), the provisions for noncompliance with the condition that are provided in the section establishing the condition shall apply in lieu of subsections (a) through (c) of this section.

(2) RELEVANT CONDITIONS.—For purposes of paragraph (1):

(A) In the case of the program established in section 1911, a condition referred to in this paragraph is the condition established in section 1912(d) and the condition established in section 1915(b).

(B) In the case of the program established in section 1921, a condition referred to in this paragraph is the condition established in section 1926 and the condition established in section 1930.

(e) OPPORTUNITY FOR HEARING.—Before taking action against a State under any of subsections (a) through (c) (or under a section referred to in subsection (d)(2), as the case may be), the Secretary shall provide to the State involved adequate notice and an opportunity for a hearing.

(f) REQUIREMENT OF HEARING IN CERTAIN CIRCUMSTANCES.—

(1) IN GENERAL.—If the Secretary receives a complaint that a State has failed to maintain material compliance with the agreements or other conditions required for receiving a grant under the program involved (including any condition referred to for purposes of subsection (d)), and there appears to be reasonable evidence to support the complaint, the Secretary shall promptly conduct a hearing with respect to the complaint.

(2) FINDING OF MATERIAL NONCOMPLIANCE.—If in a hearing under paragraph (1) the Secretary finds that the State involved has failed to maintain material compliance with the agreement or other condition involved, the Secretary shall take such action under this section as may be appropriate to ensure that material compliance is so maintained, or such action as may be required in a section referred to in subsection (d)(2), as the case may be.

(g) CERTAIN INVESTIGATIONS.—

(1) REQUIREMENT REGARDING SECRETARY.—The Secretary shall in fiscal year 1994 and each subsequent fiscal year conduct in not less than 10 States investigations of the expenditure of grants received by the States under section 1911 or 1921 in order to evaluate compliance with the agreements required under the program involved.

(2) PROVISION OF RECORDS ETC. UPON REQUEST.—Each State receiving a grant under section 1911 or 1921, and each entity receiving funds from the grant, shall make appropriate books, documents, papers, and records available to the Secretary or the Comptroller General, or any of their duly authorized representatives, for examination, copying, or mechanical reproduction on or off the premises of the appropriate entity upon a reasonable request therefor.

(3) LIMITATIONS ON AUTHORITY.—The Secretary may not institute proceedings under subsection (c) unless the Secretary has conducted an investigation concerning whether the State has expended payments under the program involved in accordance with the agreements required under the program. Any such investigation shall be conducted within the State by qualified investigators.

SEC. 1946.[300x–56] PROHIBITIONS REGARDING RECEIPT OF FUNDS.

(a) ESTABLISHMENT.—

(1) CERTAIN FALSE STATEMENTS AND REPRESENTATIONS.—A person shall not knowingly and willfully make or cause to be made any false statement or representation of a material fact in connection with the furnishing of items or services for which payments may be made by a State from a grant made to the State under section 1911 or 1921.

(2) CONCEALING OR FAILING TO DISCLOSE CERTAIN EVENTS.—A person with knowledge of the occurrence of any event affecting the initial or continued right of the person to receive any payments from a grant made to a State under section 1911 or 1921 shall not conceal or fail to disclose any such event with an intent fraudulently to secure such payment either in a greater amount than is due or when no such amount is due.

(b) CRIMINAL PENALTY FOR VIOLATION OF PROHIBITION.—Any person who violates any prohibition established in subsection (a) shall for each violation be fined in accordance with title 18, United States Code, or imprisoned for not more than 5 years, or both.

SEC. 1947.[300x–57] NONDISCRIMINATION.

(a) IN GENERAL.—

(1) RULE OF CONSTRUCTION REGARDING CERTAIN CIVIL RIGHTS LAWS.—For the purpose of applying the prohibitions against discrimination on the basis of age under the Age Discrimination Act of 1975, on the basis of handicap under section 504 of the Rehabilitation Act of 1973, on the basis of sex under title IX of the Education Amendments of 1972, or on the basis of race, color, or national origin under title VI of the Civil Rights Act of 1964, programs and activities funded in whole or in part with funds made available under section 1911 or 1921

shall be considered to be programs and activities receiving Federal financial assistance.

(2) PROHIBITION.—No person shall on the ground of sex (including, in the case of a woman, on the ground that the woman is pregnant), or on the ground of religion, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any program or activity funded in whole or in part with funds made available under section 1911 or 1921.

(b) ENFORCEMENT.—

(1) REFERRALS TO ATTORNEY GENERAL AFTER NOTICE.—Whenever the Secretary finds that a State, or an entity that has received a payment pursuant to section 1911 or 1921, has failed to comply with a provision of law referred to in subsection (a)(1), with subsection (a)(2), or with an applicable regulation (including one prescribed to carry out subsection (a)(2)), the Secretary shall notify the chief executive officer of the State and shall request the chief executive officer to secure compliance. If within a reasonable period of time, not to exceed 60 days, the chief executive officer fails or refuses to secure compliance, the Secretary may—

(A) refer the matter to the Attorney General with a recommendation that an appropriate civil action be instituted;

(B) exercise the powers and functions provided by the Age Discrimination Act of 1975, section 504 of the Rehabilitation Act of 1973, title IX of the Education Amendments of 1972, or title VI of the Civil Rights Act of 1964, as may be applicable; or

(C) take such other actions as may be authorized by law.

(2) AUTHORITY OF ATTORNEY GENERAL.—When a matter is referred to the Attorney General pursuant to paragraph (1)(A), or whenever the Attorney General has reason to believe that a State or an entity is engaged in a pattern or practice in violation of a provision of law referred to in subsection (a)(1) or in violation of subsection (a)(2), the Attorney General may bring a civil action in any appropriate district court of the United States for such relief as may be appropriate, including injunctive relief.

SEC. 1948.[300x–58] TECHNICAL ASSISTANCE AND PROVISION OF SUPPLIES AND SERVICES IN LIEU OF GRANT FUNDS.

(a) TECHNICAL ASSISTANCE.—The Secretary shall, without charge to a State receiving a grant under section 1911 or 1921, provide to the State (or to any public or nonprofit private entity within the State) technical assistance with respect to the planning, development, and operation of any program or service carried out pursuant to the program involved. The Secretary may provide such technical assistance directly, through contract, or through grants.

(b) PROVISION OF SUPPLIES AND SERVICES IN LIEU OF GRANT FUNDS.—

(1) IN GENERAL.—Upon the request of a State receiving a grant under section 1911 or 1921, the Secretary may, subject to paragraph (2), provide supplies, equipment, and services for

the purpose of aiding the State in carrying out the program involved and, for such purpose, may detail to the State any officer or employee of the Department of Health and Human Services.

(2) CORRESPONDING REDUCTION IN PAYMENTS.—With respect to a request described in paragraph (1), the Secretary shall reduce the amount of payments under the program involved to the State by an amount equal to the costs of detailing personnel and the fair market value of any supplies, equipment, or services provided by the Secretary. The Secretary shall, for the payment of expenses incurred in complying with such request, expend the amounts withheld.

SEC. 1949.[11] [300x–59] PLANS FOR PERFORMANCE PARTNERSHIPS.

(a) DEVELOPMENT.—The Secretary in conjunction with States and other interested groups shall develop separate plans for the programs authorized under subparts I and II for creating more flexibility for States and accountability based on outcome and other performance measures. The plans shall each include—

(1) a description of the flexibility that would be given to the States under the plan;

(2) the common set of performance measures that would be used for accountability, including measures that would be used for the program under subpart II for pregnant addicts, HIV transmission, tuberculosis, and those with a co-occurring substance abuse and mental disorders, and for programs under subpart I for children with serious emotional disturbance and adults with serious mental illness and for individuals with co-occurring mental health and substance abuse disorders;

(3) the definitions for the data elements to be used under the plan;

(4) the obstacles to implementation of the plan and the manner in which such obstacles would be resolved;

(5) the resources needed to implement the performance partnerships under the plan; and

(6) an implementation strategy complete with recommendations for any necessary legislation.

(b) SUBMISSION.—Not later than 2 years after the date of the enactment of this Act[12], the plans developed under subsection (a) shall be submitted to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Commerce of the House of Representatives.

(c) INFORMATION.—As the elements of the plans described in subsection (a) are developed, States are encouraged to provide information to the Secretary on a voluntary basis.

(d) PARTICIPANTS.—The Secretary shall include among those interested groups that participate in the development of the plan

[11] Section 1949 appears according to the probable intent of the Congress. Section 3403(a) of Public Law 106–310 (114 Stat. 1219) provides that the section "is amended as follows:". No amendatory instructions were then given, but a substitute text was provided. The amendment probably should have instructed that section 1949 "is amended to read as follows:".

[12] The probable intent of the Congress was that the reference to "this Act" be a reference to the Children's Health Act of 2000 (Public Law 106–310), which provided a substitute text for section 1949 (see footnote 1), including subsection (b) above. That Act was enacted October 17, 2000. (A reference to "this Act" is a reference to the Public Health Service Act, which was enacted July 1, 1944.)

consumers of mental health or substance abuse services, providers, representatives of political divisions of States, and representatives of racial and ethnic groups including Native Americans.

SEC. 1950.[300x–60] RULE OF CONSTRUCTION REGARDING DELEGATION OF AUTHORITY TO STATES.

With respect to States receiving grants under section 1911 or 1921, this part may not be construed to authorize the Secretary to delegate to the States the primary responsibility for interpreting the governing provisions of this part.

SEC. 1951.[300x–61] SOLICITATION OF VIEWS OF CERTAIN ENTITIES.

In carrying out this part, the Secretary, as appropriate, shall solicit the views of the States and other appropriate entities.

SEC. 1952.[13][300x–62] AVAILABILITY TO STATES OF GRANT PAYMENTS.

Any amounts paid to a State for a fiscal year under section 1911 or 1921 shall be available for obligation and expenditure until the end of the fiscal year following the fiscal year for which the amounts were paid.

SEC. 1953.[300x–63] CONTINUATION OF CERTAIN PROGRAMS.

(a) IN GENERAL.—Of the amount allotted to the State of Hawaii under section 1911, and the amount allotted to such State under section 1921, an amount equal to the proportion of Native Hawaiians residing in the State to the total population of the State shall be available, respectively, for carrying out the program involved for Native Hawaiians.

(b) EXPENDITURE OF AMOUNTS.—The amount made available under subsection (a) may be expended only through contracts entered into by the State of Hawaii with public and private nonprofit organizations to enable such organizations to plan, conduct, and administer comprehensive substance abuse and treatment programs for the benefit of Native Hawaiians. In entering into contracts under this section, the State of Hawaii shall give preference to Native Hawaiian organizations and Native Hawaiian health centers.

(c) DEFINITIONS.—For the purposes of this subsection[14], the terms "Native Hawaiian", "Native Hawaiian organization", and "Native Hawaiian health center" have the meaning given such terms in section 2308 of subtitle D of title II of the Anti-Drug Abuse Act of 1988.

SEC. 1954.[300x–64] DEFINITIONS.

(a) DEFINITIONS FOR SUBPART III.—For purposes of this subpart:

(1) The term "program involved" means the program of grants established in section 1911 or 1921, or both, as indicated by whether the State involved is receiving or is applying to receive a grant under section 1911 or 1921, or both.

[13] Section 1952 appears according to the probable intent of the Congress. Section 3403(b) of Public Law 106–310 (114 Stat. 1220) provides that the section "is amended as follows:". No amendatory instructions were then given, but a substitute text was provided. The amendment probably should have instructed that section 1952 "is amended to read as follows:".

[14] So in law. See section 203 of Public Law 102–321 (106 Stat. 409). Probably should be "section".

(2)(A) The term "funding agreement", with respect to a grant under section 1911, has the meaning given such term in section 1919.

(B) The term "funding agreement", with respect to a grant under section 1921, has the meaning given such term in section 1934.

(b) DEFINITIONS FOR PART B.—For purposes of this part:

(1) The term "Comptroller General" means the Comptroller General of the United States.

(2) The term "State", except as provided in sections 1918(c)(5) and 1933(c)(5), means each of the several States, the District of Columbia, and each of the territories of the United States.

(3) The term "territories of the United States" means each of the Commonwealth of Puerto Rico, American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, the Virgin Islands, Palau, the Marshall Islands, and Micronesia.

(4) The term "interim services", in the case of an individual in need of treatment for substance abuse who has been denied admission to a program of such treatment on the basis of the lack of the capacity of the program to admit the individual, means services for reducing the adverse health effects of such abuse, for promoting the health of the individual, and for reducing the risk of transmission of disease, which services are provided until the individual is admitted to such a program.

SEC. 1955.[300x–65] SERVICES PROVIDED BY NONGOVERNMENTAL ORGANIZATIONS.[15].

(a) PURPOSES.—The purposes of this section are—

(1) to prohibit discrimination against nongovernmental organizations and certain individuals on the basis of religion in the distribution of government funds to provide substance abuse services under this title and title V, and the receipt of services under such titles; and

(2) to allow the organizations to accept the funds to provide the services to the individuals without impairing the religious character of the organizations or the religious freedom of the individuals.

(b) RELIGIOUS ORGANIZATIONS INCLUDED AS NONGOVERNMENTAL PROVIDERS.—

(1) IN GENERAL.—A State may administer and provide substance abuse services under any program under this title or title V through grants, contracts, or cooperative agreements to provide assistance to beneficiaries under such titles with nongovernmental organizations.

(2) REQUIREMENT.—A State that elects to utilize nongovernmental organizations as provided for under paragraph (1) shall consider, on the same basis as other nongovernmental organizations, religious organizations to provide services under

[15] Part G of title V of this Act (the second part G; see page 677) also relates to religious organizations as providers of substance abuse services. That part was added by section 144 of the Community Renewal Tax Relief Act of 2000 (as enacted into law by section 1(a)(7) of Public Law 106–554; 114 Stat. 2763A–619). Section 1955 above was added by section 3305 of Public Law 106–310 (114 Stat. 1212).

substance abuse programs under this title or title V, so long as the programs under such titles are implemented in a manner consistent with the Establishment Clause of the first amendment to the Constitution. Neither the Federal Government nor a State or local government receiving funds under such programs shall discriminate against an organization that provides services under, or applies to provide services under, such programs, on the basis that the organization has a religious character.

(c) RELIGIOUS CHARACTER AND INDEPENDENCE.—

(1) IN GENERAL.—A religious organization that provides services under any substance abuse program under this title or title V shall retain its independence from Federal, State, and local governments, including such organization's control over the definition, development, practice, and expression of its religious beliefs.

(2) ADDITIONAL SAFEGUARDS.—Neither the Federal Government nor a State or local government shall require a religious organization—

(A) to alter its form of internal governance; or

(B) to remove religious art, icons, scripture, or other symbols,

in order to be eligible to provide services under any substance abuse program under this title or title V.

(d) EMPLOYMENT PRACTICES.—

(1) SUBSTANCE ABUSE.—A religious organization that provides services under any substance abuse program under this title or title V may require that its employees providing services under such program adhere to rules forbidding the use of drugs or alcohol.

(2) TITLE VII EXEMPTION.—The exemption of a religious organization provided under section 702 or 703(e)(2) of the Civil Rights Act of 1964 (42 U.S.C. 2000e–1, 2000e–2(e)(2)) regarding employment practices shall not be affected by the religious organization's provision of services under, or receipt of funds from, any substance abuse program under this title or title V.

(e) RIGHTS OF BENEFICIARIES OF ASSISTANCE.—

(1) IN GENERAL.—If an individual described in paragraph (3) has an objection to the religious character of the organization from which the individual receives, or would receive, services funded under any substance abuse program under this title or title V, the appropriate Federal, State, or local governmental entity shall provide to such individual (if otherwise eligible for such services) within a reasonable period of time after the date of such objection, services that—

(A) are from an alternative provider that is accessible to the individual; and

(B) have a value that is not less than the value of the services that the individual would have received from such organization.

(2) NOTICE.—The appropriate Federal, State, or local governmental entity shall ensure that notice is provided to individuals described in paragraph (3) of the rights of such individuals under this section.

(3) INDIVIDUAL DESCRIBED.—An individual described in this paragraph is an individual who receives or applies for services under any substance abuse program under this title or title V.

(f) NONDISCRIMINATION AGAINST BENEFICIARIES.—A religious organization providing services through a grant, contract, or cooperative agreement under any substance abuse program under this title or title V shall not discriminate, in carrying out such program, against an individual described in subsection (e)(3) on the basis of religion, a religious belief, a refusal to hold a religious belief, or a refusal to actively participate in a religious practice.

(g) FISCAL ACCOUNTABILITY.—

(1) IN GENERAL.—Except as provided in paragraph (2), any religious organization providing services under any substance abuse program under this title or title V shall be subject to the same regulations as other nongovernmental organizations to account in accord with generally accepted accounting principles for the use of such funds provided under such program.

(2) LIMITED AUDIT.—Such organization shall segregate government funds provided under such substance abuse program into a separate account. Only the government funds shall be subject to audit by the government.

(h) COMPLIANCE.—Any party that seeks to enforce such party's rights under this section may assert a civil action for injunctive relief exclusively in an appropriate Federal or State court against the entity, agency or official that allegedly commits such violation.

(i) LIMITATIONS ON USE OF FUNDS FOR CERTAIN PURPOSES.—No funds provided through a grant or contract to a religious organization to provide services under any substance abuse program under this title or title V shall be expended for sectarian worship, instruction, or proselytization.

(j) EFFECT ON STATE AND LOCAL FUNDS.—If a State or local government contributes State or local funds to carry out any substance abuse program under this title or title V, the State or local government may segregate the State or local funds from the Federal funds provided to carry out the program or may commingle the State or local funds with the Federal funds. If the State or local government commingles the State or local funds, the provisions of this section shall apply to the commingled funds in the same manner, and to the same extent, as the provisions apply to the Federal funds.

(k) TREATMENT OF INTERMEDIATE CONTRACTORS.—If a nongovernmental organization (referred to in this subsection as an "intermediate organization"), acting under a contract or other agreement with the Federal Government or a State or local government, is given the authority under the contract or agreement to select nongovernmental organizations to provide services under any substance abuse program under this title or title V, the intermediate organization shall have the same duties under this section as the government but shall retain all other rights of a nongovernmental organization under this section.

SEC. 1956.[300x–66] SERVICES FOR INDIVIDUALS WITH CO-OCCURRING DISORDERS.

States may use funds available for treatment under sections 1911 and 1921 to treat persons with co-occurring substance abuse and mental disorders as long as funds available under such sections are used for the purposes for which they were authorized by law and can be tracked for accounting purposes.

PART C—CERTAIN PROGRAMS REGARDING MENTAL HEALTH AND SUBSTANCE ABUSE

Subpart I—Data Infrastructure Development

SEC. 1971.[300y] DATA INFRASTRUCTURE DEVELOPMENT.

(a) IN GENERAL.—The Secretary may make grants to, and enter into contracts or cooperative agreements with States for the purpose of developing and operating mental health or substance abuse data collection, analysis, and reporting systems with regard to performance measures including capacity, process, and outcomes measures.

(b) PROJECTS.—The Secretary shall establish criteria to ensure that services will be available under this section to States that have a fundamental basis for the collection, analysis, and reporting of mental health and substance abuse performance measures and States that do not have such basis. The Secretary will establish criteria for determining whether a State has a fundamental basis for the collection, analysis, and reporting of data.

(c) CONDITION OF RECEIPT OF FUNDS.—As a condition of the receipt of an award under this section a State shall agree to collect, analyze, and report to the Secretary within 2 years of the date of the award on a core set of performance measures to be determined by the Secretary in conjunction with the States.

(d) MATCHING REQUIREMENT.—

(1) IN GENERAL.—With respect to the costs of the program to be carried out under subsection (a) by a State, the Secretary may make an award under such subsection only if the applicant agrees to make available (directly or through donations from public or private entities) non-Federal contributions toward such costs in an amount that is not less than 50 percent of such costs.

(2) DETERMINATION OF AMOUNT CONTRIBUTED.—Non-Federal contributions under paragraph (1) may be in cash or in kind, fairly evaluated, including plant, equipment, or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such contributions.

(e) DURATION OF SUPPORT.—The period during which payments may be made for a project under subsection (a) may be not less than 3 years nor more than 5 years.

(f) AUTHORIZATION OF APPROPRIATION.—

(1) IN GENERAL.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as

may be necessary for each of the fiscal years 2001, 2002 and 2003.

(2) ALLOCATION.—Of the amounts appropriated under paragraph (1) for a fiscal year, 50 percent shall be expended to support data infrastructure development for mental health and 50 percent shall be expended to support data infrastructure development for substance abuse.

Subpart II—Interim Maintenance Treatment of Narcotics Dependence

SEC. 1976.[300y–11] INTERIM MAINTENANCE TREATMENT.

(a) REQUIREMENT REGARDING SECRETARY.—Subject to the following subsections of this section, for the purpose of reducing the incidence of the transmission of HIV disease pursuant to the intravenous abuse of heroin or other morphine-like drugs, the Secretary, in establishing conditions for the use of methadone in public or nonprofit private programs of treatment for dependence on such drugs, shall authorize such programs—

(1) to dispense methadone for treatment purposes to individuals who—

(A) meet the conditions for admission to such programs that dispense methadone as part of comprehensive treatment for such dependence; and

(B) are seeking admission to such programs that so dispense methadone, but as a result of the limited capacity of the programs, will not gain such admission until 14 or more days after seeking admission to the programs; and

(2) in dispensing methadone to such individuals, to provide only minimum ancillary services during the period in which the individuals are waiting for admission to programs of comprehensive treatment.

(b) INAPPLICABILITY OF REQUIREMENT IN CERTAIN CIRCUMSTANCES.—

(1) IN GENERAL.—The requirement established in subsection (a) for the Secretary does not apply if any or all of the following conditions are met:

(A) The preponderance of scientific research indicates that the risk of the transmission of HIV disease pursuant to the intravenous abuse of drugs is minimal.

(B) The preponderance of scientific research indicates that the medically supervised dispensing of methadone is not an effective method of reducing the extent of dependence on heroin and other morphine-like drugs.

(C) The preponderance of available data indicates that, of treatment programs that dispense methadone as part of comprehensive treatment, a substantial majority admit all individuals seeking services to the programs not later than 14 days after the individuals seek admission to the programs.

(2) EVALUATION BY SECRETARY.—In evaluating whether any or all of the conditions described in paragraph (1) have

been met, the Secretary shall consult with the National Commission on Acquired Immune Deficiency Syndrome.

(c) CONDITIONS FOR OBTAINING AUTHORIZATION FROM SECRETARY.—

(1) IN GENERAL.—In carrying out the requirement established in subsection (a), the Secretary shall, after consultation with the National Commission on Acquired Immune Deficiency Syndrome, by regulation issue such conditions for treatment programs to obtain authorization from the Secretary to provide interim maintenance treatment as may be necessary to carry out the purpose described in such subsection. Such conditions shall include conditions for preventing the unauthorized use of methadone.

(2) COUNSELING ON HIV DISEASE.—The regulations issued under paragraph (1) shall provide that an authorization described in such paragraph may not be issued to a treatment program unless the program provides to recipients of the treatment counseling on preventing exposure to and the transmission of HIV disease.

(3) PERMISSION OF RELEVANT STATE AS CONDITION OF AUTHORIZATION.—The regulations issued under paragraph (1) shall provide that the Secretary may not provide an authorization described in such paragraph to any treatment program in a State unless the chief public health officer of the State has certified to the Secretary that—

(A) such officer does not object to the provision of such authorizations to treatment programs in the State; and

(B) the provision of interim maintenance services in the State will not reduce the capacity of comprehensive treatment programs in the State to admit individuals to the programs (relative to the date on which such officer so certifies).

(4) DATE CERTAIN FOR ISSUANCE OF REGULATIONS; FAILURE OF SECRETARY.—The Secretary shall issue the final rule for purposes of the regulations required in paragraph (1), and such rule shall be effective, not later than the expiration of the 180-day period beginning on the date of the enactment of the ADAMHA Reorganization Act[16]. If the Secretary fails to meet the requirement of the preceding sentence, the proposed rule issued on March 2, 1989, with respect to part 291 of title 21, Code of Federal Regulations (docket numbered 88N–0444; 54 Fed. Reg. 8973 et seq.) is deemed to take effect as a final rule upon the expiration of such period, and the provisions of paragraph (3) of this subsection are deemed to be incorporated into such rule.

(d) DEFINITIONS.—For purposes of this section:

(1) The term "interim maintenance services" means the provision of methadone in a treatment program under the circumstances described in paragraphs (1) and (2) of subsection (a).

(2) The term "HIV disease" means infection with the etiologic agent for acquired immune deficiency syndrome.

[16] Enacted July 10, 1992.

(3) The term "treatment program" means a public or non-profit private program of treatment for dependence on heroin or other morphine-like drugs.

December 13, 2013

PUBLIC HEALTH SERVICE ACT

As Amended Through P.L. 112–240, Enacted January 2, 2013

TITLE XX—ADOLESCENT FAMILY LIFE DEMONSTRATION PROJECTS

FINDINGS AND PURPOSES.

SEC. 2001.[300z] (a) The Congress finds that—

(1) in 1978, an estimated one million one hundred thousand teenagers became pregnant, more than five hundred thousand teenagers carried their babies to term, and over one-half of the babies born to such teenagers were born out of wedlock;

(2) adolescents aged seventeen and younger accounted for more than one-half of the out of wedlock births to teenagers;

(3) in a high proportion of cases, the pregnant adolescent is herself the product of an unmarried parenthood during adolescence and is continuing the pattern in her own lifestyle;

(4) it is estimated that approximately 80 per centum of unmarried teenagers who carry their pregnancies to term live with their families before and during their pregnancy and remain with their families after the birth of the child;

(5) pregnancy and childbirth among unmarried adolescents, particularly young adolescents, often results in severe adverse health, social, and economic consequences including: a higher percentage of pregnancy and childbirth complications; a higher incidence of low birth weight babies; a higher infant mortality and morbidity; a greater likelihood that an adolescent marriage will end in divorce; a decreased likelihood of completing schooling; and higher risks of unemployment and welfare dependency; and therefore, education, training, and job research services are important for adolescent parents;

(6)(A) adoption is a positive option for unmarried pregnant adolescents who are unwilling or unable to care for their children since adoption is a means of providing permanent families for such children from available approved couples who are unable or have difficulty in conceiving or carrying children of their own to term; and

(B) at present, only 4 per centum of unmarried pregnant adolescents who carry their babies to term enter into an adoption plan or arrange for their babies to be cared for by relatives or friends;

(7) an unmarried adolescent who becomes pregnant once is likely to experience recurrent pregnancies and childbearing, with increased risks;

(8)(A) the problems of adolescent premarital sexual relations, pregnancy, and parenthood are multiple and complex

and are frequently associated with or are a cause of other troublesome situations in the family; and

(B) such problems are best approached through a variety of integrated and essential services provided to adolescents and their families by other family members, religious and charitable organizations, voluntary associations, and other groups in the private sector as well as services provided by publicly sponsored initiatives;

(9) a wide array of educational, health, and supportive services are not available to adolescents with such problems or to their families, or when available frequently are fragmented and thus are of limited effectiveness in discouraging adolescent premarital sexual relations and the consequences of such relations;

(10)(A) prevention of adolescent sexual activity and adolescent pregnancy depends primarily upon developing strong family values and close family ties, and since the family is the basic social unit in which the values and attitudes of adolescents concerning sexuality and pregnancy are formed, programs designed to deal with issues of sexuality and pregnancy will be successful to the extent that such programs encourage and sustain the role of the family in dealing with adolescent sexual activity and adolescent pregnancy;

(B) Federal policy therefore should encourage the development of appropriate health, educational, and social services where such services are now lacking or inadequate, and the better coordination of existing services where they are available; and

(C) services encouraged by the Federal Government should promote the involvement of parents with their adolescent children, and should emphasize the provision of support by other family members, religious and charitable organizations, voluntary associations, and other groups in the private sector in order to help adolescents and their families deal with complex issues of adolescent premarital sexual relations and the consequences of such relations; and

(11)(A) there has been limited research concerning the societal causes and consequences of adolescent pregnancy;

(B) there is limited knowledge concerning which means of intervention are effective in mediating or eliminating adolescent premarital sexual relations and adolescent pregnancy; and

(C) it is necessary to expand and strengthen such knowledge in order to develop an array of approaches to solving the problems of adolescent premarital sexual relations and adolescent pregnancy in both urban and rural settings.

(b) Therefore, the purposes of this title are—

(1) to find effective means, within the context of the family, of reaching adolescents before they become sexually active in order to maximize the guidance and support available to adolescents from parents and other family members, and to promote self discipline and other prudent approaches to the problem of adolescent premarital sexual relations, including adolescent pregnancy;

(2) to promote adoption as an alternative for adolescent parents;

(3) to establish innovative, comprehensive, and integrated approaches to the delivery of care services both for pregnant adolescents, with primary emphasis on unmarried adolescents who are seventeen years of age or under, and for adolescent parents, which shall be based upon an assessment of existing programs and, where appropriate, upon efforts to establish better coordination, integration, and linkages among such existing programs in order to—

(A) enable pregnant adolescents to obtain proper care and assist pregnant adolescents and adolescent parents to become productive independent contributors to family and community life; and

(B) assist families of adolescents to understand and resolve the societal causes which are associated with adolescent pregnancy;

(4) to encourage and support research projects and demonstration projects concerning the societal causes and consequences of adolescent premarital sexual relations, contraceptive use, pregnancy, and child rearing;

(5) to support evaluative research to identify effective services which alleviate, eliminate, or resolve any negative consequences of adolescent premarital sexual relations and adolescent childbearing for the parents, the child, and their families; and

(6) to encourage and provide for the dissemination of results, findings, and information from programs and research projects relating to adolescent premarital sexual relations, pregnancy, and parenthood.

DEFINITIONS.

SEC. 2002.[300z–1] (a) For the purposes of this title, the term—

(1) "Secretary" means the Secretary of Health and Human Services;

(2) "eligible person" means—

(A) with regard to the provision of care services, a pregnant adolescent, an adolescent parent, or the family of a pregnant adolescent or an adolescent parent; or

(B) with regard to the provision of prevention services and referral to such other services which may be appropriate, a nonpregnant adolescent;

(3) "eligible grant recipient" means a public or nonprofit private organization or agency which demonstrates, to the satisfaction of the Secretary—

(A) in the case of an organization which will provide care services, the capability of providing all care services in a single setting or the capability of creating a network through which all care services would be provided; or

(B) in the case of an organization which will provide prevention services, the capability of providing such services;

(4) "necessary services" means services which may be provided by grantees which are—

(A) pregnancy testing and maternity counseling;

(B) adoption counseling and referral services which present adoption as an option for pregnant adolescents, including referral to licensed adoption agencies in the community if the eligible grant recipient is not a licensed adoption agency;

(C) primary and preventive health services including prenatal and postnatal care;

(D) nutrition information and counseling;

(E) referral for screening and treatment of venereal disease;

(F) referral to appropriate pediatric care;

(G) educational services relating to family life and problems associated with adolescent premarital sexual relations, including—

(i) information about adoption;

(ii) education on the responsibilities of sexuality and parenting;

(iii) the development of material to support the role of parents as the provider of sex education; and

(iv) assistance to parents, schools, youth agencies, and health providers to educate adolescents and preadolescents concerning self-discipline and responsibility in human sexuality;

(H) appropriate educational and vocational services;

(I) referral to licensed residential care or maternity home services; and

(J) mental health services and referral to mental health services and to other appropriate physical health services;

(K) child care sufficient to enable the adolescent parent to continue education or to enter into employment;

(L) consumer education and homemaking;

(M) counseling for the immediate and extended family members of the eligible person;

(N) transportation;

(O) outreach services to families of adolescents to discourage sexual relations among unemancipated minors;

(P) family planning services; and

(Q) such other services consistent with the purposes of this title as the Secretary may approve in accordance with regulations promulgated by the Secretary;

(5) "core services" means those services which shall be provided by a grantee, as determined by the Secretary by regulation;

(6) "supplemental services" means those services which may be provided by a grantee, as determined by the Secretary by regulation;

(7) "care services" means necessary services for the provision of care to pregnant adolescents and adolescent parents and includes all core services with respect to the provision of such care prescribed by the Secretary by regulation;

(8) "prevention services" means necessary services to prevent adolescent sexual relations, including the services described in subparagraphs (A), (D), (E), (G), (H), (M), (N), (O), and (Q) of paragraph (4);

(9) "adolescent" means an individual under the age of nineteen; and

(10) "unemancipated minor" means a minor who is subject to the control, authority, and supervision of his or her parents or guardians, as determined under State law.

(b) Until such time as the Secretary promulgates regulations pursuant to the second sentence of this subsection, the Secretary shall use the regulations promulgated under title VI of the Health Services and Centers Amendments of 1978 which were in effect on the date of enactment of this title, to determine which necessary services are core services for purposes of this title. The Secretary may promulgate regulations to determine which necessary services are core services for purposes of this title based upon an evaluation of and information concerning which necessary services are essential to carry out the purposes of this title and taking into account (1) factors such as whether services are to be provided in urban or rural areas, the ethnic groups to be served, and the nature of the populations to be served, and (2) the results of the evaluations required under section 2006(b). The Secretary may from time to time revise such regulations.

AUTHORITY TO MAKE GRANTS FOR DEMONSTRATION PROJECTS.

SEC. 2003.[300z–2] (a) The Secretary may make grants to further the purposes of this title to eligible grant recipients which have submitted an application which the Secretary finds meets the requirements of section 2006 for demonstration projects which the Secretary determines will help communities provide appropriate care and prevention services in easily accessible locations. Demonstration projects shall, as appropriate, provide, supplement, or improve the quality of such services. Demonstration projects shall use such methods as will strengthen the capacity of families to deal with the sexual behavior, pregnancy, or parenthood of adolescents and to make use of support systems such as other family members, friends, religious and charitable organizations, and voluntary associations.

(b) Grants under this title for demonstration projects may be for the provision of—

(1) care services;

(2) prevention services; or

(3) a combination of care services and prevention services.

USES OF GRANTS FOR DEMONSTRATION PROJECTS FOR SERVICES.

SEC. 2004.[300z–3] (a) Except as provided in subsection (b), funds provided for demonstration projects for services under this title may be used by grantees only to—

(1) provide to eligible persons—

(A) care services;

(B) prevention services; or

(C) care and prevention services (in the case of a grantee who is providing a combination of care and prevention services);

(2) coordinate, integrate, and provide linkages among providers of care, prevention, and other services for eligible persons in furtherance of the purposes of this title;

(3) provide supplemental services where such services are not adequate or not available to eligible persons in the community and which are essential to the care of pregnant adolescents and to the prevention of adolescent premarital sexual relations and adolescent pregnancy;

(4) plan for the administration and coordination of pregnancy prevention services and programs of care for pregnant adolescents and adolescent parents which will further the objectives of this title; and

(5) fulfill assurances required for grant approval by section 2006.

(b)(1) No funds provided for a demonstration project for services under this title may be used for the provision of family planning services (other than counseling and referral services) to adolescents unless appropriate family planning services are not otherwise available in the community.

(2) Any grantee who receives funds for a demonstration project for services under this title and who, after determining under paragraph (1) that appropriate family planning services are not otherwise available in the community, provides family planning services (other than counseling and referral services) to adolescents may only use funds provided under this title for such family planning services if all funds received by such grantee from all other sources to support such family planning services are insufficient to support such family planning services.

(c) Grantees who receive funds for a demonstration project for services under this title shall charge fees for services pursuant to a fee schedule approved by the Secretary as a part of the application described in section 2006 which bases fees charged by the grantee on the income of the eligible person or the parents or legal guardians of the eligible person and takes into account the difficulty adolescents face in obtaining resources to pay for services. A grantee who receives funds for a demonstration project for services under this title may not, in any case, discriminate with regard to the provision of services to any individual because of that individual's inability to provide payment for such services, except that in determining the ability of an unemancipated minor to provide payment for services, the income of the family of an unemancipated minor shall be considered in determining the ability of such minor to make such payments unless the parents or guardians of the unemancipated minor refuse to make such payments.

PRIORITIES, AMOUNTS, AND DURATION OF GRANTS FOR DEMONSTRATION PROJECTS FOR SERVICES.

SEC. 2005.[300z–4] (a) In approving applications for grants for demonstration projects for services under this title, the Secretary shall give priority to applicants who—

(1) serve an area where there is a high incidence of adolescent pregnancy;

(2) serve an area with a high proportion of low-income families and where the availability of programs of care for pregnant adolescents and adolescent parents is low;

(3) show evidence—

(A) in the case of an applicant who will provide care services, of having the ability to bring together a wide range of needed core services and, as appropriate, supplemental services in comprehensive single-site projects, or to establish a well-integrated network of such services (appropriate for the target population and geographic area to be served including the special needs of rural areas) for pregnant adolescents or adolescent parents; or

(B) in the case of an applicant who will provide prevention services, of having the ability to provide prevention services for adolescents and their families which are appropriate for the target population and the geographic area to be served, including the special needs of rural areas;

(4) will utilize to the maximum extent feasible existing available programs and facilities such as neighborhood and primary health care centers, maternity homes which provide or can be equipped to provide services to pregnant adolescents, agencies serving families, youth, and children with established programs of service to pregnant adolescents and vulnerable families, licensed adoption agencies, children and youth centers, maternal and infant health centers, regional rural health facilities, school and other educational programs, mental health programs, nutrition programs, recreation programs, and other ongoing pregnancy prevention services and programs of care for pregnant adolescents and adolescent parents;

(5) make use, to the maximum extent feasible, of other Federal, State, and local funds, programs, contributions, and other third-party reimbursements;

(6) can demonstrate a community commitment to the program by making available to the demonstration project non-Federal funds, personnel, and facilities;

(7) have involved the community to be served, including public and private agencies, adolescents, and families, in the planning and implementation of the demonstration project; and

(8) will demonstrate innovative and effective approaches in addressing the problems of adolescent premarital sexual relations, pregnancy, or parenthood, including approaches to provide pregnant adolescents with adequate information about adoption.

(b)(1) The amount of a grant for a demonstration project for services under this title shall be determined by the Secretary, based on factors such as the incidence of adolescent pregnancy in the geographic area to be served, and the adequacy of pregnancy prevention services and programs of care for pregnant adolescents and adolescent parents in such area.

(2) In making grants for demonstration projects for services under this title, the Secretary shall consider the special needs of

rural areas and, to the maximum extent practicable, shall distribute funds taking into consideration the relative number of adolescents in such areas in need of such services.

(c)(1) A grantee may not receive funds for a demonstration project for services under this title for a period in excess of 5 years.

(2)(A) Subject to paragraph (3), a grant for a demonstration project for services under this title may not exceed—

(i) 70 per centum of the costs of the project for the first and second years of the project;

(ii) 60 per centum of such costs for the third year of the project;

(iii) 50 per centum of such costs for the fourth year of the project; and

(iv) 40 per centum of such costs for the fifth year of the project.

(B) Non-Federal contributions required by subparagraph (A) may be in cash or in kind, fairly evaluated, including plant, equipment, or services.

(3) The Secretary may waive the limitation specified in paragraph (2)(A) for any year in accordance with criteria established by regulation.

REQUIREMENTS FOR APPLICATIONS.

SEC. 2006.[300z–5] (a) An application for a grant for a demonstration project for services under this title shall be in such form and contain such information as the Secretary may require, and shall include—

(1) an identification of the incidence of adolescent pregnancy and related problems;

(2) a description of the economic conditions and income levels in the geographic area to be served;

(3) a description of existing pregnancy prevention services and programs of care for pregnant adolescents and adolescent parents (including adoption services), and including where, how, by whom, and to which population groups such services are provided, and the extent to which they are coordinated in the geographic area to be served;

(4) a description of the major unmet needs for services for adolescents at risk of initial or recurrent pregnancies and an estimate of the number of adolescents not being served in the area;

(5)(A) in the case of an applicant who will provide care services, a description of how all core services will be provided in the demonstration project using funds under this title or will otherwise be provided by the grantee in the area to be served, the population to which such services will be provided, how such services will be coordinated, integrated, and linked with other related programs and services and the source or sources of funding of such core services in the public and private sectors; or

(B) in the case of an applicant who will provide prevention services, a description of the necessary services to be provided and how the applicant will provide such services;

(6) a description of the manner in which adolescents needing services other than the services provided directly by the applicant will be identified and how access and appropriate referral to such other services (such as medicaid; licensed adoption agencies; maternity home services; public assistance; employment services; child care services for adolescent parents; and other city, county, and State programs related to adolescent pregnancy) will be provided, including a description of a plan to coordinate such other services with the services supported under this title;

(7) a description of the applicant's capacity to continue services as Federal funds decrease and in the absence of Federal assistance;

(8) a description of the results expected from the provision of services, and the procedures to be used for evaluating those results;

(9) a summary of the views of public agencies, providers of services, and the general public in the geographic area to be served, concerning the proposed use of funds provided for a demonstration project for services under this title and a description of procedures used to obtain those views, and, in the case of applicants who propose to coordinate services administered by a State, the written comments of the appropriate State officials responsible for such services;

(10) assurances that the applicant will have an ongoing quality assurance program;

(11) assurances that, where appropriate, the applicant shall have a system for maintaining the confidentiality of patient records in accordance with regulations promulgated by the Secretary;

(12) assurances that the applicant will demonstrate its financial responsibility by the use of such accounting procedures and other requirements as may be prescribed by the Secretary;

(13) assurances that the applicant (A) has or will have a contractual or other arrangement with the agency of the State (in which the applicant provides services) that administers or supervises the administration of a State plan approved under title XIX of the Social Security Act for the payment of all or a part of the applicant's costs in providing health services to persons who are eligible for medical assistance under such a State plan, or (B) has made or will make every reasonable effort to enter into such an arrangement;

(14) assurances that the applicant has made or will make and will continue to make every reasonable effort to collect appropriate reimbursement for its costs in providing health services to persons who are entitled to benefits under title V of the Social Security Act, to medical assistance under a State plan approved under title XIX of such Act, or to assistance for medical expenses under any other public assistance program or private health insurance program;

(15) assurances that the applicant has or will make and will continue to make every reasonable effort to collect appropriate reimbursement for its costs in providing services to per-

sons entitled to services under parts B and E of title IV and title XX of the Social Security Act;

(16)(A) a description of—

(i) the schedule of fees to be used in the provision of services, which shall comply with section 2004(c) and which shall be designed to cover all reasonable direct and indirect costs incurred by the applicant in providing services; and

(ii) a corresponding schedule of discounts to be applied to the payment of such fees, which shall comply with section 2004(c) and which shall be adjusted on the basis of the ability of the eligible person to pay;

(B) assurances that the applicant has made and will continue to make every reasonable effort—

(i) to secure from eligible persons payment for services in accordance with such schedules;

(ii) to collect reimbursement for health or other services provided to persons who are entitled to have payment made on their behalf for such services under any Federal or other government program or private insurance program; and

(iii) to seek such reimbursement on the basis of the full amount of fees for services without application of any discount; and

(C) assurances that the applicant has submitted or will submit to the Secretary such reports as the Secretary may require to determine compliance with this paragraph;

(17) assurances that the applicant will make maximum use of funds available under title X of this Act;

(18) assurances that the acceptance by any individual of family planning services or family planning information (including educational materials) provided through financial assistance under this title shall be voluntary and shall not be a prerequisite to eligibility for or receipt of any other service furnished by the applicant;

(19) assurances that fees collected by the applicant for services rendered in accordance with this title shall be used by the applicant to further the purposes of this title;

(20) assurances that the applicant, if providing both prevention and care services will not exclude or discriminate against any adolescent who receives prevention services and subsequently requires care services as a pregnant adolescent;

(21) a description of how the applicant will, as appropriate in the provision of services—

(A) involve families of adolescents in a manner which will maximize the role of the family in the solution of problems relating to the parenthood or pregnancy of the adolescent;

(B) involve religious and charitable organizations, voluntary associations, and other groups in the private sector as well as services provided by publicly sponsored initiatives;

(22)(A) assurances that—

(i) except as provided in subparagraph (B) and subject to clause (ii), the applicant will notify the parents or guardians of any unemancipated minor requesting services from the applicant and, except as provided in subparagraph (C), will obtain the permission of such parents or guardians with respect to the provision of such services; and

(ii) in the case of a pregnant unemancipated minor requesting services from the applicant, the applicant will notify the parents or guardians of such minor under clause (i) within a reasonable period of time;

(B) assurances that the applicant will not notify or request the permission of the parents or guardian of any unemancipated minor without the consent of the minor—

(i) who solely is requesting from the applicant pregnancy testing or testing or treatment for venereal disease;

(ii) who is the victim of incest involving a parent; or

(iii) if an adult sibling of the minor or an adult aunt, uncle, or grandparent who is related to the minor by blood certifies to the grantee that notification of the parents or guardians of such minor would result in physical injury to such minor; and

(C) assurances that the applicant will not require, with respect to the provision of services, the permission of the parents or guardians of any pregnant unemancipated minor if such parents or guardians are attempting to compel such minor to have an abortion;

(23) assurances that primary emphasis for services supported under this title shall be given to adolescents seventeen and under who are not able to obtain needed assistance through other means;

(24) assurances that funds received under this title shall supplement and not supplant funds received from any other Federal, State, or local program or any private sources of funds; and

(25) a plan for the conduct of, and assurances that the applicant will conduct, evaluations of the effectiveness of the services supported under this title in accordance with subsection (b).

(b)(1) Each grantee which receives funds for a demonstration project for services under this title shall expend at least 1 per centum but not in excess of 5 per centum of the amounts received under this title for the conduct of evaluations of the services supported under this title. The Secretary may, for a particular grantee upon good cause shown, waive the provisions of the preceding sentence with respect to the amounts to be expended on evaluations, but may not waive the requirement that such evaluations be conducted.

(2) Evaluations required by paragraph (1) shall be conducted by an organization or entity which is independent of the grantee providing services supported under this title. To assist in conducting the evaluations required by paragraph (1), each grantee shall develop a working relationship with a college or university located in the grantee's State which will provide or assist in pro-

viding monitoring and evaluation of services supported under this title unless no college or university in the grantee's State is willing or has the capacity to provide or assist in providing such monitoring and assistance.

(3) The Secretary may provide technical assistance with respect to the conduct of evaluations required under this subsection to any grantee which is unable to develop a working relationship with a college or university in the applicant's State for the reasons described in paragraph (2).

(c) Each grantee which receives funds for a demonstration project for services under this title shall make such reports concerning its use of Federal funds as the Secretary may require. Reports shall include, at such times as are considered appropriate by the Secretary, the results of the evaluations of the services supported under this title.

(d)(1) A grantee shall periodically notify the Secretary of the exact number of instances in which a grantee does not notify the parents or guardians of a pregnant unemancipated minor under subsection (a)(22)(B)(iii).

(2) For purposes of subsection (a)(22)(B)(iii), the term "adult" means an adult as defined by State law.

(e) Each applicant shall provide the Governor of the State in which the applicant is located a copy of each application submitted to the Secretary for a grant for a demonstration project for services under this title. The Governor shall submit to the applicant comments on any such application within the period of sixty days beginning on the day when the Governor receives such copy. The applicant shall include the comments of the Governor with such application.

(f) No application submitted for a grant for a demonstration project for care services under this title may be approved unless the Secretary is satisfied that core services shall be available through the applicant within a reasonable time after such grant is received.

COORDINATION OF FEDERAL AND STATE PROGRAMS.

SEC. 2007.[300z–6] (a) The Secretary shall coordinate Federal policies and programs providing services relating to the prevention of adolescent sexual relations and initial and recurrent adolescent pregnancies and providing care services for pregnant adolescents. In achieving such coordination, the Secretary shall—

(1) require grantees who receive funds for demonstration projects for services under this title to report periodically to the Secretary concerning Federal, State, and local policies and programs that interfere with the delivery of and coordination of pregnancy prevention services and other programs of care for pregnant adolescents and adolescent parents;

(2) provide technical assistance to facilitate coordination by State and local recipients of Federal assistance;

(3) review all programs administered by the Department of Health and Human Services which provide prevention services or care services to determine if the policies of such programs are consistent with the policies of this title, consult with other

departments and agencies of the Federal Government who administer programs that provide such services, and encourage such other departments and agencies to make recommendations, as appropriate, for legislation to modify such programs in order to facilitate the use of all Government programs which provide such services as a basis for delivery of more comprehensive prevention services and more comprehensive programs of care for pregnant adolescents and adolescent parents;

(4) give priority in the provision of funds, where appropriate, to applicants using single or coordinated grant applications for multiple programs; and

(5) give priority, where appropriate, to the provision of funds under Federal programs administered by the Secretary (other than the program established by this title) to projects providing comprehensive prevention services and comprehensive programs of care for pregnant adolescents and adolescent parents.

(b) Any recipient of a grant for a demonstration project for services under this title shall coordinate its activities with any other recipient of such a grant which is located in the same locality.

RESEARCH.

SEC. 2008.[300z–7] (a)(1) The Secretary may make grants and enter into contracts with public agencies or private organizations or institutions of higher education to support the research and dissemination activities described in paragraphs (4), (5), and (6) of section 2001(b).

(2) The Secretary may make grants or enter into contracts under this section for a period of one year. A grant or contract under this section for a project may be renewed for four additional one-year periods, which need not be consecutive.

(3) A grant or contract for any one-year period under this section may not exceed $100,000 for the direct costs of conducting research or disemination[1] activities under this section and may include such additional amounts for the indirect costs of conducting such activities as the Secretary determines appropriate. The Secretary may waive the preceding sentence with respect to a specific project if he determines that—

(A) exceptional circumstances warrant such waiver and that the project will have national impact; or

(B) additional amounts are necessary for the direct costs of conducting limited demonstration projects for the provision of necessary services in order to provide data for research carried out under this title.

(4) The amount of any grant or contract made under this section may remain available for obligation or expenditure after the close of the one-year period for which such grant or contract is made in order to assist the recipient in preparing the report required by subsection (f)(1).

(b)(1) Funds provided for research under this section may be used for descriptive or explanatory surveys, longitudinal studies, or

[1] So in law. Probably should be "dissemination".

limited demonstration projects for services that are for the purpose of increasing knowledge and understanding of the matters described in paragraphs (4) and (5) of section 2001(b).

(2) Funds provided under this section may not be used for the purchase or improvement of land, or the purchase, construction, or permanent improvement (other than minor remodeling) of any building or facility.

(c) The Secretary may not make any grant or enter into any contract to support research or dissemination activities under this section unless—

(1) the Secretary has received an application for such grant or contract which is in such form and which contains such information as the Secretary may by regulation require;

(2) the applicant has demonstrated that the applicant is capable of conducting one or more of the types of research or dissemination activities described in paragraph (4), (5), or (6) of section 2001(b); and

(3) in the case of an application for a research project, the panel established by subsection (e)(2) has determined that the project is of scientific merit.

(d) The Secretary shall, where appropriate, coordinate research and dissemination activities carried out under this section with research and dissemination activities carried out by the National Institutes of Health.

(e)(1) The Secretary shall establish a system for the review of applications for grants and contracts under this section. Such system shall be substantially similar to the system for scientific peer review of the National Institutes of Health and shall meet the requirements of paragraphs (2) and (3).

(2) In establishing the system required by paragraph (1), the Secretary shall establish a panel to review applications under this section. Not more than 25 per centum of the members of the panel shall be physicians. The panel shall meet as often as may be necessary to facilitate the expeditious review of applications under this section, but not less than once each year. The panel shall review each project for which an application is made under this section, evaluate the scientific merit of the project, determine whether the project is of scientific merit, and make recommendations to the Secretary concerning whether the application for the project should be approved.

(3) The Secretary shall make grants under this section from among the projects which the panel established by paragraph (2) has determined to be of scientific merit and may only approve an application for a project if the panel has made such determination with respect to such a project. The Secretary shall make a determination with respect to an application within one month after receiving the determinations and recommendations of such panel with respect to the application.

(f)(1)(A) The recipient of a grant or contract for a research project under this section shall prepare and transmit to the Secretary a report describing the results and conclusions of such research. Except as provided in subparagraph (B), such report shall be transmitted to the Secretary not later than eighteen months after the end of the year for which funds are provided under this

section. The recipient may utilize reprints of articles published or accepted for publication in professional journals to supplement or replace such report if the research contained in such articles was supported under this section during the year for which the report is required.

(B) In the case of any research project for which assistance is provided under this section for two or more consecutive one-year periods, the recipient of such assistance shall prepare and transmit the report required by subparagraph (A) to the Secretary not later than twelve months after the end of each one-year period for which such funding is provided.

(2) Recipients of grants and contracts for dissemination under this section shall submit to the Secretary such reports as the Secretary determines appropriate.

EVALUATION AND ADMINISTRATION.

SEC. 2009.[300z–8] (a) Of the funds appropriated under this title, the Secretary shall reserve not less than 1 per centum and not more than 3 per centum for the evaluation of activities carried out under this title. The Secretary shall submit to the appropriate committees of the Congress a summary of each evaluation conducted under this section.

(b) The officer or employee of the Department of Health and Human Services designated by the Secretary to carry out the provisions of this title shall report directly to the Assistant Secretary for Health with respect to the activities of such officer or employee in carrying out such provisions.

AUTHORIZATION OF APPROPRIATIONS.

SEC. 2010.[300z–9] (a) For the purpose of carrying out this title, there are authorized to be appropriated $30,000,000 for the fiscal year ending September 30, 1982, $30,000,000 for the fiscal year ending September 30, 1983, $30,000,000 for the fiscal year ending September 30, 1984, and $30,000,000 for the fiscal year ending September 30, 1985.

(b) At least two-thirds of the amounts appropriated to carry out this title shall be used to make grants for demonstration projects for services.

(c) Not more than one-third of the amounts specified under subsection (b) for use for grants for demonstration projects for services shall be used for grants for demonstration projects for prevention services.

RESTRICTIONS.

SEC. 2011.[300z–10] (a) Grants or payments may be made only to programs or projects which do not provide abortions or abortion counseling or referral, or which do not subcontract with or make any payment to any person who provides abortions or abortion counseling or referral, except that any such program or project may provide referral for abortion counseling to a pregnant adolescent if such adolescent and the parents or guardians of such adolescent request such referral; and grants may be made only to projects

or programs which do not advocate, promote, or encourage abortion.

(b) The Secretary shall ascertain whether programs or projects comply with subsection (a) and take appropriate action if programs or projects do not comply with such subsection, including withholding of funds.

PUBLIC HEALTH SERVICE ACT

As Amended Through P.L. 112–240, Enacted January 2, 2013

TITLE XXI—VACCINES

Subtitle 1—National Vaccine Program

ESTABLISHMENT.

SEC. 2101.[300aa–1] The Secretary shall establish in the Department of Health and Human Services a National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines. The Program shall be administered by a Director selected by the Secretary.

PROGRAM RESPONSIBILITIES.

SEC. 2102.[300aa–2] (a) The Director of the Program shall have the following responsibilities:

(1) VACCINE RESEARCH.—The Director of the Program shall, through the plan issued under section 2103, coordinate and provide direction for research carried out in or through the National Institutes of Health, the Centers for Disease Control and Prevention, the Office of Biologics Research and Review of the Food and Drug Administration, the Department of Defense, and the Agency for International Development on means to induce human immunity against naturally occurring infectious diseases and to prevent adverse reactions to vaccines.

(2) VACCINE DEVELOPMENT.—The Director of the Program shall, through the plan issued under section 2103, coordinate and provide direction for activities carried out in or through the National Institutes of Health, the Office of Biologics Research and Review of the Food and Drug Administration, the Department of Defense, and the Agency for International Development to develop the techniques needed to produce safe and effective vaccines.

(3) SAFETY AND EFFICACY TESTING OF VACCINES.—The Director of the Program shall, through the plan issued under section 2103, coordinate and provide direction for safety and efficacy testing of vaccines carried out in or through the National Institutes of Health, the Centers for Disease Control and Prevention, the Office of Biologics Research and Review of the Food and Drug Administration, the Department of Defense, and the Agency for International Development.

(4) LICENSING OF VACCINE MANUFACTURERS AND VACCINES.—The Director of the Program shall, through the plan issued under section 2103, coordinate and provide direction for

the allocation of resources in the implementation of the licensing program under section 353.

(5) PRODUCTION AND PROCUREMENT OF VACCINES.—The Director of the Program shall, through the plan issued under section 2103, ensure that the governmental and non-governmental production and procurement of safe and effective vaccines by the Public Health Service, the Department of Defense, and the Agency for International Development meet the needs of the United States population and fulfill commitments of the United States to prevent human infectious diseases in other countries.

(6) DISTRIBUTION AND USE OF VACCINES.—The Director of the Program shall, through the plan issued under section 2103, coordinate and provide direction to the Centers for Disease Control and Prevention and assistance to States, localities, and health practitioners in the distribution and use of vaccines, including efforts to encourage public acceptance of immunizations and to make health practitioners and the public aware of potential adverse reactions and contraindications to vaccines.

(7) EVALUATING THE NEED FOR AND THE EFFECTIVENESS AND ADVERSE EFFECTS OF VACCINES AND IMMUNIZATION ACTIVITIES.—The Director of the Program shall, through the plan issued under section 2103, coordinate and provide direction to the National Institutes of Health, the Centers for Disease Control and Prevention, the Office of Biologics Research and Review of the Food and Drug Administration, the National Center for Health Statistics, the National Center for Health Services Research and Health Care Technology Assessment, and the Centers for Medicare & Medicaid Services in monitoring the need for and the effectiveness and adverse effects of vaccines and immunization activities.

(8) COORDINATING GOVERNMENTAL AND NON-GOVERNMENTAL ACTIVITIES.—The Director of the Program shall, through the plan issued under section 2103, provide for the exchange of information between Federal agencies involved in the implementation of the Program and non-governmental entities engaged in the development and production of vaccines and in vaccine research and encourage the investment of non-governmental resources complementary to the governmental activities under the Program.

(9) FUNDING OF FEDERAL AGENCIES.—The Director of the Program shall make available to Federal agencies involved in the implementation of the plan issued under section 2103 funds appropriated under section 2106 to supplement the funds otherwise available to such agencies for activities under the plan.

(b) In carrying out subsection (a) and in preparing the plan under section 2103, the Director shall consult with all Federal agencies involved in research on and development, testing, licensing, production, procurement, distribution, and use of vaccines.

PLAN.

SEC. 2103.[300aa–3] The Director of the Program shall prepare and issue a plan for the implementation of the responsibilities

of the Director under section 2102. The plan shall establish priorities in research and the development, testing, licensing, production, procurement, distribution, and effective use of vaccines, describe an optimal use of resources to carry out such priorities, and describe how each of the various departments and agencies will carry out their vaccine functions in consultation and coordination with the Program and in conformity with such priorities. The first plan under this section shall be prepared not later than January 1, 1987, and shall be revised not later than January 1 of each succeeding year.

NATIONAL VACCINE ADVISORY COMMITTEE.

SEC. 2105.[1][300aa–5] (a) There is established the National Vaccine Advisory Committee. The members of the Committee shall be appointed by the Director of the Program, in consultation with the National Academy of Sciences, from among individuals who are engaged in vaccine research or the manufacture of vaccines or who are physicians, members of parent organizations concerned with immunizations, or representatives of State or local health agencies or public health organizations.

(b) The Committee shall—

(1) study and recommend ways to encourage the availability of an adequate supply of safe and effective vaccination products in the States,

(2) recommend research priorities and other measures the Director of the Program should take to enhance the safety and efficacy of vaccines,

(3) advise the Director of the Program in the implementation of sections 2102, 2103, and 2104, and

(4) identify annually for the Director of the Program the most important areas of government and non-government cooperation that should be considered in implementing sections 2102, 2103, and 2104.

AUTHORIZATIONS.

SEC. 2106.[300aa–6] (a) To carry out this subtitle other than section 2102(9) there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2004 and 2005.

(b) To carry out section 2102(9) there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2004 and 2005.

Subtitle 2—National Vaccine Injury Compensation Program

PART A—PROGRAM REQUIREMENTS

ESTABLISHMENT OF PROGRAM.

SEC. 2110.[300aa–10] (a) PROGRAM ESTABLISHED.—There is established the National Vaccine Injury Compensation Program to be administered by the Secretary under which compensation may be paid for a vaccine-related injury or death.

[1] Section 2104 was repealed by section 601(a)(1)(H) of Public Law 105–362.

(b) ATTORNEY'S OBLIGATION.—It shall be the ethical obligation of any attorney who is consulted by an individual with respect to a vaccine-related injury or death to advise such individual that compensation may be available under the program for such injury or death.

(c) PUBLICITY.—The Secretary shall undertake reasonable efforts to inform the public of the availability of the Program.

PETITIONS FOR COMPENSATION.

SEC. 2111.[300aa–11] (a) GENERAL RULE.—

(1) A proceeding for compensation under the Program for a vaccine-related injury or death shall be initiated by service upon the Secretary and the filing of a petition containing the matter prescribed by subsection (c) with the United States Claims Court. The clerk of the United States Claims Court shall immediately forward the filed petition to the chief special master for assignment to a special master under section 2112(d)(1).

(2)(A) No person may bring a civil action for damages in an amount greater than $1,000 or in an unspecified amount against a vaccine administrator or manufacturer in a State or Federal court for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this part, and no such court may award damages in an amount greater than $1,000 in a civil action for damages for such a vaccine-related injury or death,

unless a petition has been filed, in accordance with section 2116, for compensation under the Program for such injury or death and—

(i)(I) the United States Claims Court has issued a judgment under section 2112 on such petition, and

(II) such person elects under section 2121(a) to file such an action, or

(ii) such person elects to withdraw such petition under section 2121(b) or such petition is considered withdrawn under such section.

(B) If a civil action which is barred under subparagraph (A) is filed in a State or Federal court, the court shall dismiss the action. If a petition is filed under this section with respect to the injury or death for which such civil action was brought, the date such dismissed action was filed shall, for purposes of the limitations of actions prescribed by section 2116, be considered the date the petition was filed if the petition was filed within one year of the date of the dismissal of the civil action.

(3) No vaccine administrator or manufacturer may be made a party to a civil action (other than a civil action which may be brought under paragraph (2)) for damages for a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this part.[2]

(4) If in a civil action brought against a vaccine administrator or manufacturer before the effective date of this part damages were denied for a vaccine-related injury or death or

[2] Effective October 1, 1988.

if such civil action was dismissed with prejudice, the person who brought such action may file a petition under subsection (b) for such injury or death.

(5)(A) A plaintiff who on the effective date of this part has pending a civil action for damages for a vaccine-related injury or death may, at any time within 2 years after the effective date of this part or before judgment, whichever occurs first, petition to have such action dismissed without prejudice or costs and file a petition under subsection (b) for such injury or death.

(B) If a plaintiff has pending a civil action for damages for a vaccine-related injury or death, such person may not file a petition under subsection (b) for such injury or death.

(6) If a person brings a civil action after November 15, 1988[3] for damages for a vaccine-related injury or death associated with the administration of a vaccine before November 15, 1988, such person may not file a petition under subsection (b) for such injury or death.

(7) If in a civil action brought against a vaccine administrator or manufacturer for a vaccine-related injury or death damages are awarded under a judgment of a court or a settlement of such action, the person who brought such action may not file a petition under subsection (b) for such injury or death.

(8) If on the effective date of this part there was pending an appeal or rehearing with respect to a civil action brought against a vaccine administrator or manufacturer and if the outcome of the last appellate review of such action or the last rehearing of such action is the denial of damages for a vaccine-related injury or death, the person who brought such action may file a petition under subsection (b) for such injury or death.

(9) This subsection applies only to a person who has sustained a vaccine-related injury or death and who is qualified to file a petition for compensation under the Program.

(10) The Clerk of the United States Claims Court is authorized to continue to receive, and forward, petitions for compensation for a vaccine-related injury or death associated with the administration of a vaccine on or after October 1, 1992.

(b) PETITIONERS.—

(1)(A) Except as provided in subparagraph (B), any person who has sustained a vaccine-related injury, the legal representative of such person if such person is a minor or is disabled, or the legal representative of any person who died as the result of the administration of a vaccine set forth in the Vaccine Injury Table may, if the person meets the requirements of subsection (c)(1), file a petition for compensation under the Program.

(B) No person may file a petition for a vaccine-related injury or death associated with a vaccine administered before the effective date of this part if compensation has been paid under this subtitle for 3500 petitions for such injuries or deaths.

[3] So in law. Probably should be followed by a comma.

(2) Only one petition may be filed with respect to each administration of a vaccine.

(c) PETITION CONTENT.—A petition for compensation under the Program for a vaccine-related injury or death shall contain—

(1) except as provided in paragraph (3), an affidavit, and supporting documentation, demonstrating that the person who suffered such injury or who died—

(A) received a vaccine set forth in the Vaccine Injury Table or, if such person did not receive such a vaccine, contracted polio, directly or indirectly, from another person who received an oral polio vaccine,

(B)(i) if such person received a vaccine set forth in the Vaccine Injury Table—

(I) received the vaccine in the United States or in its trust territories,

(II) received the vaccine outside the United States or a trust territory and at the time of the vaccination such person was a citizen of the United States serving abroad as a member of the Armed Forces or otherwise as an employee of the United States or a dependent of such a citizen, or

(III) received the vaccine outside the United States or a trust territory and the vaccine was manufactured by a vaccine manufacturer located in the United States and such person returned to the United States not later than 6 months after the date of the vaccination,

(ii) if such person did not receive such a vaccine but contracted polio from another person who received an oral polio vaccine, was a citizen of the United States or a dependent of such a citizen,

(C)(i) sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table in association with the vaccine referred to in subparagraph (A) or died from the administration of such vaccine, and the first symptom or manifestation of the onset or of the significant aggravation of any such illness, disability, injury, or condition or the death occurred within the time period after vaccine administration set forth in the Vaccine Injury Table, or

(ii)(I) sustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by a vaccine referred to in subparagraph (A), or

(II) sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table the first symptom or manifestation of the onset or significant aggravation of which did not occur within the time period set forth in the Table but which was caused by a vaccine referred to in subparagraph (A),

(D)(i) suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine, or (ii) died from the administration of the vaccine, or (iii) suf-

fered such illness, disability, injury, or condition from the vaccine which resulted in inpatient hospitalization and surgical intervention, and

(E) has not previously collected an award or settlement of a civil action for damages for such vaccine-related injury or death,

(2) except as provided in paragraph (3), maternal prenatal and delivery records, newborn hospital records (including all physicians' and nurses' notes and test results), vaccination records associated with the vaccine allegedly causing the injury, pre- and post-injury physician or clinic records (including all relevant growth charts and test results), all post-injury inpatient and outpatient records (including all provider notes, test results, and medication records), if applicable, a death certificate, and if applicable, autopsy results, and

(3) an identification of any records of the type described in paragraph (1) or (2) which are unavailable to the petitioner and the reasons for their unavailability.

(d) ADDITIONAL INFORMATION.—A petition may also include other available relevant medical records relating to the person who suffered such injury or who died from the administration of the vaccine.

(e) SCHEDULE.—The petitioner shall submit in accordance with a schedule set by the special master assigned to the petition assessments, evaluations, and prognoses and such other records and documents as are reasonably necessary for the determination of the amount of compensation to be paid to, or on behalf of, the person who suffered such injury or who died from the administration of the vaccine.

JURISDICTION.

SEC. 2112.[300aa–12] (a) GENERAL RULE.—The United States Claims Court and the United States Claims Court special masters shall, in accordance with this section, have jurisdiction over proceedings to determine if a petitioner under section 2111 is entitled to compensation under the Program and the amount of such compensation. The United States Claims Court may issue and enforce such orders as the court deems necessary to assure the prompt payment of any compensation awarded.

(b) PARTIES.—

(1) In all proceedings brought by the filing of a petition under section 2111(b), the Secretary shall be named as the respondent, shall participate, and shall be represented in accordance with section 518(a) of title 28, United States Code.

(2) Within 30 days after the Secretary receives service of any petition filed under section 2111 the Secretary shall publish notice of such petition in the Federal Register. The special master designated with respect to such petition under subsection (c) shall afford all interested persons an opportunity to submit relevant, written information—

(A) relating to the existence of the evidence described in section 2113(a)(1)(B), or

(B) relating to any allegation in a petition with respect to the matters described in section 2111(c)(1)(C)(ii).

(c) UNITED STATES CLAIMS COURT SPECIAL MASTERS.—

(1) There is established within the United States Claims Court an office of special masters which shall consist of not more than 8 special masters. The judges of the United States Claims Court shall appoint the special masters, 1 of whom, by designation of the judges of the United States Claims Court, shall serve as chief special master. The appointment and reappointment of the special masters shall be by the concurrence of a majority of the judges of the court.

(2) The chief special master and other special masters shall be subject to removal by the judges of the United States Claims Court for incompetency, misconduct, or neglect of duty or for physical or mental disability or for other good cause shown.

(3) A special master's office shall be terminated if the judges of the United States Claims Court determine, upon advice of the chief special master, that the services performed by that office are no longer needed.

(4) The appointment of any individual as a special master shall be for a term of 4 years, subject to termination under paragraphs (2) and (3). Individuals serving as special masters upon the date of the enactment of this subsection shall serve for 4 years from the date of their original appointment, subject to termination under paragraphs (2) and (3). The chief special master in office on the date of the enactment of this subsection shall continue to serve as chief special master for the balance of the master's term, subject to termination under paragraphs (2) and (3).

(5) The compensation of the special masters shall be determined by the judges of the United States Claims Court, upon advice of the chief special master. The salary of the chief special master shall be the annual rate of basic pay for level IV of the Executive Schedule, as prescribed by section 5315, title 5, United States Code. The salaries of the other special masters shall not exceed the annual rate of basic pay of level V of the Executive Schedule, as prescribed by section 5316, title 5, United States Code.

(6) The chief special master shall be responsible for the following:

(A) Administering the office of special masters and their staff, providing for the efficient, expeditious, and effective handling of petitions, and performing such other duties related to the Program as may be assigned to the chief special master by a concurrence of a majority of the United States Claims Courts [4] judges.

(B) Appointing and fixing the salary and duties of such administrative staff as are necessary. Such staff shall be subject to removal for good cause by the chief special master.

(C) Managing and executing all aspects of budgetary and administrative affairs affecting the special masters and their staff, subject to the rules and regulations of the

[4] So in law. Probably should be "United States Court of Federal Claims".

Judicial Conference of the United States. The Conference rules and regulations pertaining to United States magistrates shall be applied to the special masters.

(D) Coordinating with the United States Claims Court the use of services, equipment, personnel, information, and facilities of the United States Claims Court without reimbursement.

(E) Reporting annually to the Congress and the judges of the United States Claims Court on the number of petitions filed under section 2111 and their disposition, the dates on which the vaccine-related injuries and deaths for which the petitions were filed occurred, the types and amounts of awards, the length of time for the disposition of petitions, the cost of administering the Program, and recommendations for changes in the Program.

(d) SPECIAL MASTERS.—

(1) Following the receipt and filing of a petition under section 2111, the clerk of the United States Claims Court shall forward the petition to the chief special master who shall designate a special master to carry out the functions authorized by paragraph (3).

(2) The special masters shall recommend rules to the Claims Court and, taking into account such recommended rules, the Claims Court shall promulgate rules pursuant to section 2071 of title 28, United States Code. Such rules shall—

(A) provide for a less-adversarial, expeditious, and informal proceeding for the resolution of petitions,

(B) include flexible and informal standards of admissibility of evidence,

(C) include the opportunity for summary judgment,

(D) include the opportunity for parties to submit arguments and evidence on the record without requiring routine use of oral presentations, cross examinations, or hearings, and

(E) provide for limitations on discovery and allow the special masters to replace the usual rules of discovery in civil actions in the United States Claims Court.

(3)(A) A special master to whom a petition has been assigned shall issue a decision on such petition with respect to whether compensation is to be provided under the Program and the amount of such compensation. The decision of the special master shall—

(i) include findings of fact and conclusions of law, and

(ii) be issued as expeditiously as practicable but not later than 240 days, exclusive of suspended time under subparagraph (C), after the date the petition was filed.

The decision of the special master may be reviewed by the United States Claims Court in accordance with subsection (e).

(B) In conducting a proceeding on a petition a special master—

(i) may require such evidence as may be reasonable and necessary,

(ii) may require the submission of such information as may be reasonable and necessary,

(iii) may require the testimony of any person and the production of any documents as may be reasonable and necessary,

(iv) shall afford all interested persons an opportunity to submit relevant written information—

(I) relating to the existence of the evidence described in section 2113(a)(1)(B), or

(II) relating to any allegation in a petition with respect to the matters described in section 2111(c)(1)(C)(ii), and

(v) may conduct such hearings as may be reasonable and necessary.

There may be no discovery in a proceeding on a petition other than the discovery required by the special master.

(C) In conducting a proceeding on a petition a special master shall suspend the proceedings one time for 30 days on the motion of either party. After a motion for suspension is granted, further motions for suspension by either party may be granted by the special master, if the special master determines the suspension is reasonable and necessary, for an aggregate period not to exceed 150 days.

(D) If, in reviewing proceedings on petitions for vaccine-related injuries or deaths associated with the administration of vaccines before the effective date of this part, the chief special master determines that the number of filings and resultant workload place an undue burden on the parties or the special master involved in such proceedings, the chief special master may, in the interest of justice, suspend proceedings on any petition for up to 30 months (but for not more than 6 months at a time) in addition to the suspension time under subparagraph (C).

(4)(A) Except as provided in subparagraph (B), information submitted to a special master or the court in a proceeding on a petition may not be disclosed to a person who is not a party to the proceeding without the express written consent of the person who submitted the information.

(B) A decision of a special master or the court in a proceeding shall be disclosed, except that if the decision is to include information—

(i) which is trade secret or commercial or financial information which is privileged and confidential, or

(ii) which are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy,

and if the person who submitted such information objects to the inclusion of such information in the decision, the decision shall be disclosed without such information.

(e) ACTION BY THE UNITED STATES CLAIMS COURT.—

(1) Upon issuance of the special master's decision, the parties shall have 30 days to file with the clerk of the United States Claims Court a motion to have the court review the decision. If such a motion is filed, the other party shall file a response with the clerk of the United States Claims Court no later than 30 days after the filing of such motion.

(2) Upon the filing of a motion under paragraph (1) with respect to a petition, the United States Claims Court shall have jurisdiction to undertake a review of the record of the proceedings and may thereafter—

(A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,

(B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or

(C) remand the petition to the special master for further action in accordance with the court's direction.

The court shall complete its action on a petition within 120 days of the filing of a response under paragraph (1) excluding any days the petition is before a special master as a result of a remand under subparagraph (C). The court may allow not more than 90 days for remands under subparagraph (C).

(3) In the absence of a motion under paragraph (1) respecting the special master's decision or if the United States Claims Court takes the action described in paragraph (2)(A) with respect to the special master's decision, the clerk of the United States Claims Court shall immediately enter judgment in accordance with the special master's decision.

(f) APPEALS.—The findings of fact and conclusions of law of the United States Claims Court on a petition shall be final determinations of the matters involved, except that the Secretary or any petitioner aggrieved by the findings or conclusions of the court may obtain review of the judgment of the court in the United States court of appeals for the Federal Circuit upon petition filed within 60 days of the date of the judgment with such court of appeals within 60 days of the date of entry of the United States Claims Court's[5] judgment with such court of appeals.

(g)[6] NOTICE.—If—

(1) a special master fails to make a decision on a petition within the 240 days prescribed by subsection (d)(3)(A)(ii) (excluding (A) any period of suspension under subsection (d)(3)(C) or (d)(3)(D), and (B) any days the petition is before a special master as a result of a remand under subsection (e)(2)(C)), or

(2) the United States Claims Court fails to enter a judgment under this section on a petition within 420 days (excluding (A) any period of suspension under subsection (d)(3)(C) or (d)(3)(D), and (B) any days the petition is before a special master as a result of a remand under subsection (e)(2)(C)) after the date on which the petition was filed,

the special master or court shall notify the petitioner under such petition that the petitioner may withdraw the petition under sec-

[5] So in law. Probably should be a reference to the United States Court of Federal Claims.

[6] Subsection (i)(2) of section 201 of Public Law 102–168 (105 Stat. 1104), which was enacted on November 26, 1991, provided that the amendments made by subsections (d) and (f) of such section "shall take effect as if the amendments had been in effect on and after October 1, 1988". Such subsections (d) and (f) related to actions by petitioners, and to annuities, respectively, and involved amendments to sections 2112(g), 2115(f)(4), 2116(c), and 2121(b).

tion 2121(b) or the petitioner may choose under section 2121(b) to have the petition remain before the special master or court, as the case may be.

DETERMINATION OF ELIGIBILITY AND COMPENSATION.

SEC. 2113.[300aa–13] (a) GENERAL RULE.—

(1) Compensation shall be awarded under the Program to a petitioner if the special master or court finds on the record as a whole—

(A) that the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition by section 2111(c)(1), and

(B) that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition.

The special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.

(2) For purposes of paragraph (1), the term "factors unrelated to the administration of the vaccine"—

(A) does not include any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition, and

(B) may, as documented by the petitioner's evidence or other material in the record, include infection, toxins, trauma (including birth trauma and related anoxia), or metabolic disturbances which have no known relation to the vaccine involved, but which in the particular case are shown to have been the agent or agents principally responsible for causing the petitioner's illness, disability, injury, condition, or death.

(b) MATTERS TO BE CONSIDERED.—

(1) In determining whether to award compensation to a petitioner under the Program, the special master or court shall consider, in addition to all other relevant medical and scientific evidence contained in the record—

(A) any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death, and

(B) the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions.

Any such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court. In evaluating the weight to be afforded to any such diagnosis, conclusion, judgment, test result, report, or summary, the special master or court shall consider the entire record and the course of the injury, disability, illness, or condition until the date of the judgment of the special master or court.

(2) The special master or court may find the first symptom or manifestation of onset or significant aggravation of an in-

jury, disability, illness, condition, or death described in a petition occurred within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period. Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset or significant aggravation of the injury, disability, illness, condition, or death described in the petition did in fact occur within the time period described in the Vaccine Injury Table.

(c) RECORD DEFINED.—For purposes of this section, the term "record" means the record established by the special masters of the United States Claims Court in a proceeding on a petition filed under section 2111.

VACCINE INJURY TABLE.

SEC. 2114.[300aa–14] (a) INITIAL TABLE.—The following is a table of vaccines, the injuries, disabilities, illnesses, conditions, and deaths resulting from the administration of such vaccines, and the time period in which the first symptom or manifestation of onset or of the significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths is to occur after vaccine administration for purposes of receiving compensation under the Program:

VACCINE INJURY TABLE

I.	DTP; P; DTP/Polio Combination; or Any Other Vaccine Containing Whole Cell Pertussis Bacteria, Extracted or Partial Cell Bacteria, or Specific Pertussis Antigen(s).	
	Illness, disability, injury, or condition covered:	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration:
	A. Anaphylaxis or anaphylactic shock	24 hours
	B. Encephalopathy (or encephalitis)	3 days
	C. Shock-collapse or hypotonic-hyporesponsive collapse	3 days
	D. Residual seizure disorder in accordance with subsection (b)(2)	3 days
	E. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable
II.	Measles, mumps, rubella, or any vaccine containing any of the foregoing as a component; DT; Td; or Tetanus Toxoid.	
	A. Anaphylaxis or anaphylactic shock	24 hours
	B. Encephalopathy (or encephalitis)	15 days (for mumps, rubella, measles, or any vaccine containing any of the foregoing as a component). 3 days (for DT, Td, or tetanus toxoid).

	C. Residual seizure disorder in accordance with subsection (b)(2)	15 days (for mumps, rubella, measles, or any vaccine containing any of the foregoing as a component). 3 days (for DT, Td, or tetanus toxoid).
	D. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable
III.	Polio Vaccines (other than Inactivated Polio Vaccine).	
	A. Paralytic polio	
	—in a non-immunodeficient recipient	30 days
	—in an immunodeficient recipient	6 months
	—in a vaccine-associated community case	Not applicable
	B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable
IV.	Inactivated Polio Vaccine.	
	A. Anaphylaxis or anaphylactic shock	24 hours
	B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable

(b) QUALIFICATIONS AND AIDS TO INTERPRETATION.—The following qualifications and aids to interpretation shall apply to the Vaccine Injury Table in subsection (a):

(1) A shock-collapse or a hypotonic-hyporesponsive collapse may be evidenced by indicia or symptoms such as decrease or loss of muscle tone, paralysis (partial or complete), hemiplegia or hemiparesis, loss of color or turning pale white or blue, unresponsiveness to environmental stimuli, depression of consciousness, loss of consciousness, prolonged sleeping with difficulty arousing, or cardiovascular or respiratory arrest.

(2) A petitioner may be considered to have suffered a residual seizure disorder if the petitioner did not suffer a seizure or convulsion unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit before the first seizure or convulsion after the administration of the vaccine involved and if—

(A) in the case of a measles, mumps, or rubella vaccine or any combination of such vaccines, the first seizure or convulsion occurred within 15 days after administration of the vaccine and 2 or more seizures or convulsions occurred within 1 year after the administration of the vaccine which were unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit, and

(B) in the case of any other vaccine, the first seizure or convulsion occurred within 3 days after administration of the vaccine and 2 or more seizures or convulsions occurred within 1 year after the administration of the vaccine which were unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit.

(3)(A) The term "encephalopathy" means any significant acquired abnormality of, or injury to, or impairment of function of the brain. Among the frequent manifestations of encephalopathy are focal and diffuse neurologic signs, increased intracranial pressure, or changes lasting at least 6 hours in level of consciousness, with or without convulsions. The neurological signs and symptoms of encephalopathy may be temporary with complete recovery, or may result in various degrees of permanent impairment. Signs and symptoms such as high pitched and unusual screaming, persistent unconsolable crying, and bulging fontanel are compatible with an encephalopathy, but in and of themselves are not conclusive evidence of encephalopathy. Encephalopathy usually can be documented by slow wave activity on an electroencephalogram.

(B) If in a proceeding on a petition it is shown by a preponderance of the evidence that an encephalopathy was caused by infection, toxins, trauma, or metabolic disturbances the encephalopathy shall not be considered to be a condition set forth in the table. If at the time a judgment is entered on a petition filed under section 2111 for a vaccine-related injury or death it is not possible to determine the cause, by a preponderance of the evidence, of an encephalopathy, the encephalopathy shall be considered to be a condition set forth in the table. In determining whether or not an encephalopathy is a condition set forth in the table, the court shall consider the entire medical record.

(4) For purposes of paragraphs (2) and (3), the terms "seizure" and "convulsion" include grand mal, petit mal, absence, myoclonic, tonic-clonic, and focal motor seizures and signs. If a provision of the table to which paragraph (1), (2), (3), or (4) applies is revised under subsection (c) or (d), such paragraph shall not apply to such provision after the effective date of the revision unless the revision specifies that such paragraph is to continue to apply.

(c) ADMINISTRATIVE REVISION OF THE TABLE.—

(1) The Secretary may promulgate regulations to modify in accordance with paragraph (3) the Vaccine Injury Table. In promulgating such regulations, the Secretary shall provide for notice and opportunity for a public hearing and at least 180 days of public comment.

(2) Any person (including the Advisory Commission on Childhood Vaccines) may petition the Secretary to propose regulations to amend the Vaccine Injury Table. Unless clearly frivolous, or initiated by the Commission, any such petition shall be referred to the Commission for its recommendations. Following—

(A) receipt of any recommendation of the Commission, or

(B) 180 days after the date of the referral to the Commission,

whichever occurs first, the Secretary shall conduct a rulemaking proceeding on the matters proposed in the petition or publish in the Federal Register a statement of reasons for not conducting such proceeding.

(3) A modification of the Vaccine Injury Table under paragraph (1) may add to, or delete from, the list of injuries, disabilities, illnesses, conditions, and deaths for which compensation may be provided or may change the time periods for the first symptom or manifestation of the onset or the significant aggravation of any such injury, disability, illness, condition, or death.

(4) Any modification under paragraph (1) of the Vaccine Injury Table shall apply only with respect to petitions for compensation under the Program which are filed after the effective date of such regulation.

(d) ROLE OF COMMISSION.—Except with respect to a regulation recommended by the Advisory Commission on Childhood Vaccines, the Secretary may not propose a regulation under subsection (c) or any revision thereof, unless the Secretary has first provided to the Commission a copy of the proposed regulation or revision, requested recommendations and comments by the Commission, and afforded the Commission at least 90 days to make such recommendations.

(e)[7] ADDITIONAL VACCINES.—

(1) VACCINES RECOMMENDED BEFORE AUGUST 1, 1993.—By August 1, 1995, the Secretary shall revise the Vaccine Injury Table included in subsection (a) to include—

(A) vaccines which are recommended to the Secretary by the Centers for Disease Control and Prevention before August 1, 1993, for routine administration to children,

(B) the injuries, disabilities, illnesses, conditions, and deaths associated with such vaccines, and

(C) the time period in which the first symptoms or manifestations of onset or other significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths associated with such vaccines may occur.

(2) VACCINES RECOMMENDED AFTER AUGUST 1, 1993.—When after August 1, 1993, the Centers for Disease Control and Prevention recommends a vaccine to the Secretary for routine administration to children, the Secretary shall, within 2 years of such recommendation, amend the Vaccine Injury Table included in subsection (a) to include—

(A) vaccines which were recommended for routine administration to children,

(B) the injuries, disabilities, illnesses, conditions, and deaths associated with such vaccines, and

[7] Section 13632(a)(3) of Public Law 103-66 (107 Stat. 646) provides as follows:

"(3) EFFECTIVE DATE.—A revision by the Secretary under section 2114(e) of the Public Health Service Act (42 U.S.C. 300aa–14(e)) (as amended by paragraph (2)) shall take effect upon the effective date of a tax enacted to provide funds for compensation paid with respect to the vaccine to be added to the vaccine injury table in section 2114(a) of the Public Health Service Act (42 U.S.C. 300aa–14(a)).".

(C) the time period in which the first symptoms or manifestations of onset or other significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths associated with such vaccines may occur.

COMPENSATION.

SEC. 2115.[300aa–15] (a) GENERAL RULE.—Compensation awarded under the Program to a petitioner under section 2111 for a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this part[8] shall include the following:

(1)(A) Actual unreimbursable expenses incurred from the date of the judgment awarding such expenses and reasonable projected unreimbursable expenses which—

(i) result from the vaccine-related injury for which the petitioner seeks compensation,

(ii) have been or will be incurred by or on behalf of the person who suffered such injury, and

(iii)(I) have been or will be for diagnosis and medical or other remedial care determined to be reasonably necessary, or

(II) have been or will be for rehabilitation, developmental evaluation, special education, vocational training and placement, case management services, counseling, emotional or behavioral therapy, residential and custodial care and service expenses, special equipment, related travel expenses, and facilities determined to be reasonably necessary.

(B) Subject to section 2116(a)(2), actual unreimbursable expenses incurred before the date of the judgment awarding such expenses which—

(i) resulted from the vaccine-related injury for which the petitioner seeks compensation,

(ii) were incurred by or on behalf of the person who suffered such injury, and

(iii) were for diagnosis, medical or other remedial care, rehabilitation, developmental evaluation, special education, vocational training and placement, case management services, counseling, emotional or behavioral therapy, residential and custodial care and service expenses, special equipment, related travel expenses, and facilities determined to be reasonably necessary.

(2) In the event of a vaccine-related death, an award of $250,000 for the estate of the deceased.

(3)(A) In the case of any person who has sustained a vaccine-related injury after attaining the age of 18 and whose earning capacity is or has been impaired by reason of such person's vaccine-related injury for which compensation is to be awarded, compensation for actual and anticipated loss of earnings determined in accordance with generally recognized actuarial principles and projections.

[8] Effective October 1, 1988.

(B) In the case of any person who has sustained a vaccine-related injury before attaining the age of 18 and whose earning capacity is or has been impaired by reason of such person's vaccine-related injury for which compensation is to be awarded and whose vaccine-related injury is of sufficient severity to permit reasonable anticipation that such person is likely to suffer impaired earning capacity at age 18 and beyond, compensation after attaining the age of 18 for loss of earnings determined on the basis of the average gross weekly earnings of workers in the private, non-farm sector, less appropriate taxes and the average cost of a health insurance policy, as determined by the Secretary.

(4) For actual and projected pain and suffering and emotional distress from the vaccine-related injury, an award not to exceed $250,000.

(b) VACCINES ADMINISTERED BEFORE THE EFFECTIVE DATE.—Compensation awarded under the Program to a petitioner under section 2111 for a vaccine-related injury or death associated with the administration of a vaccine before the effective date of this part[9] may include the compensation described in paragraphs (1)(A) and (2) of subsection (a) and may also include an amount, not to exceed a combined total of $30,000, for—

(1) lost earnings (as provided in paragraph (3) of subsection (a)),

(2) pain and suffering (as provided in paragraph (4) of subsection (a)), and

(3) reasonable attorneys' fees and costs (as provided in subsection (e)[10].

(c) RESIDENTIAL AND CUSTODIAL CARE AND SERVICE.—The amount of any compensation for residential and custodial care and service expenses under subsection (a)(1) shall be sufficient to enable the compensated person to remain living at home.

(d) TYPES OF COMPENSATION PROHIBITED.—Compensation awarded under the Program may not include the following:

(1) Punitive or exemplary damages.

(2) Except with respect to compensation payments under paragraphs (2) and (3) of subsection (a), compensation for other than the health, education, or welfare of the person who suffered the vaccine-related injury with respect to which the compensation is paid.

(e) ATTORNEYS' FEES.—

(1) In awarding compensation on a petition filed under section 2111 the special master or court shall also award as part of such compensation an amount to cover—

(A) reasonable attorneys' fees, and

(B) other costs,

incurred in any proceeding on such petition. If the judgment of a special master or court on such a petition does not award compensation, the special master or court may award an amount of compensation to cover petitioner's reasonable attorneys' fees and other costs incurred in any proceeding on such

[9] Effective October 1, 1988.

[10] So in law. Probably should be a closing parenthesis after "subsection (e)".

petition if the special master or court determines that the petition was brought in good faith and there was a reasonable basis for the claim for which the petition was brought.

(2) If the petitioner, before the effective date of this part,[11] filed a civil action for damages for any vaccine-related injury or death for which compensation may be awarded under the Program, and petitioned under section 2111(a)(5) to have such action dismissed and to file a petition for compensation under the Program, in awarding compensation on such petition the special master or court may include an amount of compensation limited to the costs and expenses incurred by the petitioner and the attorney of the petitioner before the effective date of this part in preparing, filing, and prosecuting such civil action (including the reasonable value of the attorney's time if the civil action was filed under contingent fee arrangements).

(3) No attorney may charge any fee for services in connection with a petition filed under section 2111 which is in addition to any amount awarded as compensation by the special master or court under paragraph (1).

(f) PAYMENT OF COMPENSATION.—

(1) Except as provided in paragraph (2), no compensation may be paid until an election has been made, or has been deemed to have been made, under section 2121(a) to receive compensation.

(2) Compensation described in subsection (a)(1)(A)(iii) shall be paid from the date of the judgment of the United States Claims Court under section 2112 awarding the compensation. Such compensation may not be paid after an election under section 2121(a) to file a civil action for damages for the vaccine-related injury or death for which such compensation was awarded.

(3) Payments of compensation under the Program and the costs of carrying out the Program shall be exempt from reduction under any order issued under part C of the Balanced Budget and Emergency Deficit Control Act of 1985.

(4)(A)[12] Except as provided in subparagraph (B), payment of compensation under the Program shall be determined on the basis of the net present value of the elements of the compensation and shall be paid from the Vaccine Injury Compensation Trust Fund established under section 9510 of the Internal Revenue Code of 1986 in a lump sum of which all or a portion may be used as ordered by the special master to purchase an annuity or otherwise be used, with the consent of the petitioner, in a manner determined by the special master to be in the best interests of the petitioner.

(B) In the case of a payment of compensation under the Program to a petitioner for a vaccine-related injury or death associated with the administration of a vaccine before the effective date of this part[13] the compensation shall be determined on the basis of the net present value of the elements of compensation and paid in 4 equal annual installments of which

[11] Effective October 1, 1988.
[12] See footnote for section 2112(g).
[13] Effective October 1, 1988.

all or a portion of the proceeds[14] may be used as ordered by the special master to purchase an annuity or otherwise be used, with the consent of the petitioner, in a manner determined by the special master to be in the best interests of the petitioner. Any reasonable attorneys' fees and costs shall be paid in a lump sum. If the appropriations under subsection (j) are insufficient to make a payment of an annual installment, the limitation on civil actions prescribed by section 2121(a) shall not apply to a civil action for damages brought by the petitioner entitled to the payment.

(C) In purchasing an annuity under subparagraph (A) or (B), the Secretary may purchase a guarantee for the annuity, may enter into agreements regarding the purchase price for and rate of return of the annuity, and may take such other actions as may be necessary to safeguard the financial interests of the United States regarding the annuity. Any payment received by the Secretary pursuant to the preceding sentence shall be paid to the Vaccine Injury Compensation Trust Fund established under section 9510 of the Internal Revenue Code of 1986, or to the appropriations account from which the funds were derived to purchase the annuity, whichever is appropriate.

(g) PROGRAM NOT PRIMARILY LIABLE.—Payment of compensation under the Program shall not be made for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to such item or service (1) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program (other than under title XIX of the Social Security Act), or (2) by an entity which provides health services on a prepaid basis.

(h) LIABILITY OF HEALTH INSURANCE CARRIERS, PREPAID HEALTH PLANS, AND BENEFIT PROVIDERS.—No policy of health insurance may make payment of benefits under the policy secondary to the payment of compensation under the Program and—

(1) no State, and

(2) no entity which provides health services on a prepaid basis or provides health benefits,

may make the provision of health services or health benefits secondary to the payment of compensation under the Program, except that this subsection shall not apply to the provision of services or benefits under title XIX of the Social Security Act.

(i) SOURCE OF COMPENSATION.—

(1) Payment of compensation under the Program to a petitioner for a vaccine-related injury or death associated with the administration of a vaccine before the effective date of this part[15] shall be made by the Secretary from appropriations under subsection (j).

[14] Section 201(e)(1)(B) of Public Law 102–168 (105 Stat. 1103) provided that this subparagraph is amended by striking out "paid in 4 equal installments of which all or portion of the proceeds" and inserting in lieu thereof "shall be paid from appropriations made available under subsection (j) in a lump sum of which all or a portion". The amendment cannot be executed because the term to be struck does not appear in the law. (Compare "equal installments" with "equal annual installments" and "or portion" with "or a portion".)

[15] Effective October 1, 1988.

(2) Payment of compensation under the Program to a petitioner for a vaccine-related injury or death associated with the administration of a vaccine on or after the effective date of this part shall be made from the Vaccine Injury Compensation Trust Fund established under section 9510 of the Internal Revenue Code of 1986.

(j) AUTHORIZATION.—For the payment of compensation under the Program to a petitioner for a vaccine-related injury or death associated with the administration of a vaccine before the effective date of this part there are authorized to be appropriated to the Department of Health and Human Services $80,000,000 for fiscal year 1989, $80,000,000 for fiscal year 1990, $80,000,000 for fiscal year 1991, $80,000,000 for fiscal year 1992, $110,000,000 for fiscal year 1993, and $110,000,000 for each succeeding fiscal year in which a payment of compensation is required under subsection (f)(4)(B). Amounts appropriated under this subsection shall remain available until expended.

LIMITATIONS OF ACTIONS.

SEC. 2116.[300aa–16] (a) GENERAL RULE.—In the case of—

(1) a vaccine set forth in the Vaccine Injury Table which is administered before the effective date of this part, if a vaccine-related injury or death occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury or death after the expiration of 28 months after the effective date of this part and no such petition may be filed if the first symptom or manifestation of onset or of the significant aggravation of such injury occurred more than 36 months after the date of administration of the vaccine,

(2) a vaccine set forth in the Vaccine Injury Table which is administered after the effective date of this part, if a vaccine-related injury occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury, and

(3) a vaccine set forth in the Vaccine Injury Table which is administered after the effective date of this part,[16] if a death occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such death after the expiration of 24 months from the date of the death and no such petition may be filed more than 48 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of the injury from which the death resulted.

(b) EFFECT OF REVISED TABLE.—If at any time the Vaccine Injury Table is revised and the effect of such revision is to permit an individual who was not, before such revision, eligible to seek compensation under the Program, or to significantly increase the likelihood of obtaining compensation, such person may, notwithstanding

[16] Effective October 1, 1988.

section 2111(b)(2), file a petition for such compensation not later than 2 years after the effective date of the revision, except that no compensation may be provided under the Program with respect to a vaccine-related injury or death covered under the revision of the table if—

(1) the vaccine-related death occurred more than 8 years before the date of the revision of the table, or

(2) the vaccine-related injury occurred more than 8 years before the date of the revision of the table.

(c)[17] STATE LIMITATIONS OF ACTIONS.—If a petition is filed under section 2111 for a vaccine-related injury or death, limitations of actions under State law shall be stayed with respect to a civil action brought for such injury or death for the period beginning on the date the petition is filed and ending on the date (1) an election is made under section 2121(a) to file the civil action or (2) an election is made under section 2121(b) to withdraw the petition.

SUBROGRATION.

SEC. 2117.[300aa–17] (a) GENERAL RULE.—Upon payment of compensation to any petitioner under the Program, the trust fund which has been established to provide such compensation shall be subrograted[18] to all rights of the petitioner with respect to the vaccine-related injury or death for which compensation was paid, except that the trust fund may not recover under such rights an amount greater than the amount of compensation paid to the petitioner.

(b) DISPOSITION OF AMOUNTS RECOVERED.—Amounts recovered under subsection (a) shall be collected on behalf of, and deposited in, the Vaccine Injury Compensation Trust Fund established under section 9510 of the Internal Revenue Code of 1986.

ADVISORY COMMISSION ON CHILDHOOD VACCINES.

SEC. 2119.[300aa–19] (a) ESTABLISHMENT.—There is established the Advisory Commission on Childhood Vaccines. The Commission shall be composed of:

(1) Nine members appointed by the Secretary as follows:

(A) Three members who are health professionals, who are not employees of the United States, and who have expertise in the health care of children, the epidemiology, etiology, and prevention of childhood diseases, and the adverse reactions associated with vaccines, of whom at least two shall be pediatricians.

(B) Three members from the general public, of whom at least two shall be legal representatives of children who have suffered a vaccine-related injury or death.

(C) Three members who are attorneys, of whom at least one shall be an attorney whose specialty includes representation of persons who have suffered a vaccine-related injury or death and of whom one shall be an attorney whose specialty includes representation of vaccine manufacturers.

[17] See footnote for section 2112(g).
[18] So in law. Probably should be "subrogated".

(2) The Director of the National Institutes of Health, the Assistant Secretary for Health, the Director of the Centers for Disease Control and Prevention, and the Commissioner of Food and Drugs (or the designees of such officials), each of whom shall be a nonvoting ex officio member.

The Secretary shall select members of the Commission within 90 days of the effective date of this part.[19] The members of the Commission shall select a Chair from among the members.

(b) TERM OF OFFICE.—Appointed members of the Commission shall be appointed for a term of office of 3 years, except that of the members first appointed, 3 shall be appointed for a term of 1 year, 3 shall be appointed for a term of 2 years, and 3 shall be appointed for a term of 3 years, as determined by the Secretary.

(c) MEETINGS.—The Commission shall first meet within 60 days after all members of the Commission are appointed, and thereafter shall meet not less often than four times per year and at the call of the chair. A quorum for purposes of a meeting is 5. A decision at a meeting is to be made by a ballot of a majority of the voting members of the Commission present at the meeting.

(d) COMPENSATION.—Members of the Commission who are officers or employees of the Federal Government shall serve as members of the Commission without compensation in addition to that received in their regular public employment. Members of the Commission who are not officers or employees of the Federal Government shall be compensated at a rate not to exceed the daily equivalent of the rate in effect for grade GS–18 of the General Schedule for each day (including traveltime) they are engaged in the performance of their duties as members of the Commission. All members, while so serving away from their homes or regular places of business, may be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as such expenses are authorized by section 5703, title 5, United States Code, for employees serving intermittently.

(e) STAFF.—The Secretary shall provide the Commission with such professional and clerical staff, such information, and the services of such consultants as may be necessary to assist the Commission in carrying out effectively its functions under this section.

(f) FUNCTIONS.—The Commission shall—

(1) advise the Secretary on the implementation of the Program,

(2) on its own initiative or as the result of the filing of a petition, recommend changes in the Vaccine Injury Table,

(3) advise the Secretary in implementing the Secretary's responsibilities under section 2127 regarding the need for childhood vaccination products that result in fewer or no significant adverse reactions,

(4) survey Federal, State, and local programs and activities relating to the gathering of information on injuries associated with the administration of childhood vaccines, including the adverse reaction reporting requirements of section 2125(b), and advise the Secretary on means to obtain, compile, publish, and

[19] Effective October 1, 1988.

use credible data related to the frequency and severity of adverse reactions associated with childhood vaccines, and

(5) recommend to the Director of the National Vaccine Program research related to vaccine injuries which should be conducted to carry out this subtitle.

PART B—ADDITIONAL REMEDIES

AUTHORITY TO BRING ACTIONS.

SEC. 2121.[300aa–21] (a) ELECTION.—After judgment has been entered by the United States Claims Court or, if an appeal is taken under section 2112(f), after the appellate court's mandate is issued, the petitioner who filed the petition under section 2111 shall file with the clerk of the United States Claims Court—

(1) if the judgment awarded compensation, an election in writing to receive the compensation or to file a civil action for damages for such injury or death, or

(2) if the judgment did not award compensation, an election in writing to accept the judgment or to file a civil action for damages for such injury or death.

An election shall be filed under this subsection not later than 90 days after the date of the court's final judgment with respect to which the election is to be made. If a person required to file an election with the court under this subsection does not file the election within the time prescribed for filing the election, such person shall be deemed to have filed an election to accept the judgment of the court. If a person elects to receive compensation under a judgment of the court in an action for a vaccine-related injury or death associated with the administration of a vaccine before the effective date of this part or is deemed to have accepted the judgment of the court in such an action, such person may not bring or maintain a civil action for damages against a vaccine administrator or manufacturer for the vaccine-related injury or death for which the judgment was entered. For limitations on the bringing of civil actions for vaccine-related injuries or deaths associated with the administration of a vaccine after the effective date of this part[20], see section 2111(a)(2).

(b)[21] CONTINUANCE OR WITHDRAWAL OF PETITION.[22]—A petitioner under a petition filed under section 2111 may submit to the United States Claims Court a notice in writing choosing to continue or to withdraw the petition if—

(1) a special master fails to make a decision on such petition within the 240 days prescribed by section 2112(d)(3)(A)(ii) (excluding (i) any period of suspension under section 2112(d)(3)(C) or 2112(d)(3)(D), and (ii) any

[20] Effective October 1, 1988.

[21] See footnote for section 2112(g).

[22] The amendment described in section 201(d)(3)(C) of Public Law 102–168 (105 Stat. 1103) has been executed according to the probable intent of the Congress. After redesignating former subparagraphs (A) and (B) as paragraphs (1) and (2), the amendatory instructions of the section provided that section 2121(b) is amended "by running the text of paragraph (1) into the subsection heading and making the margin of the text full measure". The instructions were applied to portions of the matter preceding paragraph (1) as redesignated, rather than to the text of paragraph (1). (That is, the instructions were applied to the former paragraph (1).)

days the petition is before a special master as a result of a remand under section 2112(e)(2)(C)), or

(2) the court fails to enter a judgment under section 2112 on the petition within 420 days (excluding (i) any period of suspension under section 2112(d)(3)(C) or 2112(d)(3)(D), and (ii) any days the petition is before a special master as a result of a remand under section 2112(e)(2)(C)) after the date on which the petition was filed.

Such a notice shall be filed within 30 days of the provision of the notice required by section 2112(g).

(c) LIMITATIONS OF ACTIONS.—A civil action for damages arising from a vaccine-related injury or death for which a petition was filed under section 2111 shall, except as provided in section 2116(c), be brought within the period prescribed by limitations of actions under State law applicable to such civil action.

STANDARDS OF RESPONSIBILITY.

SEC. 2122.[300aa–22] (a) GENERAL RULE.—Except as provided in subsections (b), (c), and (e) State law shall apply to a civil action brought for damages for a vaccine-related injury or death.

(b) UNAVOIDABLE ADVERSE SIDE EFFECTS; WARNINGS.—

(1) No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this part[23] if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.

(2) For purposes of paragraph (1), a vaccine shall be presumed to be accompanied by proper directions and warnings if the vaccine manufacturer shows that it complied in all material respects with all requirements under the Federal Food, Drug, and Cosmetic Act and section 351 of the Public Health Service Act (including regulations issued under such provisions) applicable to the vaccine and related to vaccine-related injury or death for which the civil action was brought unless the plaintiff shows—

(A) that the manufacturer engaged in the conduct set forth in subparagraph (A) or (B) of section 2123(d)(2), or

(B) by clear and convincing evidence that the manufacturer failed to exercise due care notwithstanding its compliance with such Act and section (and regulations issued under such provisions).

(c) DIRECT WARNINGS.—No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this part[24] solely due to the manufacturer's failure to provide direct warnings to the injured party (or the injured party's legal representative) of the potential dangers result-

[23] Effective October 1, 1988.
[24] Effective October 1, 1988.

ing from the administration of the vaccine manufactured by the manufacturer.

(d) CONSTRUCTION.—The standards of responsibility prescribed by this section are not to be construed as authorizing a person who brought a civil action for damages against a vaccine manufacturer for a vaccine-related injury or death in which damages were denied or which was dismissed with prejudice to bring a new civil action against such manufacturer for such injury or death.

(e) PREEMPTION.—No State may establish or enforce a law which prohibits an individual from bringing a civil action against a vaccine manufacturer for damages for a vaccine-related injury or death if such civil action is not barred by this subtitle.

TRIAL.

SEC. 2123.[300aa–23] (a) GENERAL RULE.—A civil action against a vaccine manufacturer for damages for a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this part which is not barred by section 2111(a)(2) shall be tried in three stages.

(b) LIABILITY.—The first stage of such a civil action shall be held to determine if a vaccine manufacturer is liable under section 2122.

(c) GENERAL DAMAGES.—The second stage of such a civil action shall be held to determine the amount of damages (other than punitive damages) a vaccine manufacturer found to be liable under section 2122 shall be required to pay.

(d) PUNITIVE DAMAGES.—

(1) If sought by the plaintiff, the third stage of such an action shall be held to determine the amount of punitive damages a vaccine manufacturer found to be liable under section 2122 shall be required to pay.

(2) If in such an action the manufacturer shows that it complied, in all material respects, with all requirements under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act applicable to the vaccine and related to the vaccine injury or death with respect to which the action was brought, the manufacturer shall not be held liable for punitive damages unless the manufacturer engaged in—

(A) fraud or intentional and wrongful withholding of information from the Secretary during any phase of a proceeding for approval of the vaccine under section 351,

(B) intentional and wrongful withholding of information relating to the safety or efficacy of the vaccine after its approval, or

(C) other criminal or illegal activity relating to the safety and effectiveness of vaccines,

which activity related to the vaccine-related injury or death for which the civil action was brought.

(e) EVIDENCE.—In any stage of a civil action, the Vaccine Injury Table, any finding of fact or conclusion of law of the United States Claims Court or a special master in a proceeding on a petition filed under section 2111 and the final judgment of the United States Claims Court and subsequent appellate review on such a petition shall not be admissible.

PART C—ASSURING A SAFER CHILDHOOD VACCINATION PROGRAM IN THE UNITED STATES

RECORDING AND REPORTING OF INFORMATION.

SEC. 2125.[300aa–25] (a) GENERAL RULE.—Each health care provider who administers a vaccine set forth in the Vaccine Injury Table to any person shall record, or ensure that there is recorded, in such person's permanent medical record (or in a permanent office log or file to which a legal representative shall have access upon request) with respect to each such vaccine—

(1) the date of administration of the vaccine,

(2) the vaccine manufacturer and lot number of the vaccine,

(3) the name and address and, if appropriate, the title of the health care provider administering the vaccine, and

(4) any other identifying information on the vaccine required pursuant to regulations promulgated by the Secretary.

(b) REPORTING.—

(1) Each health care provider and vaccine manufacturer shall report to the Secretary—

(A) the occurrence of any event set forth in the Vaccine Injury Table, including the events set forth in section 2114(b) which occur within 7 days of the administration of any vaccine set forth in the Table or within such longer period as is specified in the Table or section,

(B) the occurrence of any contraindicating reaction to a vaccine which is specified in the manufacturer's package insert, and

(C) such other matters as the Secretary may by regulation require.

Reports of the matters referred to in subparagraphs (A) and (B) shall be made beginning 90 days after the effective date of this part.[25] The Secretary shall publish in the Federal Register as soon as practicable after such date a notice of the reporting requirement.

(2) A report under paragraph (1) respecting a vaccine shall include the time periods after the administration of such vaccine within which vaccine-related illnesses, disabilities, injuries, or conditions, the symptoms and manifestations of such illnesses, disabilities, injuries, or conditions, or deaths occur, and the manufacturer and lot number of the vaccine.

(3) The Secretary shall issue the regulations referred to in paragraph (1)(C) within 180 days of the effective date of this part.[26]

(c) RELEASE OF INFORMATION.—

(1) Information which is in the possession of the Federal Government and State and local governments under this section and which may identify an individual shall not be made available under section 552 of title 5, United States Code, or otherwise, to any person except—

(A) the person who received the vaccine, or

[25] Effective December 22, 1987.
[26] Effective December 22, 1987.

(B) the legal representative of such person.

(2) For purposes of paragraph (1), the term "information which may identify an individual" shall be limited to the name, street address, and telephone number of the person who received the vaccine and of that person's legal representative and the medical records of such person relating to the administration of the vaccine, and shall not include the locality and State of vaccine administration, the name of the health care provider who administered the vaccine, the date of the vaccination, or information concerning any reported illness, disability, injury, or condition resulting from the administration of the vaccine, any symptom or manifestation of such illness, disability, injury, or condition, or death resulting from the administration of the vaccine.

(3) Except as provided in paragraph (1), all information reported under this section shall be available to the public.

VACCINE INFORMATION.

SEC. 2126.[300aa–26] (a) GENERAL RULE.—Not later than 1 year after the effective date of this part, the Secretary shall develop and disseminate vaccine information materials for distribution by health care providers to the legal representatives of any child or to any other individual receiving a vaccine set forth in the Vaccine Injury Table. Such materials shall be published in the Federal Register and may be revised.

(b) DEVELOPMENT AND REVISION OF MATERIALS.—Such materials shall be developed or revised—

(1) after notice to the public and 60 days of comment thereon, and

(2) in consultation with the Advisory Commission on Childhood Vaccines, appropriate health care providers and parent organizations, the Centers for Disease Control and Prevention, and the Food and Drug Administration.

(c) INFORMATION REQUIREMENTS.—The information in such materials shall be based on available data and information, shall be presented in understandable terms and shall include—

(1) a concise description of the benefits of the vaccine,

(2) a concise description of the risks associated with the vaccine,

(3) a statement of the availability of the National Vaccine Injury Compensation Program, and

(4) such other relevant information as may be determined by the Secretary.

(d) HEALTH CARE PROVIDER DUTIES.—On and after a date determined by the Secretary which is—

(1) after the Secretary develops the information materials required by subsection (a), and

(2) not later than 6 months after the date such materials are published in the Federal Register,

each health care provider who administers a vaccine set forth in the Vaccine Injury Table shall provide to the legal representatives of any child or to any other individual to whom such provider intends to administer such vaccine a copy of the information mate-

rials developed pursuant to subsection (a), supplemented with visual presentations or oral explanations, in appropriate cases. Such materials shall be provided prior to the administration of such vaccine.

MANDATE FOR SAFER CHILDHOOD VACCINES.

SEC. 2127.[300aa–27] (a) GENERAL RULE.—In the administration of this subtitle and other pertinent laws under the jurisdiction of the Secretary, the Secretary shall—

(1) promote the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market on the effective date of this part[27] and promote the refinement of such vaccines, and

(2) make or assure improvements in, and otherwise use the authorities of the Secretary with respect to, the licensing, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse reaction reporting, and recall of reactogenic lots or batches, of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines.

(b) TASK FORCE.—

(1) The Secretary shall establish a task force on safer childhood vaccines which shall consist of the Director of the National Institutes of Health, the Commissioner of the Food and Drug Administration, and the Director of the Centers for Disease Control.

(2) The Director of the National Institutes of Health shall serve as chairman of the task force.

(3) In consultation with the Advisory Commission on Childhood Vaccines, the task force shall prepare recommendations to the Secretary concerning implementation of the requirements of subsection (a).

(c) REPORT.—Within 2 years after the effective date of this part, and periodically thereafter, the Secretary shall prepare and transmit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report describing the actions taken pursuant to subsection (a) during the preceding 2-year period.

MANUFACTURER RECORDKEEPING AND REPORTING.

SEC. 2128.[300aa–28] (a) GENERAL RULE.—Each vaccine manufacturer of a vaccine set forth in the Vaccine Injury Table or any other vaccine the administration of which is mandated by the law or regulations of any State, shall, with respect to each batch, lot, or other quantity manufactured or licensed after the effective date of this part—

(1) prepare and maintain records documenting the history of the manufacturing, processing, testing, repooling, and reworking of each batch, lot, or other quantity of such vaccine, including the identification of any significant problems encountered in the production, testing, or handling of such batch, lot, or other quantity,

[27] Effective December 22, 1987.

(2) if a safety test on such batch, lot, or other quantity indicates a potential imminent or substantial public health hazard is presented, report to the Secretary within 24 hours of such safety test which the manufacturer (or manufacturer's representative) conducted, including the date of the test, the type of vaccine tested, the identity of the batch, lot, or other quantity tested, whether the batch, lot, or other quantity tested is the product of repooling or reworking of previous batches, lots, or other quantities (and, if so, the identity of the previous batches, lots, or other quantities which were repooled or reworked), the complete test results, and the name and address of the person responsible for conducting the test,

(3) include with each such report a certification signed by a responsible corporate official that such report is true and complete, and

(4) prepare, maintain, and upon request submit to the Secretary product distribution records for each such vaccine by batch, lot, or other quantity number.

(b) SANCTION.—Any vaccine manufacturer who intentionally destroys, alters, falsifies, or conceals any record or report required under paragraph (1) or (2) of subsection (a) shall—

(1) be subject to a civil penalty of up to $100,000 per occurrence, or

(2) be fined $50,000 or imprisoned for not more than 1 year, or both.

Such penalty shall apply to the person who intentionally destroyed, altered, falsified, or concealed such record or report, to the person who directed that such record or report be destroyed, altered, falsified, or concealed, and to the vaccine manufacturer for which such person is an agent, employee, or representative. Each act of destruction, alteration, falsification, or concealment shall be treated as a separate occurrence.

PART D—GENERAL PROVISIONS

CITIZEN'S ACTIONS.

SEC. 2131.[300aa–31] (a) GENERAL RULE.—Except as provided in subsection (b), any person may commence in a district court of the United States a civil action on such person's own behalf against the Secretary where there is alleged a failure of the Secretary to perform any act or duty under this subtitle.

(b) NOTICE.—No action may be commenced under subsection (a) before the date which is 60 days after the person bringing the action has given written notice of intent to commence such action to the Secretary.

(c) COSTS OF LITIGATION.—The court, in issuing any final order in any action under this section, may award costs of litigation (including reasonable attorney and expert witness fees) to any plaintiff who substantially prevails on one or more significant issues in the action.

JUDICIAL REVIEW.

SEC. 2132.[300aa–32] A petition for review of a regulation under this subtitle may be filed in a court of appeals of the United States within 60 days from the date of the promulgation of the regulation or after such date if such petition is based solely on grounds arising after such 60th day.

DEFINITIONS.

SEC. 2133.[28][300aa–33] For purposes of this subtitle:

(1) The term "health care provider" means any licensed health care professional, organization, or institution, whether public or private (including Federal, State, and local departments, agencies, and instrumentalities) under whose authority a vaccine set forth in the Vaccine Injury Table is administered.

(2) The term "legal representative" means a parent or an individual who qualifies as a legal guardian under State law.

(3) The term "manufacturer" means any corporation, organization, or institution, whether public or private (including Federal, State, and local departments, agencies, and instrumentalities), which manufactures, imports, processes, or distributes under its label any vaccine set forth in the Vaccine Injury Table, except that, for purposes of section 2128, such term shall include the manufacturer of any other vaccine covered by that section. The term "manufacture" means to manufacture, import, process, or distribute a vaccine.

(4) The term "significant aggravation" means any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health.

(5) The term "vaccine-related injury or death" means an illness, injury, condition, or death associated with one or more of the vaccines set forth in the Vaccine Injury Table, except that the term does not include an illness, injury, condition, or death associated with an adulterant or contaminant intentionally added to such a vaccine.

(6)(A) The term "Advisory Commission on Childhood Vaccines" means the Commission established under section 2119.

[28] Paragraphs (3) and (5) above appear so as to reflect the probable intent of the Congress, and former paragraph (7) has been struck to reflect such intent. Sections 1714, 1715, and 1716 of Public Law 107–296 (116 Stat. 2320, 2321) made amendments to section 2133 with respect to such paragraphs. Subsequently, section 102(a) of division L of Public Law 108–7 (117 Stat. 528) was enacted, and that section indicated the intent of the Congress to nullify those amendments. That section repealed sections 1714, 1715, and 1716 rather than directly amending paragraphs (3), (5), and (7). (That section also repealed section 1717, which related to effective dates.)

Section 102(b) of Public Law 108–7 provided as follows: "The Public Health Service Act (42 U.S.C. 201 et seq.) shall be applied and administered as if the sections repealed by subsection (a) had never been enacted.". Consistent with that provision, section 2133 is shown above to reflect the assumption that repealing a provision of law that makes a change in an Act has the effect of amending that Act so as to undo the change.

Section 102(c) of such Public Law provides as follows: "No inference shall be drawn from the enactment of sections 1714 through 1717 of the Homeland Security Act of 2002 (Public Law 107-296), or from this repeal, regarding the law prior to enactment of sections 1714 through 1717 of the Homeland Security Act of 2002 (Public Law 107-296). Further, no inference shall be drawn that subsection (a) or (b) affects any change in that prior law, or that Leroy v. Secretary of Health and Human Services, Office of Special Master, No. 02-392V (October 11, 2002), was incorrectly decided.".

(B) The term "Vaccine Injury Table" means the table set out in section 2114.

TERMINATION OF PROGRAM.

SEC. 2134.[300aa–34] (a) REVIEWS.—The Secretary shall review the number of awards of compensation made under the program to petitioners under section 2111 for vaccine-related injuries and deaths associated with the administration of vaccines on or after the effective date of this part[29] as follows:

(1) The Secretary shall review the number of such awards made in the 12-month period beginning on the effective date of this part.

(2) At the end of each 3-month period beginning after the expiration of the 12-month period referred to in paragraph (1) the Secretary shall review the number of such awards made in the 3-month period.

(b) REPORT.—

(1) If in conducting a review under subsection (a) the Secretary determines that at the end of the period reviewed the total number of awards made by the end of that period and accepted under section 2121(a) exceeds the number of awards listed next to the period reviewed in the table in paragraph (2)—

(A) the Secretary shall notify the Congress of such determination, and

(B) beginning 180 days after the receipt by Congress of a notification under paragraph (1), no petition for a vaccine-related injury or death associated with the administration of a vaccine on or after the effective date of this part may be filed under section 2111.

Section 2111(a) and part B shall not apply to civil actions for damages for a vaccine-related injury or death for which a petition may not be filed because of subparagraph (B).

(2) The table referred to in paragraph (1) is as follows:

Period reviewed:	Total number of awards by the end of the period reviewed
12 months after the effective date of part	150
13th through the 15th month after such date	188
16th through the 18th month after such date	225
19th through the 21st month after such date	263
22nd through the 24th month after such date	300
25th through the 27th month after such date	338
28th through the 30th month after such date	375
31st through the 33rd month after such date	413
34th through the 36th month after such date	450
37th through the 39th month after such date	488
40th through the 42nd month after such date	525
43rd through the 45th month after such date	563
46th through the 48th month after such date	600.

[29] Effective December 22, 1987.

PUBLIC HEALTH SERVICE ACT

As Amended Through P.L. 112–240, Enacted January 2, 2013

TITLE XXII—REQUIREMENTS FOR CERTAIN GROUP HEALTH PLANS FOR CERTAIN STATE AND LOCAL EMPLOYEES

SEC. 2201.[300bb–1] STATE AND LOCAL GOVERNMENTAL GROUP HEALTH PLANS MUST PROVIDE CONTINUATION COVERAGE TO CERTAIN INDIVIDUALS.

(a) IN GENERAL.—In accordance with regulations which the Secretary shall prescribe, each group health plan that is maintained by any State that receives funds under this Act, by any political subdivision of such a State, or by any agency or instrumentality of such a State or political subdivision, shall provide, in accordance with this title, that each qualified beneficiary who would lose coverage under the plan as a result of a qualifying event is entitled, under the plan, to elect, within the election period, continuation coverage under the plan.

(b) EXCEPTION FOR CERTAIN PLANS.—Subsection (a) shall not apply to—

(1) any group health plan for any calendar year if all employers maintaining such plan normally employed fewer than 20 employees on a typical business day during the preceding calendar year, or

(2) any group health plan maintained for employees by the government of the District of Columbia or any territory or possession of the United States or any agency or instrumentality.

SEC. 2202.[300bb–2] CONTINUATION COVERAGE.

For purposes of section 2201, the term "continuation coverage" means coverage under the plan which meets the following requirements:

(1) TYPE OF BENEFIT COVERAGE.—The coverage must consist of coverage which, as of the time the coverage is being provided, is identical to the coverage provided under the plan to similarly situated beneficiaries under the plan with respect to whom a qualifying event has not occurred. If coverage is modified under the plan for any group of similarly situated beneficiaries, such coverage shall also be modified in the same manner for all individuals who are qualified beneficiaries under the plan pursuant to this part[1] in connection with such group.

(2) PERIOD OF COVERAGE.—The coverage must extend for at least the period beginning on the date of the qualifying event and ending not earlier than the earliest of the following:

(A) MAXIMUM REQUIRED PERIOD.—

[1] So in law. This title is not divided into parts.

(i) GENERAL RULE FOR TERMINATIONS AND REDUCED HOURS.—In the case of a qualifying event described in section 2203(2), except as provided in clause (ii), the date which is 18 months after the date of the qualifying event.

(ii) SPECIAL RULE FOR MULTIPLE QUALIFYING EVENTS.—If a qualifying event occurs during the 18 months after the date of a qualifying event described in section 2203(2), the date which is 36 months after the date of the qualifying event described in section 2203(2).

(iii) GENERAL RULE FOR OTHER QUALIFYING EVENTS.—In the case of a qualifying event not described in section 2203(2), the date which is 36 months after the date of the qualifying event.

(iv) SPECIAL RULE FOR TAA-ELIGIBLE INDIVIDUALS.—In the case of a qualifying event described in section 2203(2) with respect to a covered employee who is (as of the date that the period of coverage would, but for this clause or clause (v), otherwise terminate under clause (i) or (ii)) a TAA-eligible individual (as defined in section 2205(b)(4)(B)), the period of coverage shall not terminate by reason of clause (i) or (ii), as the case may be, before the later of the date specified in such clause or the date on which such individual ceases to be such a TAA-eligible individual. The preceding sentence shall not require any period of coverage to extend beyond January 1, 2014.

(v) MEDICARE ENTITLEMENT FOLLOWED BY QUALIFYING EVENT.—In the case of a qualifying event described in section 2203(2) that occurs less than 18 months after the date the covered employee became entitled to benefits under title XVIII of the Social Security Act, the period of coverage for qualified beneficiaries other than the covered employee shall not terminate under this subparagraph before the close of the 36-month period beginning on the date the covered employee became so entitled.

(vi) SPECIAL RULE FOR DISABILITY.—In the case of a qualified beneficiary who is determined, under title II or XVI of the Social Security Act, to have been disabled at any time during the first 60 days of continuation coverage under this title, any reference in clause (i) or (ii) to 18 months with respect to such event[2] is deemed a reference to 29 months (with respect to all qualified beneficiaries), but only if the qualified beneficiary has provided notice of such determination under section 2206(3) before the end of such 18 months.

[2] Section 421(a)(1)(A)(ii)(III) of Public Law 104–191 (110 Stat. 2087) provides that the last sentence of subparagraph (A) is amended by striking "with respect to such event,". The amendment cannot be executed because the term to be struck does not appear. (Compare "with respect to such event," and "with respect to such event".)

(B) END OF PLAN.—The date on which the employer ceases to provide any group health plan to any employee.

(C) FAILURE TO PAY PREMIUM.—The date on which coverage ceases under the plan by reason of a failure to make timely payment of any premium required under the plan with respect to the qualified beneficiary. The payment of any premium (other than any payment referred to in the last sentence of paragraph (3)) shall be considered to be timely if made within 30 days after the date due or within such longer period as applies to or under the plan.

(D) GROUP HEALTH PLAN COVERAGE OR MEDICARE ENTITLEMEMT.—The date on which the qualified beneficiary first becomes, after the date of the election—

(i) covered under any other group health plan (as an employee or otherwise) which does not contain any exclusion or limitation with respect to any preexisting condition of such beneficiary (other than such an exclusion or limitation which does not apply to (or is satisfied by) such beneficiary by reason of chapter 100 of the Internal Revenue Code of 1986, part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974, or title XXVII of this Act), or

(ii) entitled to benefits under title XVIII of the Social Security Act.

(E) TERMINATION OF EXTENDED COVERAGE FOR DISABILITY.—In the case of a qualified beneficiary who is disabled at any time during the first 60 days of continuation coverage under this title, the month that begins more than 30 days after the date of the final determination under title II or XVI of the Social Security Act that the qualified beneficiary is no longer disabled.

(3) PREMIUM REQUIREMENTS.—The plan may require payment of a premium for any period of continuation coverage, except that such premium—

(A) shall not exceed 102 percent of the applicable premium for such period, and

(B) may, at the election of the payor, be made in monthly installments.

In no event may the plan require the payment of any premium before the day which is 45 days after the day on which the qualified beneficiary made the initial election for continuation coverage. In the case of an individual described in the last sentence of paragraph (2)(A), any reference in subparagraph (A) of this paragraph to "102 percent" is deemed a reference to "150 percent" for any month after the 18th month of continuation coverage described in clause (i) or (ii) of paragraph (2)(A).

(4) NO REQUIREMENT OF INSURABILITY.—The coverage may not be conditioned upon, or discriminate on the basis of lack of, evidence of insurability.

(5) CONVERSION OPTION.—In the case of a qualified beneficiary whose period of continuation coverage expires under paragraph (2)(A), the plan must, during the 180-day period ending on such expiration date, provide to the qualified bene-

ficiary the option of enrollment under a conversion health plan otherwise generally available under the plan.

SEC. 2203.[300bb–3] QUALIFYING EVENT.

For purposes of this title, the term "qualifying event" means, with respect to any covered employee, any of the following events which, but for the continuation coverage required under this title, would result in the loss of coverage of a qualified beneficiary:

(1) The death of the covered employee.

(2) The termination (other than by reason of such employee's gross misconduct), or reduction of hours, of the covered employee's employment.

(3) The divorce or legal separation of the covered employee from the employee's spouse.

(4) The covered employee becoming entitled to benefits under title XVIII of the Social Security Act.

(5) A dependent child ceasing to be a dependent child under the generally applicable requirements of the plan.

SEC. 2204.[300bb–4] APPLICABLE PREMIUM.

For purposes of this title—

(1) IN GENERAL.—The term "applicable premium" means, with respect to any period of continuation coverage of qualified beneficiaries, the cost to the plan for such period of the coverage for similarly situated beneficiaries with respect to whom a qualifying event has not occurred (without regard to whether such cost is paid by the employer or employee).

(2) SPECIAL RULE FOR SELF-INSURED PLANS.—To the extent that a plan is a self-insured plan—

(A) IN GENERAL.—Except as provided in subparagraph (B), the applicable premium for any period of continuation coverage of qualified beneficiaries shall be equal to a reasonable estimate of the cost of providing coverage for such period for similarly situated beneficiaries which—

(i) is determined on an actuarial basis, and

(ii) takes into account such factors as the Secretary may prescribe in regulations.

(B) DETERMINATION ON BASIS OF PAST COST.—If a plan administrator elects to have this subparagraph apply, the applicable premium for any period of continuation coverage of qualified beneficiaries shall be equal to—

(i) the cost to the plan for similarly situated beneficiaries for the same period occurring during the preceding determination period under paragraph (3), adjusted by

(ii) the percentage increase or decrease in the implicit price deflator of the gross national product (calculated by the Department of Commerce and published in the Survey of Current Business) for the 12-month period ending on the last day of the sixth month of such preceding determination period.

(C) SUBPARAGRAPH (B) NOT TO APPLY WHERE SIGNIFICANT CHANGE.—A plan administrator may not elect to have subparagraph (B) apply in any case in which there is any significant difference, between the determination pe-

riod and the preceding determination period, in coverage under, or in employees covered by, the plan. The determination under the preceding sentence for any determination period shall be made at the same time as the determination under paragraph (3).

(3) DETERMINATION PERIOD.—The determination of any applicable premium shall be made for a period of 12 months and shall be made before the beginning of such period.

SEC. 2205.[300bb–5] ELECTION.

(a) IN GENERAL.—For purposes of this title—

(1) ELECTION PERIOD.—The term "election period" means the period which—

(A) begins not later than the date on which coverage terminates under the plan by reason of a qualifying event,

(B) is of at least 60 days' duration, and

(C) ends not earlier than 60 days after the later of—

(i) the date described in subparagraph (A), or

(ii) in the case of any qualified beneficiary who receives notice under section 2206(4), the date of such notice.

(2) EFFECT OF ELECTION ON OTHER BENEFICIARIES.—Except as otherwise specified in an election, any election of continuation coverage by a qualified beneficiary described in subparagraph (A)(i) or (B) of section 2208(3) shall be deemed to include an election of continuation coverage on behalf of any other qualified beneficiary who would lose coverage under the plan by reason of the qualifying event. If there is a choice among types of coverage under the plan, each qualified beneficiary is entitled to make a separate selection among such types of coverage.

(b) TEMPORARY EXTENSION OF COBRA ELECTION PERIOD FOR CERTAIN INDIVIDUALS.—

(1) IN GENERAL.—In the case of a nonelecting TAA-eligible individual and notwithstanding subsection (a), such individual may elect continuation coverage under this title during the 60-day period that begins on the first day of the month in which the individual becomes a TAA-eligible individual, but only if such election is made not later than 6 months after the date of the TAA-related loss of coverage.

(2) COMMENCEMENT OF COVERAGE; NO REACH-BACK.—Any continuation coverage elected by a TAA-eligible individual under paragraph (1) shall commence at the beginning of the 60-day election period described in such paragraph and shall not include any period prior to such 60-day election period.

(3) PREEXISTING CONDITIONS.—With respect to an individual who elects continuation coverage pursuant to paragraph (1), the period—

(A) beginning on the date of the TAA-related loss of coverage, and

(B) ending on the first day of the 60-day election period described in paragraph (1),

shall be disregarded for purposes of determining the 63-day periods referred to in section 2701(c)(2), section 701(c)(2) of the

Employee Retirement Income Security Act of 1974, and section 9801(c)(2) of the Internal Revenue Code of 1986.

(4) DEFINITIONS.—For purposes of this subsection:

(A) NONELECTING TAA-ELIGIBLE INDIVIDUAL.—The term "nonelecting TAA-eligible individual" means a TAA-eligible individual who—

(i) has a TAA-related loss of coverage; and

(ii) did not elect continuation coverage under this part during the TAA-related election period.

(B) TAA-ELIGIBLE INDIVIDUAL.—The term "TAA-eligible individual" means—

(i) an eligible TAA recipient (as defined in paragraph (2) of section 35(c) of the Internal Revenue Code of 1986), and

(ii) an eligible alternative TAA recipient (as defined in paragraph (3) of such section).

(C) TAA-RELATED ELECTION PERIOD.—The term "TAA-related election period" means, with respect to a TAA-related loss of coverage, the 60-day election period under this part which is a direct consequence of such loss.

(D) TAA-RELATED LOSS OF COVERAGE.—The term "TAA-related loss of coverage" means, with respect to an individual whose separation from employment gives rise to being an TAA-eligible individual, the loss of health benefits coverage associated with such separation.

SEC. 2206.[300bb–6] NOTICE REQUIREMENTS.

In accordance with regulations prescribed by the Secretary—

(1) the group health plan shall provide, at the time of commencement of coverage under the plan, written notice to each covered employee and spouse of the employee (if any) of the rights provided under this subsection,[3]

(2) the employer of an employee under a plan must notify the plan administrator of a qualifying event described in paragraph (1), (2), or (4) of section 2203 within 30 days of the date of the qualifying event,

(3) each covered employee or qualified beneficiary is responsible for notifying the plan administrator of the occurrence of any qualifying event described in paragraph (3) or (5) of section 2203 within 60 days after the date of the qualifying event and each qualified beneficiary who is determined, under title II or XVI of the Social Security Act, to have been disabled at any time during the first 60 days of continuation coverage under this title is responsible for notifying the plan administrator of such determination within 60 days after the date of the determination and for notifying the plan administrator within 30 days after the date of any final determination under such title or titles that the qualified beneficiary is no longer disabled, and

(4) the plan administrator shall notify—

(A) in the case of a qualifying event described in paragraph (1), (2), or (4) of section 2203, any qualified beneficiary with respect to such event, and

[3] So in law. Probably should be "this title".

(B) in the case of a qualifying event described in paragraph (3) or (5) of section 2203 where the covered employee notifies the plan administrator under paragraph (3), any qualified beneficiary with respect to such event,

of such beneficiary's rights under this subsection.[4]

For purposes of paragraph (4), any notification shall be made within 14 days of the date on which the plan administrator is notified under paragraph (2) or (3), whichever is applicable, and any such notification to an individual who is a qualified beneficiary as the spouse of the covered employee shall be treated as notification to all other qualified beneficiaries residing with such spouse at the time such notification is made.

SEC. 2207.[5][300bb–7] ENFORCEMENT.

Any individual who is aggrieved by the failure of a State, political subdivision, or agency or instrumentality thereof, to comply with the requirements of this title may bring an action for appropriate equitable relief.

SEC. 2208.[300bb–8] DEFINITIONS.

For purposes of this title—

(1) GROUP HEALTH PLAN.—The term "group health plan" has the meaning given such term in 5000(b)[6] of the Internal Revenue Code of 1986. Such term shall not include any plan substantially all of the coverage under which is for qualified long-term care services (as defined in section 7702B(c) of such Code).

(2) COVERED EMPLOYEE.—The term "covered employee" means an individual who is (or was) provided coverage under a group health plan by virtue of the performance of services by the individual for 1 or more persons maintaining the plan (including as an employee defined in section 401(c)(1) of the Internal Revenue Code of 1986).

(3) QUALIFIED BENEFICIARY.—

(A) IN GENERAL.—The term "qualified beneficiary" means, with respect to a covered employee under a group health plan, any other individual who, on the day before the qualifying event for that employee, is a beneficiary under the plan—

(i) as the spouse of the covered employee, or

(ii) as the dependent child of the employee.

Such term shall also include a child who is born to or placed for adoption with the covered employee during the period of continuation coverage under this title.[7]

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[4] So in law. Probably should be "this title".

[5] Section 13631(d) of Public Law 103-66 (107 Stat. 643) provides as follows:

(d) CONTINUED COVERAGE OF COSTS OF A PEDIATRIC VACCINE UNDER CERTAIN GROUP HEALTH PLANS.—

(1) REQUIREMENT.—The requirement of this paragraph, with respect to a group health plan for plan years beginning after the date of the enactment of this Act, is that the group health plan not reduce its coverage of the costs of pediatric vaccines (as defined under section 1928(h)(6) of the Social Security Act) below the coverage it provided as of May 1, 1993.

(2) ENFORCEMENT.—For purposes of section 2207 of the Public Health Service Act, the requirement of paragraph (1) is deemed a requirement of title XXII of such Act.

[6] So in law. The word "section" does not appear. See section 102(d) of Public Law 104–191 (110 Stat. 1978).

[7] Indentation is so in law. See section 401(a)(3) of Public Law 104–191 (110 Stat. 2085).

(B) SPECIAL RULE FOR TERMINATIONS AND REDUCED EMPLOYMENT.—In the case of a qualifying event described in section 2203(2), the term "qualified beneficiary" includes the covered employee.

(4) PLAN ADMINISTRATOR.—The term "plan administrator" has the meaning given the term "administrator" by section 3(16)(A) of the Employee Retirement Income Security Act of 1974.

PUBLIC HEALTH SERVICE ACT

As Amended Through P.L. 112–240, Enacted January 2, 2013

TITLE XXIII—RESEARCH WITH RESPECT TO ACQUIRED IMMUNE DEFICIENCY SYNDROME [1]

PART A—ADMINISTRATION OF RESEARCH PROGRAMS

SEC. 2302.[300cc–1] REQUIREMENT OF EXPEDITING AWARDS OF GRANTS AND CONTRACTS FOR RESEARCH.

(a) IN GENERAL.—The Secretary shall expedite the award of grants, contracts, and cooperative agreements for research projects relating to acquired immune deficiency syndrome (including such research projects initiated independently of any solicitation by the Secretary for proposals for such research projects).

(b) TIME LIMITATIONS WITH RESPECT TO CERTAIN APPLICATIONS.—

(1) With respect to programs of grants, contracts, and cooperative agreements described in subsection (a), any application submitted in response to a solicitation by the Secretary for proposals pursuant to such a program—

(A) may not be approved if the application is submitted after the expiration of the 3-month period beginning on the date on which the solicitation is issued; and

(B) shall be awarded, or otherwise finally acted upon, not later than the expiration of the 6-month period beginning on the expiration of the period described in subparagraph (A).

(2) If the Secretary makes a determination that it is not practicable to administer a program referred to in paragraph (1) in accordance with the time limitations described in such paragraph, the Secretary may adjust the time limitations accordingly.

(c) REQUIREMENTS WITH RESPECT TO ADJUSTMENTS IN TIME LIMITATIONS.—With respect to any program for which a determination described in subsection (b)(2) is made, the Secretary shall—

(1) if the determination is made before the Secretary issues a solicitation for proposals pursuant to the program, ensure that the solicitation describes the time limitations as adjusted by the determination; and

(2) if the determination is made after the Secretary issues such a solicitation for proposals, issue a statement describing the time limitations as adjusted by the determination and individually notify, with respect to the determination, each appli-

[1] Subtitle E of title II of Public Law 100–607 (102 Stat. 3108) established various authorities regarding acquired immune deficiency syndrome.

Section 2301 was repealed by section 104(b)(2)(C) of Public Law 109–482.

cant whose application is submitted before the expiration of the 3-month period beginning on the date on which the solicitation was issued.

(d) ANNUAL REPORTS TO CONGRESS.—Except as provided in subsection (e), the Secretary shall annually prepare, for inclusion in the comprehensive report required in section 2301, a report—

(A)[2] summarizing programs for which the Secretary has made a determination described in subsection (b)(2), including a description of the time limitations as adjusted by the determination and including a summary of the solicitation issued by the Secretary for proposals pursuant to the program; and

(B) summarizing applications that—

(i) were submitted pursuant to a program of grants, contracts, or cooperative agreements referred to in paragraph (1) of subsection (b) for which a determination described in paragraph (2) of such subsection has not been made; and

(ii) were not processed in accordance with the time limitations described in such paragraph (1).

(e) QUARTERLY REPORTS FOR FISCAL YEAR 1989.—For fiscal year 1989, the report required in subsection (d) shall, not less than quarterly, be prepared and submitted to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate.

SEC. 2303.[300cc–2] REQUIREMENTS WITH RESPECT TO PROCESSING OF REQUESTS FOR PERSONNEL AND ADMINISTRATIVE SUPPORT.

(a) IN GENERAL.—The Director of the Office of Personnel Management or the Administrator of General Services, as the case may be, shall respond to any priority request made by the Administrator of the Alcohol, Drug Abuse, and Mental Health Administration, the Director of the Centers for Disease Control and Prevention, the Commissioner of Food and Drugs, or the Director of the National Institutes of Health, not later than 21 days after the date on which such request is made. If the Director of the Office of Personnel Management or the Administrator of General Services, as the case may be, does not disapprove a priority request during the 21-day period, the request shall be deemed to be approved.

(b) NOTICE TO SECRETARY AND TO ASSISTANT SECRETARY FOR HEALTH.—The Administrator of the Substance Abuse and Mental Health Services Administration, the Director of the Centers for Disease Control and Prevention, the Commissioner of Food and Drugs, and the Director of the National Institutes of Health, shall, respectively, transmit to the Secretary and the Assistant Secretary for Health a copy of each priority request made under this section by the agency head involved. The copy shall be transmitted on the date on which the priority request involved is made.

(c) DEFINITION OF PRIORITY REQUEST.—For purposes of this section, the term "priority request" means any request that—

(1) is designated as a priority request by the Administrator of the Substance Abuse and Mental Health Services Adminis-

[2] Designations are so in law. Subparagraphs (A) and (B) should probably be designated paragraphs (1) and (2), respectively. Similarly, clauses (i) and (ii) of subparagraph (B) should probably be designated subparagraphs (A) and (B), respectively.

tration, the Director of the Centers for Disease Control and Prevention, the Commissioner of Food and Drugs, or the Director of the National Institutes of Health; and

(2)(A) is made to the Director of the Office of Personnel Management for the allocation of personnel to carry out activities with respect to acquired immune deficiency syndrome; or

(B) is made to the Administrator of General Services for administrative support or space in carrying out such activities.

SEC. 2304.[300cc–3] ESTABLISHMENT OF RESEARCH ADVISORY COMMITTEE.

(a) IN GENERAL.—After consultation with the Commissioner of Food and Drugs, the Secretary, acting through the Director of the National Institute of Allergy and Infectious Diseases, shall establish within such Institute an advisory committee to be known as the AIDS Research Advisory Committee (hereafter in this section referred to as the "Committee").

(b) COMPOSITION.—The Committee shall be composed of physicians whose clinical practice includes a significant number of patients with acquired immune deficiency syndrome.

(c) DUTIES.—The Committee shall—

(1) advise the Director of such Institute (and may provide advice to the Directors of other agencies of the National Institutes of Health, as appropriate) on appropriate research activities to be undertaken with respect to clinical treatment of such syndrome, including advice with respect to—

(A) research on drugs for preventing or minimizing the development of symptoms or conditions arising from infection with the etiologic agent for such syndrome, including recommendations on the projects of research with respect to diagnosing immune deficiency and with respect to predicting, diagnosing, preventing, and treating opportunistic cancers and infectious diseases; and

(B) research on the effectiveness of treating such symptoms or conditions with drugs that—

(i) are not approved by the Commissioner of Food and Drugs for the purpose of treating such symptoms or conditions; and

(ii) are being utilized for such purpose by individuals infected with such etiologic agent;

(2)(A) review ongoing publicly and privately supported research on clinical treatment for acquired immune deficiency syndrome, including research on drugs described in paragraph (1); and

(B) periodically issue, and make available to health care professionals, reports describing and evaluating such research;

(3) conduct studies and convene meetings for the purpose of determining the recommendations among physicians in clinical practice on clinical treatment of acquired immune deficiency syndrome, including treatment with the drugs described in paragraph (1); and

(4) conduct a study for the purpose of developing, with respect to individuals infected with the etiologic agent for acquired immune deficiency syndrome, a consensus among health care professionals on clinical treatments for preventing or

minimizing the development of symptoms or conditions arising from infection with such etiologic agent.

PART B—RESEARCH AUTHORITY

SEC. 2311.[300cc–11] CLINICAL EVALUATION UNITS AT NATIONAL INSTITUTES OF HEALTH.

(a) IN GENERAL.—The Secretary, acting through the Director of the National Cancer Institute and the Director of the National Institute of Allergy and Infectious Diseases, shall for each such Institute establish a clinical evaluation unit at the Clinical Center at the National Institutes of Health. Each of the clinical evaluation units—

(1) shall conduct clinical evaluations of experimental treatments for acquired immune deficiency syndrome developed within the preclinical drug development program, including evaluations of methods of diagnosing immune deficiency and evaluations of methods of predicting, diagnosing, preventing, and treating opportunistic cancers and infectious diseases; and

(2) may conduct clinical evaluations of experimental treatments for such syndrome that are developed by any other national research institute of the National Institutes of Health or by any other entity.

(b) PERSONNEL AND ADMINISTRATIVE SUPPORT.—

(1) For the purposes described in subsection (a), the Secretary, acting through the Director of the National Institutes of Health, shall provide each of the clinical evaluation units required in such subsection—

(A)(i) with not less than 50 beds; or

(ii) with an outpatient clinical capacity equal to not less than twice the outpatient clinical capacity, with respect to acquired immune deficiency syndrome, possessed by the Clinical Center of the National Institutes of Health on June 1, 1988; and

(B) with such personnel, such administrative support, and such other support services as may be necessary.

(2) Facilities, personnel, administrative support, and other support services provided pursuant to paragraph (1) shall be in addition to the number or level of facilities, personnel, administrative support, and other support services that otherwise would be available at the Clinical Center at the National Institutes of Health for the provision of clinical care for individuals with diseases or disorders.

(c) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary.

SEC. 2312.[300cc–12] USE OF INVESTIGATIONAL NEW DRUGS WITH RESPECT TO ACQUIRED IMMUNE DEFICIENCY SYNDROME.

(a) ENCOURAGEMENT OF APPLICATIONS WITH RESPECT TO CLINICAL TRIALS.—

(1) If, in the determination of the Secretary, there is preliminary evidence that a new drug has effectiveness in humans with respect to the prevention or treatment of acquired im-

mune deficiency syndrome, the Secretary shall, through statements published in the Federal Register—

(A) announce the fact of such determination; and

(B) with respect to the new drug involved, encourage an application for an exemption for investigational use of the new drug under regulations issued under section 505(i) of the Federal Food, Drug, and Cosmetic Act.

(2)(A) The AIDS Research Advisory Committee established pursuant to section 2304 shall make recommendations to the Secretary with respect to new drugs appropriate for determinations described in paragraph (1).

(B) The Secretary shall, as soon as is practicable, determine the merits of recommendations received by the Secretary pursuant to subparagraph (A).

(b) ENCOURAGEMENT OF APPLICATIONS WITH RESPECT TO TREATMENT USE IN CIRCUMSTANCES OTHER THAN CLINICAL TRIALS.—

(1) In the case of a new drug with respect to which the Secretary has made a determination described in subsection (a) and with respect to which an exemption is in effect for purposes of section 505(i) of the Federal Food, Drug, and Cosmetic Act, the Secretary shall—

(A) as appropriate, encourage the sponsor of the investigation of the new drug to submit to the Secretary, in accordance with regulations issued under such section, an application to use the drug in the treatment of individuals—

(i) who are infected with the etiologic agent for acquired immune deficiency syndrome; and

(ii) who are not participating in the clinical trials conducted pursuant to such exemption; and

(B) if such an application is approved, encourage, as appropriate, licensed medical practitioners to obtain, in accordance with such regulations, the new drug from such sponsor for the purpose of treating such individuals.

(2) If the sponsor of the investigation of a new drug described in paragraph (1) does not submit to the Secretary an application described in such paragraph (relating to treatment use), the Secretary shall, through statements published in the Federal Register, encourage, as appropriate, licensed medical practitioners to submit to the Secretary such applications in accordance with regulations described in such paragraph.

(c) TECHNICAL ASSISTANCE WITH RESPECT TO TREATMENT USE.—In the case of a new drug with respect to which the Secretary has made a determination described in subsection (a), the Secretary may, directly or through grants or contracts, provide technical assistance with respect to the process of—

(1) submitting to the Secretary applications for exemptions described in paragraph (1)(B) of such subsection;

(2) submitting to the Secretary applications described in subsection (b); and

(3) with respect to sponsors of investigations of new drugs, facilitating the transfer of new drugs from such sponsors to licensed medical practitioners.

(d) DEFINITION.—For purposes of this section, the term "new drug" has the meaning given such term in section 201 of the Federal Food, Drug, and Cosmetic Act.

SEC. 2313.[300cc–13] TERRY BEIRN COMMUNITY-BASED AIDS RESEARCH INITIATIVE.

(a) IN GENERAL.—After consultation with the Commissioner of Food and Drugs, the Director of the National Institutes of Health, acting through the National Institute[3] of Allergy and Infectious Diseases, may make grants to public entities and nonprofit private entities concerned with acquired immune deficiency syndrome, and may enter into contracts with public and private such entities, for the purpose of planning and conducting, in the community involved, clinical trials of experimental treatments for infection with the etiologic agent for such syndrome that are approved by the Commissioner of Food and Drugs for investigational use under regulations issued under section 505 of the Federal Food, Drug, and Cosmetic Act.

(b) REQUIREMENT OF CERTAIN PROJECTS.—

(1) Financial assistance under subsection (a) shall include such assistance to community-based organizations and community health centers for the purpose of—

(A) retaining appropriate medical supervision;

(B) assisting with administration, data collection and record management; and

(C) conducting training of community physicians, nurse practitioners, physicians' assistants and other health professionals for the purpose of conducting clinical trials.

(2)(A) Financial assistance under subsection (a) shall include such assistance for demonstration projects designed to implement and conduct community-based clinical trials in order to provide access to the entire scope of communities affected by infections with the etiologic agent for acquired immune deficiency syndrome, including minorities, hemophiliacs and transfusion-exposed individuals, women, children, users of intravenous drugs, and individuals who are asymptomatic with respect to such infection.

(B) The Director of the National Institutes of Health may not provide financial assistance under this paragraph unless the application for such assistance is approved—

(i) by the Commissioner of Food and Drugs;

(ii) by a duly constituted Institutional Review Board that meets the requirements of part 56 of title 21, Code of Federal Regulations; and

(iii) by the Director of the National Institute of Allergy and Infectious Diseases.

(c) PARTICIPATION OF PRIVATE INDUSTRY, SCHOOLS OF MEDICINE AND PRIMARY PROVIDERS.—Programs carried out with financial assistance provided under subsection (a) shall be designed to encourage private industry and schools of medicine, osteopathic medicine, and existing consortia of primary care providers orga-

[3] So in law. Probably should be "acting through the Director of the National Institute". (Section 2617(b)(1) of Public Law 100–690 expressed the intent to so amend the provision; however, the amendment cannot be executed because the amendatory instructions are to strike "through the National Institutes of Allergy", and this term does not appear in subsection (a) (above).)

nized to conduct clinical research concerning acquired immune deficiency syndrome to participate in, and to support, the clinical trials conducted pursuant to the programs.

(d) REQUIREMENT OF APPLICATION.—The Secretary may not provide financial assistance under subsection (a) unless—

(1) an application for the assistance is submitted to the Secretary;

(2) with respect to carrying out the purpose for which the assistance is to be made, the application provides assurances of compliance satisfactory to the Secretary; and

(3) the application otherwise is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(e) AUTHORIZATION OF APPROPRIATIONS.—

(1) For the purpose of carrying out subsection (b)(1), there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1989 through 1996.

(2) For the purpose of carrying out subsection (b)(2), there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1989 through 1996.

SEC. 2314.[300cc–14] EVALUATION OF CERTAIN TREATMENTS.

(a) ESTABLISHMENT OF PROGRAM.—

(1) After consultation with the AIDS Research Advisory Committee established pursuant to section 2304, the Secretary shall establish a program for the evaluation of drugs that—

(A) are not approved by the Commissioner of Food and Drugs for the purpose of treatments with respect to acquired immune deficiency syndrome; and

(B) are being utilized for such purpose by individuals infected with the etiologic agent for such syndrome.

(2) The program established under paragraph (1) shall include evaluations of the effectiveness and the risks of the treatment involved, including the risks of foregoing treatments with respect to acquired immune deficiency syndrome that are approved by the Commissioner of Food and Drugs.

(b) AUTHORITY WITH RESPECT TO GRANTS AND CONTRACTS.—

(1) For the purpose of conducting evaluations required in subsection (a), the Secretary may make grants to, and enter into cooperative agreements and contracts with, public and nonprofit private entities.

(2) Nonprofit private entities under paragraph (1) may include nonprofit private organizations that—

(A) are established for the purpose of evaluating treatments with respect to acquired immune deficiency syndrome; and

(B) consist primarily of individuals infected with the etiologic agent for such syndrome.

(c) SCIENTIFIC AND ETHICAL GUIDELINES.—

(1) The Secretary shall establish appropriate scientific and ethical guidelines for the conduct of evaluations carried out pursuant to this section. The Secretary may not provide finan-

cial assistance under subsection (b)(1) unless the applicant for such assistance agrees to comply with such guidelines.

(2) The Secretary may establish the guidelines described in paragraph (1) only after consulting with—

(A) physicians whose clinical practice includes a significant number of individuals with acquired immune deficiency syndrome;

(B) individuals who are infected with the etiologic agent for such syndrome; and

(C) other individuals with appropriate expertise or experience.

(d) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary.

SEC. 2315.[300cc–15] SUPPORT OF INTERNATIONAL EFFORTS.

(a) GRANTS AND CONTRACTS FOR RESEARCH.—

(1) Under section 307, the Secretary, acting through the Director of the National Institutes of Health—

(A) shall, for the purpose described in paragraph (2), make grants to, enter into cooperative agreements and contracts with, and provide technical assistance to, international organizations concerned with public health; and

(B) may, for such purpose, provide technical assistance to foreign governments.

(2) The purpose referred to in paragraph (1) is promoting and expediting international research and training concerning the natural history and pathogenesis of the human immunodeficiency virus and the development and evaluation of vaccines and treatments for acquired immune deficiency syndrome and opportunistic infections.

(b) GRANTS AND CONTRACTS FOR ADDITIONAL PURPOSES.—After consultation with the Administrator of the Agency for International Development, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall under section 307 make grants to, enter into contracts with, and provide technical assistance to, international organizations concerned with public health and may provide technical assistance to foreign governments, in order to support—

(1) projects for training individuals with respect to developing skills and technical expertise for use in the prevention, diagnosis, and treatment of acquired immune deficiency syndrome; and

(2) epidemiological research relating to acquired immune deficiency syndrome.

(c) SPECIAL PROGRAMME OF WORLD HEALTH ORGANIZATION.—Support provided by the Secretary pursuant to this section shall be in furtherance of the global strategy of the World Health Organization Special Programme on Acquired Immunodeficiency Syndrome.

(d) PREFERENCES.—In providing grants, cooperative agreements, contracts, and technical assistance under subsections (a) and (b), the Secretary shall—

(1) give preference to activities under such subsections conducted by, or in cooperation with, the World Health Organization; and

(2) with respect to activities carried out under such subsections in the Western Hemisphere, give preference to activities conducted by, or in cooperation with, the Pan American Health Organization or the World Health Organization.

(e) REQUIREMENT OF APPLICATION.—The Secretary may not make a grant or enter into a cooperative agreement or contract under this section unless—

(1) an application for such assistance is submitted to the Secretary;

(2) with respect to carrying out the purpose for which such assistance is to be provided, the application provides assurances of compliance satisfactory to the Secretary; and

(3) the application otherwise is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(f) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each fiscal year.

SEC. 2316.[300cc–16] RESEARCH CENTERS.

(a) IN GENERAL.—

(1) The Secretary, acting through the Director of the National Institute of Allergy and Infectious Diseases, may make grants to, and enter into contracts with, public and nonprofit private entities to assist such entities in planning, establishing, or strengthening, and providing basic operating support for, centers for basic and clinical research into, and training in, advanced diagnostic, prevention, and treatment methods for acquired immune deficiency syndrome.

(2) A grant or contract under paragraph (1) shall be provided in accordance with policies established by the Secretary, acting through the Director of the National Institutes of Health, and after consultation with the advisory council for the National Institute of Allergy and Infectious Diseases.

(3) The Secretary shall ensure that, as appropriate, clinical research programs carried out under paragraph (1) include as research subjects women, children, hemophiliacs, and minorities.

(b) USE OF FINANCIAL ASSISTANCE.—

(1) Financial assistance under subsection (a) may be expended for—

(A) the renovation or leasing of space;

(B) staffing and other basic operating costs, including such patient care costs as are required for clinical research;

(C) clinical training with respect to acquired immune deficiency syndrome (including such training for allied health professionals); and

(D) demonstration purposes, including projects in the long-term monitoring and outpatient treatment of individuals infected with the etiologic agent for such syndrome.

(2) Financial assistance under subsection (a) may not be expended to provide research training for which National Research Service Awards may be provided under section 487.

(c) DURATION OF SUPPORT.—Support of a center under subsection (a) may be for not more than five years. Such period may be extended by the Director for additional periods of not more than five years each if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

(d) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary.

SEC. 2317.[300cc–17] INFORMATION SERVICES.

(a) ESTABLISHMENT OF PROGRAM.—The Secretary shall establish, maintain, and operate a program with respect to information on research, treatment, and prevention activities relating to infection with the etiologic agent for acquired immune deficiency syndrome. The program shall, with respect to the agencies of the Department of Health and Human Services, be integrated and coordinated.

(b) TOLL-FREE TELEPHONE COMMUNICATIONS FOR HEALTH CARE ENTITIES.—

(1) After consultation with the Director of the Office of AIDS Research, the Administrator of the Health Resources and Services Administration, and the Director of the Centers for Disease Control and Prevention, the Secretary shall provide for toll-free telephone communications to provide medical and technical information with respect to acquired immune deficiency syndrome to health care professionals, allied health care providers, and to professionals providing emergency health services.

(2) Information provided pursuant to paragraph (1) shall include—

(A) information on prevention of exposure to, and the transmission of, the etiologic agent for acquired immune deficiency syndrome; and

(B) information contained in the data banks established in subsections (c) and (d).

(c) DATA BANK ON RESEARCH INFORMATION.—

(1) After consultation with the Director of the Office of AIDS Research, the Director of the Centers for Disease Control and Prevention, and the National Library of Medicine, the Secretary shall establish a data bank of information on the results of research with respect to acquired immune deficiency syndrome conducted in the United States and other countries.

(2) In carrying out paragraph (1), the Secretary shall collect, catalog, store, and disseminate the information described in such paragraph. To the extent practicable, the Secretary shall make such information available to researchers, physi-

cians, and other appropriate individuals, of countries other than the United States.

(d) DATA BANK ON CLINICAL TRIALS AND TREATMENTS.—

(1) After consultation with the Commissioner of Food and Drugs, the AIDS Research Advisory Committee established under section 2304, and the Director of the Office of AIDS Research, the Secretary shall, in carrying out subsection (a), establish a data bank of information on clinical trials and treatments with respect to infection with the etiologic agent for acquired immune deficiency syndrome (hereafter in this section referred to as the "Data Bank").

(2) In carrying out paragraph (1), the Secretary shall collect, catalog, store, and disseminate the information described in such paragraph. The Secretary shall disseminate such information through information systems available to individuals infected with the etiologic agent for acquired immune deficiency syndrome, to other members of the public, to health care providers, and to researchers.

(e) REQUIREMENTS WITH RESPECT TO DATA BANK ON CLINICAL TRIALS AND TREATMENTS.—The Data Bank shall include the following:

(1) A registry of clinical trials of experimental treatments for acquired immune deficiency syndrome and related illnesses conducted under regulations promulgated pursuant to section 505 of the Federal Food, Drug and Cosmetic Act that provides a description of the purpose of each experimental drug protocol either with the consent of the protocol sponsor, or when a trial to test efficacy begins. Information provided shall include eligibility criteria and the location of trial sites, and must be forwarded to the Data Bank by the sponsor of the trial not later than 21 days after the approval by the Food and Drug Administration.

(2) Information pertaining to experimental treatments for acquired immune deficiency syndrome that may be available under a treatment investigational new drug application that has been submitted to the Food and Drug Administration pursuant to part 312 of title 21, Code of Federal Regulations. The Data Bank shall also include information pertaining to the results of clinical trials of such treatments, with the consent of the sponsor, of such experimental treatments, including information concerning potential toxicities or adverse effects associated with the use or administration of such experimental treatment.

SEC. 2318.[300cc–18] DEVELOPMENT OF MODEL PROTOCOLS FOR CLINICAL CARE OF INFECTED INDIVIDUALS.

(a) IN GENERAL.—

(1) The Secretary, acting through the Director of the National Institutes of Health and after consultation with the Administrator for Health Care Policy and Research, may make grants to public and nonprofit private entities for the establishment of projects to develop model protocols for the clinical care of individuals infected with the etiologic agent for acquired immune deficiency syndrome, including treatment and prevention of HIV infection and related conditions among women.

(2) The Secretary may not make a grant under paragraph (1) unless—

(A) the applicant for the grant is a provider of comprehensive primary care; or

(B) the applicant for the grant agrees, with respect to the project carried out pursuant to paragraph (1), to enter into a cooperative arrangement with an entity that is a provider of comprehensive primary care.

(b) REQUIREMENT OF PROVISION OF CERTAIN SERVICES.—The Secretary may not make a grant under subsection (a) unless the applicant for the grant agrees that, with respect to patients participating in the project carried out with the grant, services provided pursuant to the grant will include—

(1) monitoring, in clinical laboratories, of the condition of such patients;

(2) clinical intervention for infection with the etiologic agent for acquired immune deficiency syndrome, including measures for the prevention of conditions arising from the infection;

(3) information and counseling on the availability of treatments for such infection approved by the Commissioner of Food and Drugs, on the availability of treatments for such infection not yet approved by the Commissioner, and on the reports issued by the AIDS Research Advisory Committee under section 2304(c)(2)(B);

(4) support groups; and

(5) information on, and referrals to, entities providing appropriate social support services.

(c) LIMITATION ON IMPOSITION OF CHARGES FOR SERVICES.—The Secretary may not make a grant under subsection (a) unless the applicant for the grant agrees that, if the applicant will routinely impose a charge for providing services pursuant to the grant, the applicant will not impose the charge on any individual seeking such services who is unable to pay the charge.

(d) EVALUATION AND REPORTS.—

(1) The Secretary may not make a grant under subsection (a) unless the applicant for the grant agrees, with respect to the project carried out pursuant to subsection (a), to submit to the Secretary—

(A) information sufficient to assist in the replication of the model protocol developed pursuant to the project; and

(B) such reports as the Secretary may require.

(2) The Secretary shall provide for evaluations of projects carried out pursuant to subsection (a) and shall annually submit to the Congress a report describing such projects. The report shall include the findings made as a result of such evaluations and may include any recommendations of the Secretary for appropriate administrative and legislative initiatives with respect to the program established in this section.

(e) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1989 through 1991, and such sums as may be necessary for each of the fiscal years 1994 through 1996.

SEC. 2319.[300cc–19] NATIONAL BLOOD RESOURCE EDUCATION PROGRAM.

After consultation with the Director of the National Heart, Lung, and Blood Institute and the Commissioner of Food and Drugs, the Secretary shall establish a program of research and education regarding blood donations and transfusions to maintain and improve the safety of the blood supply. Education programs shall be directed at health professionals, patients, and the community to—

(1) in the case of the public and patients undergoing treatment—

(A) increase awareness that the process of donating blood is safe;

(B) promote the concept that blood donors are contributors to a national need to maintain an adequate and safe blood supply;

(C) encourage blood donors to donate more than once a year; and

(D) encourage repeat blood donors to recruit new donors;

(2) in the case of health professionals—

(A) improve knowledge, attitudes, and skills of health professionals in the appropriate use of blood and blood components;

(B) increase the awareness and understanding of health professionals regarding the risks versus benefits of blood transfusion; and

(C) encourage health professionals to consider alternatives to the administration of blood or blood components for their patients; and

(3) in the case of the community, increase coordination, communication, and collaboration among community, professional, industry, and government organizations regarding blood donation and transfusion issues.

SEC. 2320.[300cc–20] ADDITIONAL AUTHORITY WITH RESPECT TO RESEARCH.

(a) DATA COLLECTION WITH RESPECT TO NATIONAL PREVALENCE.—

(1) The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may, through representative sampling and other appropriate methodologies, provide for the continuous collection of data on the incidence in the United States of cases of acquired immune deficiency syndrome and of cases of infection with the etiologic agent for such syndrome. The Secretary may carry out the program of data collection directly or through cooperative agreements and contracts with public and nonprofit private entities.

(2) The Secretary shall encourage each State to enter into a cooperative agreement or contract under paragraph (1) with the Secretary in order to facilitate the prompt collection of the most recent accurate data on the incidence of cases described in such paragraph.

(3) The Secretary shall ensure that data collected under paragraph (1) includes data on the demographic characteristics

of the population of individuals with cases described in paragraph (1), including data on specific subpopulations at risk of infection with the etiologic agent for acquired immune deficiency syndrome.

(4) In carrying out this subsection, the Secretary shall, for the purpose of assuring the utility of data collected under this section, request entities with expertise in the methodologies of data collection to provide, as soon as is practicable, assistance to the Secretary and to the States with respect to the development and utilization of uniform methodologies of data collection.

(5) The Secretary shall provide for the dissemination of data collected pursuant to this subsection. In carrying out this paragraph, the Secretary may publish such data as frequently as the Secretary determines to be appropriate with respect to the protection of the public health. The Secretary shall publish such data not less than once each year.

(b) EPIDEMIOLOGICAL AND DEMOGRAPHIC DATA.—

(1) The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall develop an epidemiological data base and shall provide for long-term studies for the purposes of—

(A) collecting information on the demographic characteristics of the population of individuals infected with the etiologic agent for acquired immune deficiency syndrome and the natural history of such infection; and

(B) developing models demonstrating the long-term domestic and international patterns of the transmission of such etiologic agent.

(2) The Secretary may carry out paragraph (1) directly or through grants to, or cooperative agreeements[4] or contracts with, public and nonprofit private entities, including Federal agencies.

(c) LONG-TERM RESEARCH.—The Secretary may make grants to public and nonprofit private entities for the purpose of assisting grantees in conducting long-term research into treatments for acquired immune deficiency syndrome developed from knowledge of the genetic nature of the etiologic agent for such syndrome.

(d) SOCIAL SCIENCES RESEARCH.—The Secretary, acting through the Director of the National Institute of Mental Health, may make grants to public and nonprofit private entities for the purpose of assisting grantees in conducting scientific research into the psychological and social sciences as such sciences relate to acquired immune deficiency syndrome.

(e) AUTHORIZATION OF APPROPRIATIONS.—

(1) For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each fiscal year.

(2) Amounts appropriated pursuant to paragraph (1) to carry out subsection (c) shall remain available until expended.

[4] So in law. Probably should be "agreements".

PART C—RESEARCH TRAINING

SEC. 2341.[300cc–31] FELLOWSHIPS AND TRAINING.

(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control[5], shall establish fellowship and training programs to be conducted by the Centers for Disease Control to train individuals to develop skills in epidemiology, surveillance, testing, counseling, education, information, and laboratory analysis relating to acquired immune deficiency syndrome. Such programs shall be designed to enable health professionals and health personnel trained under such programs to work, after receiving such training, in national and international efforts toward the prevention, diagnosis, and treatment of acquired immune deficiency syndrome.

(b) PROGRAMS CONDUCTED BY NATIONAL INSTITUTE OF MENTAL HEALTH.—The Secretary, acting through the Director of the National Institute of Mental Health, shall conduct or support fellowship and training programs for individuals pursuing graduate or postgraduate study in order to train such individuals to conduct scientific research into the psychological and social sciences as such sciences relate to acquired immune deficiency syndrome.

(c) RELATIONSHIP TO LIMITATION ON NUMBER OF EMPLOYEES.—Any individual receiving a fellowship or receiving training under subsection (a) or (b) shall not be included in any determination of the number of full-time equivalent employees of the Department of Health and Human Services for the purpose of any limitation on the number of such employees established by law prior to, on, or after the date of the enactment of the AIDS Amendments of 1988.

(d) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each fiscal year.

PART D—OFFICE OF AIDS RESEARCH

Subpart I—Interagency Coordination of Activities

SEC. 2351.[300cc–40] ESTABLISHMENT OF OFFICE.

(a) IN GENERAL.—There is established within the National Institutes of Health an office to be known as the Office of AIDS Research. The Office shall be headed by a director, who shall be appointed by the Secretary.

(b) DUTIES.—

(1) INTERAGENCY COORDINATION OF AIDS ACTIVITIES.—With respect to acquired immune deficiency syndrome, the Director of the Office shall plan, coordinate, and evaluate research and other activities conducted or supported by the agencies of the National Institutes of Health. In carrying out the preceding sentence, the Director of the Office shall evaluate the AIDS activities of each of such agencies and shall provide for the periodic reevaluation of such activities.

[5] So in law. Section 312(d)(21) of Public Law 102–531 (106 Stat. 3505) provided that section 2341(a) is amended by striking "Centers for Disease Control" and inserting "Centers for Disease Control and Prevention". The amendment cannot be executed because it does not specify to which of the instances of such term the amendment applies.

(2) CONSULTATIONS.—The Director of the Office shall carry out this subpart (including developing and revising the plan required in section 2353) in consultation with the heads of the agencies of the National Institutes of Health, with the advisory councils of the agencies, and with the advisory council established under section 2352.

(3) COORDINATION.—The Director of the Office shall act as the primary Federal official with responsibility for overseeing all AIDS research conducted or supported by the National Institutes of Health, and

(A) shall serve to represent the National Institutes of Health AIDS Research Program at all relevant Executive branch task forces and committees; and

(B) shall maintain communications with all relevant Public Health Service agencies and with various other departments of the Federal Government, to ensure the timely transmission of information concerning advances in AIDS research and the clinical treatment of acquired immune deficiency syndrome and its related conditions, between these various agencies for dissemination to affected communities and health care providers.

SEC. 2351A.[300cc–40a] MICROBICIDE RESEARCH.

(a) FEDERAL STRATEGIC PLAN.—The Director of the Office shall—

(1) expedite the implementation of the Federal strategic plans required by section 403(a) of the Public Health Service Act (42 U.S.C. 283(a)(5)) regarding the conduct and support of research on, and development of, a microbicide to prevent the transmission of the human immunodeficiency virus; and

(2) review and, as appropriate, revise such plan to prioritize funding and activities relative to their scientific urgency and potential market readiness.

(b) COORDINATION.—In implementing, reviewing, and prioritizing elements of the plan described in subsection (a), the Director of the Office shall consult, as appropriate, with—

(1) representatives of other Federal agencies involved in microbicide research, including the Coordinator of United States Government Activities to Combat HIV/AIDS Globally, the Director of the Centers for Disease Control and Prevention, and the Administrator of the United States Agency for International Development;

(2) the microbicide research and development community; and

(3) health advocates.

SEC. 2352.[300cc–40a] ADVISORY COUNCIL; COORDINATING COMMITTEES.

(a) ADVISORY COUNCIL.—

(1) IN GENERAL.—The Secretary shall establish an advisory council for the purpose of providing advice to the Director of the Office on carrying out this part. (Such council is referred to in this subsection as the "Advisory Council".)

(2) COMPOSITION, COMPENSATION, TERMS, CHAIR, ETC.—Subsections (b) through (g) of section 406 apply to the Advisory

Council to the same extent and in the same manner as such subsections apply to advisory councils for the national research institutes, except that—

(A) in addition to the ex officio members specified in section 406(b)(2), there shall serve as such members of the Advisory Council a representative from the advisory council of each of the National Cancer Institute and the National Institute on Allergy and Infectious Diseases; and

(B) with respect to the other national research institutes, there shall serve as ex officio members of such Council, in addition to such members specified in subparagraph (A), a representative from the advisory council of each of the 2 institutes that receive the greatest funding for AIDS activities.

(b) INDIVIDUAL COORDINATING COMMITTEES REGARDING RESEARCH DISCIPLINES.—

(1) IN GENERAL.—The Director of the Office shall establish, for each research discipline in which any activity under the plan required in section 2353 is carried out, a committee for the purpose of providing advice to the Director of the Office on carrying out this part with respect to such discipline. (Each such committee is referred to in this subsection as a "coordinating committee".)

(2) COMPOSITION.—Each coordinating committee shall be composed of representatives of the agencies of the National Institutes of Health with significant responsibilities regarding the research discipline involved.

SEC. 2353.[300cc–40b] COMPREHENSIVE PLAN FOR EXPENDITURE OF APPROPRIATIONS.

(a) IN GENERAL.—Subject to the provisions of this section and other applicable law, the Director of the Office, in carrying out section 2351, shall—

(1) establish a comprehensive plan for the conduct and support of all AIDS activities of the agencies of the National Institutes of Health (which plan shall be first established under this paragraph not later than 12 months after the date of the enactment of the National Institutes of Health Revitalization Act of 1993);[6]

(2) ensure that the Plan establishes priorities among the AIDS activities that such agencies are authorized to carry out;

(3) ensure that the Plan establishes objectives regarding such activities, describes the means for achieving the objectives, and designates the date by which the objectives are expected to be achieved;

(4) ensure that all amounts appropriated for such activities are expended in accordance with the Plan;

(5) review the Plan not less than annually, and revise the Plan as appropriate; and

(6) ensure that the Plan serves as a broad, binding statement of policies regarding AIDS activities of the agencies, but does not remove the responsibility of the heads of the agencies for the approval of specific programs or projects, or for other

[6] Enacted June 10, 1993.

details of the daily administration of such activities, in accordance with the Plan.

(b) CERTAIN COMPONENTS OF PLAN.—With respect to AIDS activities of the agencies of the National Institutes of Health, the Director of the Office shall ensure that the Plan—

(1) provides for basic research;

(2) provides for applied research;

(3) provides for research that is conducted by the agencies;

(4) provides for research that is supported by the agencies;

(5) provides for proposals developed pursuant to solicitations by the agencies and for proposals developed independently of such solicitations; and

(6) provides for behavioral research and social sciences research.

(c) BUDGET ESTIMATES.—

(1) FULL-FUNDING BUDGET.—

(A) With respect to a fiscal year, the Director of the Office shall prepare and submit directly to the President, for review and transmittal to the Congress, a budget estimate for carrying out the Plan for the fiscal year, after reasonable opportunity for comment (but without change) by the Secretary, the Director of the National Institutes of Health, and the advisory council established under section 2352. The budget estimate shall include an estimate of the number and type of personnel needs for the Office.

(B) The budget estimate submitted under subparagraph (A) shall estimate the amounts necessary for the agencies of the National Institutes of Health to carry out all AIDS activities determined by the Director of the Office to be appropriate, without regard to the probability that such amounts will be appropriated.

(2) ALTERNATIVE BUDGETS.—

(A) With respect to a fiscal year, the Director of the Office shall prepare and submit to the Secretary and the Director of the National Institutes of Health the budget estimates described in subparagraph (B) for carrying out the Plan for the fiscal year. The Secretary and such Director shall consider each of such estimates in making recommendations to the President regarding a budget for the Plan for such year.

(B) With respect to the fiscal year involved, the budget estimates referred to in subparagraph (A) for the Plan are as follows:

(i) The budget estimate submitted under paragraph (1).

(ii) A budget estimate developed on the assumption that the amounts appropriated will be sufficient only for—

(I) continuing the conduct by the agencies of the National Institutes of Health of existing AIDS activities (if approved for continuation), and continuing the support of such activities by the agencies in the case of projects or programs for which

the agencies have made a commitment of continued support; and

(II) carrying out, of activities that are in addition to activities specified in subclause (I), only such activities for which the Director determines there is the most substantial need.

(iii) Such other budget estimates as the Director of the Office determines to be appropriate.

(d) FUNDING.—

(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out AIDS activities under the Plan, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1994 through 1996.

(2) RECEIPT OF FUNDS.—For the first fiscal year beginning after the date on which the Plan first established under section 2353(a)(1) has been in effect for 12 months, and for each subsequent fiscal year, the Director of the Office shall receive directly from the President and the Director of the Office of Management and Budget all funds available for AIDS activities of the National Institutes of Health.

(3) ALLOCATIONS FOR AGENCIES.—

(A) Each fiscal year the Director of the Office shall, from the amounts received under paragraph (2) for the fiscal year, allocate to the agencies of the National Institutes of Health (in accordance with the Plan) all amounts available for such year for carrying out the AIDS activities specified in subsection (c)(2)(B)(ii)(I) for such year. Such allocation shall, to the extent practicable, be made not later than 15 days after the date on which the Director receives amounts under paragraph (2).

(B) Each fiscal year the Director of the Office shall, from the amounts received under paragraph (2) for the fiscal year, allocate to the agencies of the National Institutes of Health (in accordance with the Plan) all amounts available for such year for carrying out AIDS activities that are not referred to in subparagraph (A). Such allocation shall, to the extent practicable, be made not later than 30 days after the date on which the Director receives amounts under paragraph (2).

SEC. 2354.[300cc–41] ADDITIONAL AUTHORITIES.

(a) IN GENERAL.—In carrying out AIDS research, the Director of the Office—

(1) shall develop and expand clinical trials of treatments and therapies for infection with the etiologic agent for acquired immune deficiency syndrome, including such clinical trials for women, infants, children, hemophiliacs, and minorities;

(2) may establish or support the large-scale development and preclinical screening, production, or distribution of specialized biological materials and other therapeutic substances for AIDS research and set standards of safety and care for persons using such materials;

(3) may support—

(A) AIDS research conducted outside the United States by qualified foreign professionals if such research can reasonably be expected to benefit the people of the United States;

(B) collaborative research involving American and foreign participants; and

(C) the training of American scientists abroad and foreign scientists in the United States;

(4) may encourage and coordinate AIDS research conducted by any industrial concern that evidences a particular capability for the conduct of such research;

(5)(A) may acquire, improve, repair, operate, and maintain laboratories, other research facilities, equipment, and such other real or personal property as the Director of the Office determines necessary;

(B) may make grants for the construction or renovation of facilities; and

(C) may acquire, without regard to the Act of March 3, 1877 (40 U.S.C. 34) by lease or otherwise through the Administrator of General Services, buildings or parts of buildings in the District of Columbia or communities located adjacent to the District of Columbia for the use of the National Institutes of Health for a period not to exceed ten years; and

(6) subject to section 405(b)(2) and without regard to section 3324 of title 31, United States Code, and section 3709 of the Revised Statutes (41 U.S.C. 5), may enter into such contracts and cooperative agreements with any public agency, or with any person, firm, association, corporation, or educational institution, as may be necessary to expedite and coordinate research relating to acquired immune deficiency syndrome.

(b) PROJECTS FOR COOPERATION AMONG PUBLIC AND PRIVATE HEALTH ENTITIES.—In carrying out subsection (a), the Director of the Office shall establish projects to promote cooperation among Federal agencies, State, local, and regional public health agencies, and private entities, in research concerning the diagnosis, prevention, and treatment of acquired immune deficiency syndrome.

Subpart II—Emergency Discretionary Fund

SEC. 2356.[300cc–43] EMERGENCY DISCRETIONARY FUND.

(a) IN GENERAL.—

(1) ESTABLISHMENT.—There is established a fund consisting of such amounts as may be appropriated under subsection (g). Subject to the provisions of this section, the Director of the Office, after consultation with the advisory council established under section 2352, may expend amounts in the Fund for the purpose of conducting and supporting such AIDS activities, including projects of AIDS research, as may be authorized in this Act for the National Institutes of Health.

(2) PRECONDITIONS TO USE OF FUND.—Amounts in the Fund may be expended only if—

(A) the Director identifies the particular set of AIDS activities for which such amounts are to be expended;

(B) the set of activities so identified constitutes either a new project or additional AIDS activities for an existing project;

(C) the Director of the Office has made a determination that there is a significant need for such set of activities; and

(D) as of June 30 of the fiscal year preceding the fiscal year in which the determination is made, such need was not provided for in any appropriations Act passed by the House of Representatives to make appropriations for the Departments of Labor, Health and Human Services (including the National Institutes of Health), Education, and related agencies for the fiscal year in which the determination is made.

(3) TWO-YEAR USE OF FUND FOR PROJECT INVOLVED.—In the case of an identified set of AIDS activities, obligations of amounts in the Fund may not be made for such set of activities after the expiration of the 2-year period beginning on the date on which the initial obligation of such amounts is made for such set.

(b) PEER REVIEW.—With respect to an identified set of AIDS activities carried out with amounts in the Fund, this section may not be construed as waiving applicable requirements for peer review.

(c) LIMITATIONS ON USE OF FUND.—

(1) CONSTRUCTION OF FACILITIES.—Amounts in the Fund may not be used for the construction, renovation, or relocation of facilities, or for the acquisition of land.

(2) CONGRESSIONAL DISAPPROVAL OF PROJECTS.—

(A) Amounts in the Fund may not be expended for the fiscal year involved for an identified set of AIDS activities, or a category of AIDS activities, for which—

(i)(I) amounts were made available in an appropriations Act for the preceding fiscal year; and

(II) amounts are not made available in any appropriations Act for the fiscal year involved; or

(ii) amounts are by law prohibited from being expended.

(B) A determination under subparagraph (A)(i) of whether amounts have been made available in appropriations Acts for a fiscal year shall be made without regard to whether such Acts make available amounts for the Fund.

(3) INVESTMENT OF FUND AMOUNTS.—Amounts in the Fund may not be invested.

(d) APPLICABILITY OF LIMITATION REGARDING NUMBER OF EMPLOYEES.—The purposes for which amounts in the Fund may be expended include the employment of individuals necessary to carry out identified sets of AIDS activities approved under subsection (a). Any individual employed under the preceding sentence may not be included in any determination of the number of full-time equivalent employees for the Department of Health and Human Services for the purpose of any limitation on the number of such employees es-

tablished by law prior to, on, or after the date of the enactment of the National Institutes of Health Revitalization Act of 1993.[7]

(e) DEFINITIONS.—For purposes of this section:

(1) The term "Fund" means the fund established in subsection (a).

(2) The term "identified set of AIDS activities" means a particular set of AIDS activities identified under subsection (a)(2)(A).

(f) FUNDING.—

(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of providing amounts for the Fund, there is authorized to be appropriated $100,000,000 for each of the fiscal years 1994 through 1996.

(2) AVAILABILITY.—Amounts appropriated for the Fund are available until expended.

Subpart III—General Provisions

SEC. 2359.[300cc–45] GENERAL PROVISIONS REGARDING THE OFFICE.

(a) ADMINISTRATIVE SUPPORT FOR OFFICE.—The Secretary, acting through the Director of the National Institutes of Health, shall provide administrative support and support services to the Director of the Office and shall ensure that such support takes maximum advantage of existing administrative structures at the agencies of the National Institutes of Health.

(b) EVALUATION.—Not later than 5 years after the date of the enactment of National Institutes of Health Revitalization Act of 1993, the Secretary shall conduct an evaluation to—

(1) determine the effect of this section on the planning and coordination of the AIDS research programs at the institutes, centers and divisions of the National Institutes of Health;

(2) evaluate the extent to which this part has eliminated the duplication of administrative resources among such Institutes, centers and divisions; and

(3) provide recommendations concerning future alterations with respect to this part.

(c) DEFINITIONS.—For purposes of this part:

(1) The term "AIDS activities" means AIDS research and other activities that relate to acquired immune deficiency syndrome.

(2) The term "AIDS research" means research with respect to acquired immune deficiency syndrome.

(3) The term "Office" means the Office of AIDS Research.

(4) The term "Plan" means the plan required in section 2353(a)(1).

PART E—GENERAL PROVISIONS

SEC. 2361.[300cc–51] DEFINITION.

For purposes of this title:

(1) The term "infection", with respect to the etiologic agent for acquired immune deficiency syndrome, includes opportun-

[7] Enacted June 10, 1993.

istic cancers and infectious diseases and any other conditions arising from infection with such etiologic agent.

(2) The term "treatment", with respect to the etiologic agent for acquired immune deficiency syndrome, includes primary and secondary prophylaxis.

December 13, 2013

PUBLIC HEALTH SERVICE ACT

As Amended Through P.L. 112–240, Enacted January 2, 2013

TITLE XXIV—HEALTH SERVICES WITH RESPECT TO ACQUIRED IMMUNE DEFICIENCY SYNDROME [1]

PART A—FORMULA GRANTS TO STATES FOR HOME AND COMMUNITY-BASED HEALTH SERVICES

SEC. 2401.[300dd] ESTABLISHMENT OF PROGRAM.

(a) ALLOTMENTS FOR STATES.—For the purpose described in subsection (b), the Secretary shall for each of the fiscal years 1989 and 1990 make an allotment for each State in an amount determined in accordance with section 2408. The Secretary shall make payments each such fiscal year to each State from the allotment for the State if the Secretary approves for the fiscal year involved an application submitted by the State pursuant to section 2407.

(b) PURPOSE OF GRANTS.—The Secretary may not make payments under subsection (a) for a fiscal year unless the State involved agrees to expend the payments only for the purpose of providing services in accordance with section 2402.

(c) ELIGIBLE INDIVIDUAL DEFINED.—For purposes of this part:

(1) The term "eligible individual" means an individual infected with the etiologic agent for acquired immune deficiency syndrome who either is medically dependent or chronically dependent.

(2) The term "medically dependent" means, with respect to an individual, that the individual has been certified by a physician as—

(A) requiring the routine use of appropriate medical services (which may include home intravenous drug therapy) to prevent or compensate for the individual's serious deterioration, arising from infection with the etiologic agent for acquired immune deficiency syndrome, of physical health or cognitive function, and

(B) being able to avoid long-term or repeated care as an inpatient or resident in a hospital, nursing facility, or other institution if home and community-based health services are provided to the individual.

(3) The term "chronically dependent" means, with respect to an individual, that the individual has been certified by a physician as—

(A) being unable to perform, because of physical or cognitive impairment (without substantial assistance from another individual) arising from infection with the etiologic agent for acquired immune deficiency syndrome, at

[1] See footnote at beginning of title XXIII.

least 2 of the following activities of daily living: bathing, dressing, toileting, transferring, and eating, or

(B) having a similar level of disability due to cognitive impairment (as defined by the Secretary).

(d) HOME AND COMMUNITY-BASED HEALTH SERVICES DEFINED.—For purposes of this part, the term "home and community-based health services"—

(1) means, with respect to an eligible individual, skilled health services furnished to the individual in the individual's home pursuant to a written plan of care established by a health care professional for the provision of such services and items and services described in paragraph (2);

(2) includes—

(A) durable medical equipment,

(B) homemaker/home health aide services and personal care services furnished in the individual's home,

(C) day treatment or other partial hospitalization services,

(D) home intravenous drug therapy (including prescription drugs administered intravenously as part of such therapy), and

(E) routine diagnostic tests administered in the individual's home,

furnished pursuant to such plan of care; but

(3) does not include, except as specifically provided in paragraph (2)—

(A) diagnostic tests,

(B) inpatient hospital services,

(C) nursing facility services, and

(D) prescription drugs.

SEC. 2402.[300dd–1] PROVISIONS WITH RESPECT TO CARRYING OUT PURPOSE OF GRANTS.

(a) REQUIRED USES OF FUNDS.—The Secretary may not make payments under section 2401(a) unless the State involved agrees that the State will—

(1) provide for home and community-based health services for eligible individuals pursuant to written plans of care established by health care professionals for providing such services to such individuals;

(2) provide for the identification, location, and provision of outreach to eligible individuals;

(3) provide for coordinating the provision of services under this part with the provision of similar or related services by public and private entities; and

(4) give priority to the provision of outreach and home and community-based services to eligible individuals with low incomes.

(b) AUTHORITY FOR GRANTS AND CONTRACTS.—A State may make payment for services under subsection (a) through grants to public and nonprofit private entities and through contracts with public and private entities. In providing such financial assistance, a State shall give priority to public and nonprofit private entities that have demonstrated experience in delivering home and commu-

nity-based health services to individuals infected with the etiologic agent for acquired immune deficiency syndrome.

SEC. 2403.[300dd–2] REQUIREMENT OF SUBMISSION OF DESCRIPTION OF INTENDED USES OF GRANT.

The Secretary may not make payments under section 2401(a) to a State for a fiscal year unless—

(1) the State submits to the Secretary a description of the purposes for which the State intends to expend such payments for the fiscal year;

(2) such description provides information relating to the services and activities to be provided, including a description of the manner in which such services and activities will be coordinated with any similar services and activities of public and private entities; and

(3) such description includes information relating to (A) the process for determining which eligible individuals are medically dependent or chronically dependent and (B) the process for establishing written plans of care for the provision of home and community-based health services under this part.

SEC. 2404.[300dd–3] RESTRICTIONS ON USE OF GRANT.

(a) IN GENERAL.—The Secretary may not make payments under section 2401(a) for a fiscal year to a State unless the State agrees that the payments will not be expended—

(1) to provide for items or services described in section 2401(d)(3);

(2) to make cash payments to intended recipients of services;

(3) to purchase or improve real property (other than minor remodeling of existing improvements to real property) or to purchase major medical equipment; or

(4) to satisfy any requirement for the expenditure of non-Federal funds as a condition for the receipt of Federal funds.

(b) LIMITATION ON ADMINISTRATIVE EXPENSES.—The Secretary may not make payments under section 2401(a) for a fiscal year unless the State involved agrees that the State will not expend more than 5 percent of the payments made to the State under such section for administrative expenses with respect to carrying out the purpose of this part.

(c) LIMITATION ON TOTAL PAYMENTS.—

(1) Before March 1, 1989, for fiscal year 1989 and before September 1, 1989, for fiscal year 1990, the Secretary shall determine and publish the national average monthly payments, for extended care services under part A of title XVIII of the Social Security Act, for each resident of a skilled nursing facility the Secretary estimates will be paid in the fiscal year.

(2) The Secretary may not make payments under section 2401(a) for a fiscal year to a State to the extent that the average monthly payments for eligible individuals provided home and community-based health services under this part in the State exceeds 65 percent of the national average monthly payments determined and published for the fiscal year under paragraph (1).

SEC. 2405.[300dd–4] REQUIREMENT OF REPORTS AND AUDITS BY STATES.

(a) REPORTS.—

(1) The Secretary may not make payments under section 2401(a) for a fiscal year unless the State involved agrees to prepare and submit to the Secretary, by not later than January 1 following the fiscal year, an annual report in such form and containing such information as the Secretary determines (after consultation with the States and the Comptroller General of the United States) to be necessary for—

(A) securing a record and a description of the purposes for which payments received by the State pursuant to section 2401(a) were expended and of the recipients of such payments;

(B) determining whether the payments were expended in accordance with the purpose of this part; and

(C) determining the percentage of payments received pursuant to section 2401(a) that were expended by the State for administrative expenses during the fiscal year involved.

(2) Each report by a State under paragraph (1) for a fiscal year also shall include—

(A) information on the number and type of eligible individuals provided home and community-based health services by the State under this part for the fiscal year;

(B) information on the types of home and community-based health services so provided;

(C) information on the average monthly costs of such services and a comparison of such costs with costs of providing services in hospitals, nursing facilities, and similar institutions; and

(D) such other information as the Secretary may require to provide for an evaluation of the program under this part and its cost-effectiveness.

(b) AUDITS.—

(1) The Secretary may not make payments under section 2401(a) for a fiscal year unless the State involved agrees to establish such fiscal control and fund accounting procedures as may be necessary to ensure the proper disbursal of, and accounting for, amounts received by the State under such section.

(2) The Secretary may not make payments under section 2401(a) for a fiscal year unless the State involved agrees that—

(A) the State will provide for—

(i) a financial and compliance audit of such payments; or

(ii) a single financial and compliance audit of each entity administering such payments;

(B) the audit will be performed biennially and will cover expenditures in each fiscal year; and

(C) the audit will be conducted in accordance with standards established by the Comptroller General of the United States for the audit of governmental organizations, programs, activities, and functions.

(3) The Secretary may not make payments under section 2401(a) for a fiscal year unless the State involved agrees that, not later than 30 days after the completion of an audit under paragraph (2), the State will provide a copy of the audit report to the State legislature.

(4) For purposes of paragraph (2), the term "financial and compliance audit" means an audit to determine whether the financial statements of an audited entity present fairly the financial position, and the results of financial operations, of the entity in accordance with generally accepted accounting principles, and whether the entity has complied with laws and regulations that may have a material effect upon the financial statements.

(c) AVAILABILITY TO PUBLIC.—The Secretary may not make payments under section 2401(a) unless the State involved agrees to make copies of the reports and audits described in this section available for public inspection.

(d) EVALUATIONS BY COMPTROLLER GENERAL.—The Comptroller General of the United States shall, from time to time, evaluate the expenditures by the States of payments under section 2401(a) in order to assure that expenditures are consistent with the provisions of this part.

SEC. 2406.[300dd–5] ADDITIONAL REQUIRED AGREEMENTS.

(a)[2] IN GENERAL.—The Secretary may not make payments under section 2401(a) for a fiscal year unless the State involved agrees that—

(1) the legislature of the State will conduct public hearings on the proposed use and distribution of the payments to be received from the allotments for each such fiscal year;

(2)(A) the State will, to the maximum extent practicable, ensure that services provided to an individual pursuant to the program involved will be provided without regard to the ability of the individual to pay for such services and without regard to the current or past health condition of the individual;

(B) if any charges are imposed for the provision of home and community-based health services for which assistance is provided under this part, such charges (i) will be pursuant to a public schedule of charges, (ii) will not be imposed on any eligible individual with an income that does not exceed 100 percent of the official poverty line, and (iii) for an eligible individual with an income that exceeds 100 percent of the official poverty line, will be adjusted to reflect the income of the individual;

(3) the State will provide for periodic independent peer review to assess the quality and appropriateness of home and community-based health services provided by entities that receive funds from the State pursuant to section 2401(a);

(4) the State will permit and cooperate with Federal investigations undertaken under section 2409(e);

(5) the State will maintain State expenditures for home and community-based health services for individuals infected with the etiologic agent for acquired immune deficiency syn-

[2] So in law. This section does not contain a subsection (b).

drome at a level equal to not less than the average level of such expenditures maintained by the State for the 2-year period preceding the fiscal year for which the State is applying to receive payments; and

(6) the State will not make payments from allotments made under section 2401(a) for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to that item or service (i) under any State compensation program, under an insurance policy, under any Federal or State health benefits program, or (ii) by an entity that provides health services on a prepaid basis.

SEC. 2407.[300dd–6] REQUIREMENT OF SUBMISSION OF APPLICATION CONTAINING CERTAIN AGREEMENTS AND ASSURANCES.

The Secretary may not make payments under section 2401(a) to a State for a fiscal year unless—

(1) the State submits to the Secretary an application for the payments containing agreements in accordance with sections 2401 through 2406;

(2) the agreements are made through certification from the chief executive officer of the State;

(3) with respect to such agreements, the application provides assurances of compliance satisfactory to the Secretary;

(4) the application contains the description of intended expenditures required in section 2403; and

(5) the application otherwise is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this part.

SEC. 2408.[300dd–7] DETERMINATION OF AMOUNT OF ALLOTMENTS FOR STATES.

(a) MINIMUM ALLOTMENT.—Subject to the extent of amounts made available in appropriations Acts, the amount of an allotment under section 2401(a) for—

(1) each of the several States, the District of Columbia, and the Commonwealth of Puerto Rico, for a fiscal year shall be the greater of—

(A) $100,000, and

(B) an amount determined under subsection (b); and

(2) each territory of the United States (as defined in section 2413(5)) shall be $25,000.

(b) DETERMINATION UNDER FORMULA.—

(1) The amount referred to in subsection (a)(1)(B) for a State is the product of—

(A) an amount equal to the amount appropriated pursuant to section 2414(a) for the fiscal year involved; and

(B) the ratio of the distribution factor for the State to the sum of the distribution factors for all the States.

(2) In paragraph (1)(B), the term "distribution factor" means, for a State, the product of—

(A) the number in the State of additional cases of acquired immune deficiency syndrome, as indicated by the number of such cases reported to and confirmed by the

Secretary for the most recent fiscal year for which such data are available, and

(B) the ratio (based on the most recent available data) of (i) the average per capita income of individuals in the United States to (ii) the average per capita income of individuals in the State;

except that the distribution factors for all the States and territories shall be proportionally reduced to the extent necessary to assure that the total of the allotments under subsection (a) for all the States and territories for each fiscal year does not exceed the amount appropriated pursuant to section 2414(a) for the fiscal year.

(c) INDIAN TRIBES.—

(1) Upon the request of the governing body of an Indian tribe or tribal organization within a State to the Secretary, the Secretary shall—

(A) reserve from the amount that otherwise would be allotted for the fiscal year to the State under subsection (a) an amount determined in accordance with paragraph (2); and

(B) grant the amount reserved under subparagraph (A) to the Indian tribe or tribal organization serving eligible individuals who are members of the Indian tribe or tribal organization.

(2) The amount reserved under paragraph (1)(A) shall be an amount equal to the product of—

(A) the amount that otherwise would be allotted to the State under subsection (a) for the fiscal year; and

(B) the Secretary's estimate of the proportion of the number of additional cases described in subsection (b)(2)(A) that are attributable to members of the Indian tribe or tribal organization.

(3) The Secretary may not make a grant under paragraph (1)(B) to an Indian tribe or tribal organization unless the Indian tribe or tribal organization submits to the Secretary an application meeting the requirements of such an application under section 2407.

(d) DISPOSITION OF CERTAIN FUNDS APPROPRIATED FOR ALLOTMENTS.—

(1) Amounts described in paragraph (2) shall, in accordance with paragraph (3), be allotted by the Secretary to States receiving payments under section 2401(a) for the fiscal year (other than any State referred to in paragraph (2)(B)).

(2) The amounts referred to in paragraph (1) are any amounts that are not paid to States or territories under section 2401(a) as a result of—

(A) the failure of any State or territory to submit an application under section 2407 within a reasonable time period established by the Secretary; or

(B) any State or territory informing the Secretary that the State or territory does not intend to expend the full amount of the allotment made to the State or territory.

(3) The amount of an allotment under paragraph (1) for a State for a fiscal year shall be an amount equal to the product of—

(A) an amount equal to the amount described in paragraph (2) for the fiscal year involved; and

(B) the ratio determined under subsection (b)(1)(B) for the State.

SEC. 2409.[300dd–8] FAILURE TO COMPLY WITH AGREEMENTS.

(a) REPAYMENT OF PAYMENTS.—

(1) The Secretary may, subject to subsection (c), require a State to repay any payments received by the State under section 2401(a) that the Secretary determines were not expended by the State in accordance with the agreements required to be contained in the application submitted by the State pursuant to section 2407.

(2) If a State fails to make a repayment required in paragraph (1), the Secretary may offset the amount of the repayment against the amount of any payment due to be paid to the State under section 2401(a).

(b) WITHHOLDING OF PAYMENTS.—

(1) The Secretary may, subject to subsection (c), withhold payments due under section 2401(a) if the Secretary determines that the State involved is not expending amounts received under such section in accordance with the agreements required to be contained in the application submitted by the State pursuant to section 2407.

(2) The Secretary shall cease withholding payments from a State under paragraph (1) if the Secretary determines that there are reasonable assurances that the State will expend amounts received under section 2401(a) in accordance with the agreements referred to in such paragraph.

(c) OPPORTUNITY FOR HEARING.—Before requiring repayment of payments under subsection (a)(1), or withholding payments under subsection (b)(1), the Secretary shall provide to the State an opportunity for a hearing conducted within the State.

(d) TECHNICAL VIOLATIONS.—The Secretary may not require repayment under subsection (a)(1), or withhold payments under subsection (b)(1), for a technical violation, as determined by the Secretary, of any agreement required to be contained in the application submitted by the State pursuant to section 2407.

(e) INVESTIGATIONS.—

(1) The Secretary shall conduct in several States in each fiscal year investigations of the expenditure of payments received by the States under section 2401(a) in order to evaluate compliance with the agreements required to be contained in the applications submitted to the Secretary pursuant to section 2407.

(2) Each State, and each entity receiving funds from payments made to a State under section 2401(a), shall make appropriate books, documents, papers, and records available to the Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, for examination, copying, or mechanical reproduction on or off the

premises of the appropriate entity upon a reasonable request therefor.

(3)(A) In conducting any investigation in a State, the Secretary and the Comptroller General of the United States may not make a request for any information not readily available to the State, or to an entity receiving funds from payments made to the State under section 2401(a), or make an unreasonable request for information to be compiled, collected, or transmitted in any form not readily available.

(B) Subparagraph (A) shall not apply to the collection, compilation, or transmittal of data in the course of a judicial proceeding.

SEC. 2410.[300dd–9] PROHIBITION AGAINST CERTAIN FALSE STATEMENTS.

(a) IN GENERAL.—A person may not knowingly make or cause to be made any false statement or representation of a material fact in connection with the furnishing of items or services for which amounts may be paid by a State from payments received by the State under section 2401(a).

(b) CRIMINAL PENALTY FOR VIOLATION OF PROHIBITION.—Any person who violates a prohibition established in subsection (a) may for each violation be fined in accordance with title 18, United States Code, or imprisoned for not more than 5 years, or both.

SEC. 2411.[300dd–10] TECHNICAL ASSISTANCE AND PROVISION BY SECRETARY OF SUPPLIES AND SERVICES IN LIEU OF GRANT FUNDS.

(a) TECHNICAL ASSISTANCE.—Upon the request of a State receiving payments under section 2401(a), the Secretary may, without charge to the State, provide to the State (or to any public or private entity designated by the State) technical assistance with respect to the planning, development, and operation of any program or service carried out pursuant to this part. The Secretary may provide such technical assistance directly, through contract, or through grants.

(b) PROVISION BY SECRETARY OF SUPPLIES AND SERVICES IN LIEU OF GRANT FUNDS.—

(1) Upon the request of a State receiving payments under section 2401(a), the Secretary may, subject to paragraph (2), provide supplies, equipment, and services for the purpose of aiding the State in carrying out this part and, for such purpose, may detail to the State any officer or employee of the Department of Health and Human Services.

(2) With respect to a request described in paragraph (1), the Secretary shall reduce the amount of payments under section 2401(a) to the State by an amount equal to the costs of detailing personnel and the fair market value of any supplies, equipment, or services provided by the Secretary. The Secretary shall, for the payment of expenses incurred in complying with such request, expend the amounts withheld.

SEC. 2412.[300dd–11] REPORT BY SECRETARY.

Not later than March 1, 1990, the Secretary shall report to the Congress on the activities of the States under this part. Such report shall include a recommendation as to whether or not the pro-

gram under this part should be extended beyond fiscal year 1990 and may include any recommendations of the Secretary for appropriate administrative and legislative initiatives.

SEC. 2413.[300dd–12] DEFINITIONS.

For purposes of this part:

(1) The terms "Indian tribe" and "tribal organization" have the same meaning given such terms in sections 4(b) and 4(c) of the Indian Self-Determination and Education Assistance Act.

(2) The term "infected with the etiologic agent for acquired immune deficiency syndrome" includes any condition arising from infection with such etiologic agent.

(3)(A) An individual is considered to have low income if the individual's income does not exceed 200 percent of the official poverty line.

(B) The term "official poverty line" refers, with respect to an individual, to the official poverty line defined by the Office of Management and Budget, and revised annually in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1981, applicable to a family of the size involved.

(4)(A) The term "State" means, except as provided in subparagraph (B), each of the several States, the District of Columbia, the Commonwealth of Puerto Rico, and each territory of the United States.

(B) For purposes of subsections (b) and (d) of section 2408, the term "State" means each of the several States, the District of Columbia, and the Commonwealth of Puerto Rico.

(5) The term "territory of the United States" means each of the following: the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

SEC. 2414.[300dd–13] FUNDING.

(a) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of making allotments under section 2401(a), there are authorized to be appropriated $100,000,000 for each of the fiscal years 1989 and 1990.

(b) AVAILABILITY TO STATES.—Any amounts paid to a State or territory under section 2401(a) shall remain available to the State or territory until the expiration of the 1-year period beginning on the date on which the State or territory receives such amounts.

SEC. 2415.[300dd–14] SUNSET.

Effective with respect to appropriations made for any period after fiscal year 1990, this part is repealed.

PART B—SUBACUTE CARE

SEC. 2421.[300dd–21] DEMONSTRATION PROJECTS.

(a) As used in this section:

(1) The term "individuals infected with the etiologic agent for acquired immune deficiency syndrome" means individuals who have a disease, or are recovering from a disease, attributable to the infection of such individuals with such etiologic agent, and as a result of the effects of such disease, are in need of subacute-care services.

(2) The term "subacute care" means medical and health care services that are required for individuals recovering from acute care episodes that are less intensive than the level of care provided in acute-care hospitals, and includes skilled nursing care, hospice care, and other types of health services provided in other long-term-care facilities.

(b) The Secretary shall conduct three demonstration projects to determine the effectiveness and cost of providing the subacute-care services described in subsection (b) to individuals infected with the etiologic agent for acquired immune deficiency syndrome, and the impact of such services on the health status of such individuals.

(c)(1) The services provided under each demonstration project shall be designed to meet the specific needs of individuals infected with the etiologic agent for acquired immune deficiency syndrome, and shall include—

(A) the care and treatment of such individuals by providing—

(i) subacute care;

(ii) emergency medical care and specialized diagnostic and therapeutic services as needed and where appropriate, either directly or through affiliation with a hospital that has experience in treating individuals with acquired immune deficiency syndrome; and

(iii) case management services to ensure, through existing services and programs whenever possible, appropriate discharge planning for such individuals; and

(B) technical assistance, to other facilities in the region served by such facility, that is directed toward education and training of physicians, nurses, and other health-care professionals in the subacute care and treatment of individuals infected with the etiologic agent for acquired immune deficiency syndrome.

(2) Services provided under each demonstration project may also include—

(A) hospice services;

(B) outpatient care; and

(C) outreach activities in the surrounding community to hospitals and other health-care facilities that serve individuals infected with the etiologic agent for acquired immune deficiency syndrome.

(d) The demonstration projects shall be conducted—

(1) during a 4-year period beginning not later than 9 months after the date of enactment of this section;[3] and

(2) at sites that—

(A) are geographically diverse and located in areas that are appropriate for the provision of the required and authorized services; and

(B) have the highest incidence of cases of acquired immune deficiency syndrome and the greatest need for subacute-care services.

(e) The Secretary shall evaluate the operations of the demonstration projects and shall submit to the Committee on Energy

[3] Enacted on November 4, 1988.

and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate—

(1) not later than 18 months after the beginning of the first project, a preliminary report that contains—

(A) a description of the sites at which the projects are being conducted and of the services being provided in each project; and

(B) a preliminary evaluation of the experience of the projects in the first 12 months of operation; and

(2) not later than 6 months after the completion of the last project, a final report that contains—

(A) an assessment of the costs of subacute care for individuals infected with the etiologic agent for acquired immune deficiency syndrome, including a breakdown of all other sources of funding for the care provided to cover subacute care; and

(B) recommendations for appropriate legislative changes.

(f) Each demonstration project shall provide for other research to be carried out at the site of such demonstration project including—

(1) clinical research on acquired immune deficiency syndrome, concentrating on research on the neurological manifestations resulting from infection with the etiologic agent for such syndrome; and

(2) the study of the psychological and mental health issues related to such syndrome.

(g)(1) To carry out this section, there are authorized to be appropriated $10,000,000 for fiscal year 1989 and such sums as are necessary for each of the fiscal years 1990 through 1992.

(2) Amounts appropriated pursuant to paragraph (1) shall remain available until September 10, 1992.

(h) The Secretary shall enter into an agreement with the Administrator of the Veterans' Administration to ensure that appropriate provision will be made for the furnishing, through demonstration projects, of services to eligible veterans, under contract with the Veterans' Administration pursuant to section 620 of title 38, United States Code.

PART C—OTHER HEALTH SERVICES

SEC. 2431.[300dd–31] GRANTS FOR ANONYMOUS TESTING.

The Secretary may make grants to the States for the purpose of providing opportunities for individuals—

(1) to undergo counseling and testing with respect to the etiologic agent for acquired immune deficiency syndrome without being required to provide any information relating to the identity of the individuals; and

(2) to undergo such counseling and testing through the use of a pseudonym.

SEC. 2432.[300dd–32] REQUIREMENT OF PROVISION OF CERTAIN COUNSELING SERVICES.

(a) COUNSELING BEFORE TESTING.—The Secretary may not make a grant under section 2431 to a State unless the State agrees

that, before testing an individual pursuant to such section, the State will provide to the individual appropriate counseling with respect to acquired immune deficiency syndrome (based on the most recent scientific data relating to such syndrome), including—

(1) measures for the prevention of exposure to, and the transmission of, the etiologic agent for such syndrome;

(2) the accuracy and reliability of the results of such testing;

(3) the significance of the results of such testing, including the potential for developing acquired immune deficiency syndrome; and

(4) encouraging individuals, as appropriate, to undergo testing for such etiologic agent and providing information on the benefits of such testing.

(b) COUNSELING OF INDIVIDUALS WITH NEGATIVE TEST RESULTS.—The Secretary may not make a grant under section 2431 to a State unless the State agrees that, if the results of testing conducted pursuant to such section indicate that an individual is not infected with the etiologic agent for acquired immune deficiency syndrome, the State will review for the individual the information provided pursuant to subsection (a) with respect to such syndrome, including—

(1) the information described in paragraphs (1) through (3) of such subsection; and

(2) the appropriateness of further counseling, testing, and education of the individual with respect to acquired immune deficiency syndrome.

(c) COUNSELING OF INDIVIDUALS WITH POSITIVE TEST RESULTS.—The Secretary may not make a grant under section 2431 to a State unless the State agrees that, if the results of testing conducted pursuant to such section indicate that an individual is infected with the etiologic agent for acquired immune deficiency syndrome, the State will provide to the individual appropriate counseling with respect to such syndrome, including—

(1) reviewing the information described in paragraphs (1) through (3) of subsection (a);

(2) reviewing the appropriateness of further counseling, testing, and education of the individual with respect to acquired immune deficiency syndrome;

(3) the importance of not exposing others to the etiologic agent for acquired immune deficiency syndrome;

(4) the availability in the geographic area of any appropriate services with respect to health care, including mental health care and social and support services;

(5) the benefits of locating and counseling any individual by whom the infected individual may have been exposed to the etiologic agent for acquired immune deficiency syndrome and any individual whom the infected individual may have exposed to such etiologic agent; and

(6) the availability, if any, of the services of public health authorities with respect to locating and counseling any individual described in paragraph (5).

(d) RULE OF CONSTRUCTION WITH RESPECT TO COUNSELING WITHOUT TESTING.—Agreements entered into pursuant to sub-

sections (a) through (c) may not be construed to prohibit any grantee under section 2431 from expending the grant for the purpose of providing counseling services described in such subsections to an individual who will not undergo testing described in such section as a result of the grantee or the individual determining that such testing of the individual is not appropriate.

(e) USE OF FUNDS.—

(1) The purpose of this subpart[4] is to provide for counseling and testing services to prevent and reduce exposure to, and transmission of, the etiologic agent for acquired immune deficiency syndrome.

(2) All individuals receiving counseling pursuant to this subpart are to be counseled about the harmful effects of promiscuous sexual activity and intravenous substance abuse, and the benefits of abstaining from such activities.

(3) None of the fund appropriated to carry out this subpart may be used to provide counseling that is designed to promote or encourage, directly, homosexual or heterosexual sexual activity or intravenous drug abuse.

(4) Paragraph (3) may not be construed to prohibit a counselor who has already performed the counseling of an individual required by paragraph (2), to provide accurate information about means to reduce an individual's risk of exposure to, or the transmission of, the etiologic agent for acquired immune deficiency syndrome, provided that any informational materials used are not obscene.

SEC. 2433.[300dd–33] FUNDING.

For the purpose of grants under section 2431, there are authorized to be appropriated $100,000,000 for each of the fiscal years 1989 and 1990.

[4] Probably should be "part". See section 118(b)(1)(B) of Public Law 102–321 (106 Stat. 348).

PUBLIC HEALTH SERVICE ACT

As Amended Through P.L. 112–240, Enacted January 2, 2013

TITLE XXV—PREVENTION OF ACQUIRED IMMUNE DEFICIENCY SYNDROME [1]

SEC. 2500.[300ee] USE OF FUNDS.

(a) IN GENERAL.—The purpose of this title is to provide for the establishment of education and information programs to prevent and reduce exposure to, and the transmission of, the etiologic agent for acquired immune deficiency syndrome.

(b) CONTENTS OF PROGRAMS.—All programs of education and information receiving funds under this title shall include information about the harmful effects of promiscuous sexual activity and intravenous substance abuse, and the benefits of abstaining from such activities.

(c) LIMITATION.—None of the funds appropriated to carry out this title may be used to provide education or information designed to promote or encourage, directly, homosexual or heterosexual sexual activity or intravenous substance abuse.

(d) CONSTRUCTION.—Subsection (c) may not be construed to restrict the ability of an education program that includes the information required in subsection (b) to provide accurate information about various means to reduce an individual's risk of exposure to, or the transmission of, the etiologic agent for acquired immune deficiency syndrome, provided that any informational materials used are not obscene.

PART A—FORMULA GRANTS TO STATES

SEC. 2501.[300ee–11] ESTABLISHMENT OF PROGRAM.

(a) ALLOTMENTS FOR STATES.—For the purpose described in subsection (b), the Secretary shall for each of the fiscal years 1989 through 1991 make an allotment for each State in an amount determined in accordance with section 2507. The Secretary shall make payments each such fiscal year to each State from the allotment for the State if the Secretary approves for the fiscal year involved an application submitted by the State pursuant to section 2503.

(b) PURPOSE OF GRANTS.—The Secretary may not make payments under subsection (a) for a fiscal year unless the State involved agrees to expend the payments only for the purpose of carrying out, in accordance with section 2502, public information activities with respect to acquired immune deficiency syndrome.

[1] See footnote at beginning of title XXIII.

SEC. 2502.[300ee–12] PROVISIONS WITH RESPECT TO CARRYING OUT PURPOSE OF GRANTS.

A State may expend payments received under section 2501(a)—

(1) to develop, establish, and conduct public information activities relating to the prevention and diagnosis of acquired immune deficiency syndrome for those populations or communities in the State in which there are a significant number of individuals at risk of infection with the etiologic agent for such syndrome;

(2) to develop, establish, and conduct such public information activities for the general public relating to the prevention and diagnosis of such syndrome;

(3) to develop, establish, and conduct activities to reduce risks relating to such syndrome, including research into the prevention of such syndrome;

(4) to conduct demonstration projects for the prevention of such syndrome;

(5) to provide technical assistance to public entities, to nonprofit private entities concerned with such syndrome, to schools, and to employers, for the purpose of developing information programs relating to such syndrome;

(6) with respect to education and training programs for the prevention of such syndrome, to conduct such programs for health professionals (including allied health professionals), public safety workers (including emergency response employees), teachers, school administrators, and other appropriate education personnel;

(7) to conduct appropriate programs for educating school-aged children with respect to such syndrome, after consulting with local school boards;

(8) to make available to physicians and dentists in the State information with respect to acquired immune deficiency syndrome, including measures for the prevention of exposure to, and the transmission of, the etiologic agent for such syndrome (which information is updated not less than annually with the most recently available scientific date[2] relating to such syndrome);

(9) to carry out the initial implementation of recommendations contained in the guidelines and the model curriculum developed under section 253 of the AIDS Amendments of 1988; and

(10) to make grants to public entities, and to nonprofit private entities concerned with acquired immune deficiency syndrome, for the purpose of the development, establishment, and expansion of programs for education directed toward individuals at increased risk of infection with the etiologic agent for such syndrome and activities to reduce the risks of exposure to such etiologic agent, with preference to programs directed toward populations in which there is significant evidence of such infection.

[2] So in law. Probably should be "data".

SEC. 2503.[300ee–13] REQUIREMENT OF SUBMISSION OF APPLICATION CONTAINING CERTAIN AGREEMENTS AND ASSURANCES.

(a) IN GENERAL.—The Secretary may not make payments under section 2501(a) for a fiscal year unless—

(1) the State involved submits to the Secretary a description of the purposes for which the State intends to expend the payments for the fiscal year;

(2) the description identifies the populations, areas, and localities in the State with a need for the services for which amounts may be provided by the State under this part;

(3) the description provides information relating to the programs and activities to be supported and services to be provided, including a description of the manner in which such programs and activities will be coordinated with any similar programs and activities of public and private entities;

(4) the State submits to the Secretary an application for the payments containing agreements in accordance with this part;

(5) the agreements are made through certification from the chief executive officer of the State;

(6) with respect to such agreements, the application provides assurances of compliance satisfactory to the Secretary; and

(7) the application otherwise is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this part.

(b) OPPORTUNITY FOR PUBLIC COMMENT.—The Secretary may not make payments under section 2501(a) for a fiscal year unless the State involved agrees that, in developing and carrying out the description required in subsection (a), the State will provide public notice with respect to the description (including any revisions) and will facilitate comments from interested persons.

SEC. 2504.[300ee–14] RESTRICTIONS ON USE OF GRANT.

(a) IN GENERAL.—The Secretary may not make payments under section 2501(a) for a fiscal year unless the State involved agrees that the payments will not be expended—

(1) to provide inpatient services;

(2) to make cash payments to intended recipients of services;

(3) to purchase or improve real property (other than minor remodeling of existing improvements to real property) or to purchase major medical equipment; or

(4) to satisfy any requirement for the expenditure of non-Federal funds as a condition for the receipt of Federal funds.

(b) LIMITATION ON ADMINISTRATIVE EXPENSES.—The Secretary may not make payments under section 2501(a) for a fiscal year unless the State involved agrees that the State will not expend more than 5 percent of the payments for administrative expenses with respect to carrying out the purpose described in section 2501(b).

SEC. 2505.[300ee–15] REQUIREMENT OF REPORTS AND AUDITS BY STATES.

(a) REPORTS.—The Secretary may not make payments under section 2501(a) for a fiscal year unless the State involved agrees to

prepare and submit to the Secretary an annual report in such form and containing such information as the Secretary determines to be necessary for—

(1) securing a record and a description of the purposes for which payments received by the State pursuant to such section were expended and of the recipients of such payments;

(2) determining whether the payments were expended in accordance with the needs within the State required to be identified pursuant to section 2503(a)(2);

(3) determining whether the payments were expended in accordance with the purpose described in section 2501(b); and

(4) determining the percentage of payments received pursuant to such section that were expended by the State for administrative expenses during the preceding fiscal year.

(b) AUDITS.—

(1) The Secretary may not make payments under section 2501(a) for a fiscal year unless the State involved agrees to establish such fiscal control and fund accounting procedures as may be necessary to ensure the proper disbursal of, and accounting for, amounts received by the State under such section.

(2) The Secretary may not make payments under section 2501(a) for a fiscal year unless the State involved agrees that—

(A) the State will provide for—

(i) a financial and compliance audit of such payments; or

(ii) a single financial and compliance audit of each entity administering such payments;

(B) the audit will be performed biennially and will cover expenditures in each fiscal year; and

(C) the audit will be conducted in accordance with standards established by the Comptroller General of the United States for the audit of governmental organizations, programs, activities, and functions.

(3) The Secretary may not make payments under section 2501(a) for a fiscal year unless the State involved agrees that, not later than 30 days after the completion of an audit under paragraph (2), the State will provide a copy of the audit report to the State legislature.

(4) For purposes of paragraph (2), the term "financial and compliance audit" means an audit to determine whether the financial statements of an audited entity present fairly the financial position, and the results of financial operations, of the entity in accordance with generally accepted accounting principles, and whether the entity has complied with laws and regulations that may have a material effect upon the financial statements.

(c) AVAILABILITY TO PUBLIC.—The Secretary may not make payments under section 2501(a) for a fiscal year unless the State involved agrees to make copies of the reports and audits described in this section available for public inspection.

(d) EVALUATIONS BY COMPTROLLER GENERAL.—The Comptroller General of the United States shall, from time to time, evaluate the expenditures by States of payments received under section

2501(a) in order to ensure that expenditures are consistent with the provisions of this part.

SEC. 2506.[300ee–16] ADDITIONAL REQUIRED AGREEMENTS.

(a) IN GENERAL.—The Secretary may not, except as provided in subsection (b), make payments under section 2501(a) for a fiscal year unless the State involved agrees that—

(1) all programs conducted or supported by the State with such payments will establish objectives for the program and will determine the extent to which the objectives are met;

(2) information provided under this part will be scientifically accurate and factually correct;

(3) in carrying out section 2501(b), the State will give priority to programs described in section 2502(10) for individuals described in such section;

(4) with respect to a State in which there is a substantial number of individuals who are intravenous substance abusers, the State will place priority on activities under this part directed at such substance abusers;

(5) with respect to a State in which there is a significant incidence of reported cases of acquired immune deficiency syndrome, the State will—

(A) for the purpose described in subsection (b) of section 2501, expend not less than 50 percent of payments received under subsection (a) of such section for a fiscal year—

(i) to make grants to public entities, to migrant health centers (as defined in section 329(a)), to community health centers (as defined in section 330(a))[3], and to nonprofit private entities concerned with acquired immune deficiency syndrome; or

(ii) to enter into contracts with public and private entities; and

(B) of the amounts reserved for a fiscal year by the State for expenditures required in subparagraph (A), expend not less than 50 percent to carry out section 2502(10) through grants to nonprofit private entities, including minority entities, concerned with acquired immune deficiency syndrome located in and representative of communities and subpopulations reflecting the local incidence of such syndrome;

(6) with respect to programs carried out pursuant to section 2502(10), the State will ensure that any applicant for a grant under such section agrees—

(A) that any educational or informational materials developed with a grant pursuant to such section will contain material, and be presented in a manner, that is specifically directed toward the group for which such materials are intended;

(B) to provide a description of the manner in which the applicant has planned the program in consultation with, and of the manner in which such applicant will consult during the conduct of the program with—

[3] See footnote for section 217(a).

(i) appropriate local officials and community groups for the area to be served by the program;

(ii) organizations comprised of, and representing, the specific population to which the education or prevention effort is to be directed; and

(iii) individuals having expertise in health education and in the needs of the population to be served;

(C) to provide information demonstrating that the applicant has continuing relationships, or will establish continuing relationships, with a portion of the population in the service area that is at risk of infection with the etiologic agent for acquired immune deficiency syndrome and with public and private entities in such area that provide health or other support services to individuals with such infection;

(D) to provide a description of—

(i) the objectives established by the applicant for the conduct of the program; and

(ii) the methods the applicant will use to evaluate the activities conducted under the program to determine if such objectives are met; and

(E) such other information as the Secretary may prescribe;

(7) with respect to programs carried out pursuant to section 2502(10), the State will give preference to any applicant for a grant pursuant to such section that is located in, has a history of service in, and will serve under the program, any geographic area in which—

(A) there is a significant incidence of acquired immune deficiency syndrome;

(B) there has been a significant increase in the incidence of such syndrome; or

(C) there is a significant risk of becoming infected with the etiologic agent for such syndrome;

(8) the State will establish reasonable criteria to evaluate the effective performance of entities that receive funds from payments made to the State under section 2501(a) and will establish procedures for procedural and substantive independent State review of the failure by the State to provide funds for any such entity;

(9) the State will permit and cooperate with Federal investigations undertaken in accordance with section 2508(e);

(10) the State will maintain State expenditures for services provided pursuant to section 2501 at a level equal to not less than the average level of such expenditures maintained by the State for the 2-year period preceding the fiscal year for which the State is applying to receive payments.

(b) DEFINITION.—For purposes of subsection (a)(5), the term "significant percentage" means at least a percentage of 1 percent of the number of reported cases of acquired immune deficiency syndrome in the United States.

SEC. 2507.[300ee–17] DETERMINATION OF AMOUNT OF ALLOTMENTS FOR STATES.

(a) MINIMUM ALLOTMENT.—Subject to the extent of amounts made available in appropriation Acts, the allotment for a State under section 2501(a) for a fiscal year shall be the greater of—

(1) the applicable amount specified in subsection (b); or

(2) the amount determined in accordance with subsection (c).

(b) DETERMINATION OF MINIMUM ALLOTMENT.—

(1) If the total amount appropriated under section 2514(a) for a fiscal year exceeds $100,000,000, the amount referred to in subsection (a)(1) shall be $300,000 for the fiscal year.

(2) If the total amount appropriated under section 2514(a) for a fiscal year equals or exceeds $50,000,000, but is less than $100,000,000, the amount referred to in subsection (a)(1) shall be $200,000 for the fiscal year.

(3) If the total amount appropriated under section 2514(a) for a fiscal year is less than $50,000,000, the amount referred to in subsection (a)(1) shall be $100,000 for the fiscal year.

(c) DETERMINATION UNDER FORMULA.—

(1) The amount referred to in subsection (a)(2) is the sum of—

(A) the amount determined under paragraph (2); and

(B) the amount determined under paragraph (3).

(2) The amount referred to in paragraph (1)(A) is the product of—

(A) an amount equal to 50 percent of the amounts appropriated pursuant to section 2514(a); and

(B) a percentage equal to the quotient of—

(i) the population of the State involved; divided by

(ii) the population of the United States.

(3) The amount referred to in paragraph (1)(B) is the product of—

(A) an amount equal to 50 percent of the amounts appropriated pursuant to section 2514(a); and

(B) a percentage equal to the quotient of—

(i) the number of additional cases of acquired immune deficiency syndrome reported to and confirmed by the Secretary for the State involved for the most recent fiscal year for which such data is available; divided by

(ii) the number of additional cases of such syndrome reported to and confirmed by the Secretary for the United States for such fiscal year.

(d) DISPOSITION OF CERTAIN FUNDS APPROPRIATED FOR ALLOTMENTS.—

(1) Amounts described in paragraph (2) shall be allotted by the Secretary to States receiving payments under section 2501(a) for the fiscal year (other than any State referred to in paragraph (2)(C)). Such amounts shall be allotted according to a formula established by the Secretary. The formula shall be equivalent to the formula described in this section under which the allotment under section 2501(a) for the State for the fiscal year involved was determined.

(2) The amounts referred to in paragraph (1) are any amounts that are not paid to States under section 2501(a) as a result of—

(A) the failure of any State to submit an application under section 2503;

(B) the failure, in the determination of the Secretary, of any State to prepare within a reasonable period of time such application in compliance with such section; or

(C) any State informing the Secretary that the State does not intend to expend the full amount of the allotment made to the State.

SEC. 2508.[300ee–18] FAILURE TO COMPLY WITH AGREEMENTS.

(a) REPAYMENT OF PAYMENTS.—

(1) The Secretary may, subject to subsection (c), require a State to repay any payments received by the State under section 2501(a) that the Secretary determines were not expended by the State in accordance with the agreements required to be contained in the application submitted by the State pursuant to section 2503.

(2) If a State fails to make a repayment required in paragraph (1), the Secretary may offset the amount of the repayment against the amount of any payment due to be paid to the State under section 2501(a).

(b) WITHHOLDING OF PAYMENTS.—

(1) The Secretary may, subject to subsection (c), withhold payments due under section 2501(a) if the Secretary determines that the State involved is not expending amounts received under such section in accordance with the agreements required to be contained in the application submitted by the State pursuant to section 2503.

(2) The Secretary shall cease withholding payments from a State under paragraph (1) if the Secretary determines that there are reasonable assurances that the State will expend amounts received under section 2501(a) in accordance with the agreements referred to in such paragraph.

(3) The Secretary may not withhold funds under paragraph (1) from a State for a minor failure to comply with the agreements referred to in such paragraph.

(c) OPPORTUNITY FOR HEARING.—Before requiring repayment of payments under subsection (a)(1), or withholding payments under subsection (b)(1), the Secretary shall provide to the State an opportunity for a hearing conducted within the State.

(d) PROMPT RESPONSE TO SERIOUS ALLEGATIONS.—The Secretary shall promptly respond to any complaint of a substantial or serious nature that a State has failed to expend amounts received under section 2501(a) in accordance with the agreements required to be contained in the application submitted by the State pursuant to section 2503.

(e) INVESTIGATIONS.—

(1) The Secretary shall conduct in several States in each fiscal year investigations of the expenditure of payments received by the States under section 2501(a) in order to evaluate compliance with the agreements required to be contained in

the applications submitted to the Secretary pursuant to section 2503.

(2) The Comptroller General of the United States may conduct investigations of the expenditure of funds received under section 2501(a) by a State in order to ensure compliance with the agreements referred to in paragraph (1).

(3) Each State, and each entity receiving funds from payments made to a State under section 2501(a), shall make appropriate books, documents, papers, and records available to the Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, for examination, copying, or mechanical reproduction on or off the premises of the appropriate entity upon a reasonable request therefor.

(4)(A) In conducting any investigation in a State, the Secretary and the Comptroller General of the United States may not make a request for any information not readily available to the State, or to an entity receiving funds from payments made to the State under section 2501(a), or make an unreasonable request for information to be compiled, collected, or transmitted in any form not readily available.

(B) Subparagraph (A) shall not apply to the collection, compilation, or transmittal of data in the course of a judicial proceeding.

SEC. 2509.[300ee–19] PROHIBITION AGAINST CERTAIN FALSE STATEMENTS.

(a) IN GENERAL.—

(1) A person may not knowingly make or cause to be made any false statement or representation of a material fact in connection with the furnishing of items or services for which amounts may be paid by a State from payments received by the State under section 2501(a).

(2) A person with knowledge of the occurrence of any event affecting the right of the person to receive any amounts from payments made to the State under section 2501(a) may not conceal or fail to disclose any such event with the intent of fraudulently securing such amounts.

(b) CRIMINAL PENALTY FOR VIOLATION OF PROHIBITION.—Any person who violates a prohibition established in subsection (a) may for each violation be fined in accordance with title 18, United States Code, or imprisoned for not more than 5 years, or both.

SEC. 2510.[300ee–20] TECHNICAL ASSISTANCE AND PROVISION BY SECRETARY OF SUPPLIES AND SERVICES IN LIEU OF GRANT FUNDS.

(a) TECHNICAL ASSISTANCE.—The Secretary may provide training and technical assistance to States with respect to the planning, development, and operation of any program or service carried out pursuant to this part. The Secretary may provide such technical assistance directly or through grants or contracts.

(b) PROVISION BY SECRETARY OF SUPPLIES AND SERVICES IN LIEU OF GRANT FUNDS.—

(1) Upon the request of a State receiving payments under this part, the Secretary may, subject to paragraph (2), provide supplies, equipment, and services for the purpose of aiding the

State in carrying out such part and, for such purpose, may detail to the State any officer or employee of the Department of Health and Human Services.

(2) With respect to a request described in paragraph (1), the Secretary shall reduce the amount of payments under section 2501(a) to the State by an amount equal to the costs of detailing personnel and the fair market value of any supplies, equipment, or services provided by the Secretary. The Secretary shall, for the payment of expenses incurred in complying with such request, expend the amounts withheld.

SEC. 2511.[300ee–21] EVALUATIONS.

The Secretary shall, directly or through grants or contracts, evaluate the services provided and activities carried out with payments to States under this part.

SEC. 2512.[300ee–22] REPORT BY SECRETARY.

The Secretary shall annually prepare a report on the activities of the States carried out pursuant to this part. Such report may include any recommendations of the Secretary for appropriate administrative and legislative initiatives. The report shall be submitted to the Congress through inclusion in the comprehensive report required in section 2301(a).

SEC. 2513.[300ee–23] DEFINITION.

For purposes of this part, the term "infection with the etiologic agent for acquired immune deficiency syndrome" includes any condition arising from such etiologic agent.

SEC. 2514.[300ee–24] FUNDING.

(a) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of making allotments under section 2501(a), there are authorized to be appropriated $165,000,000 for fiscal year 1989 and such sums as may be necessary for each of the fiscal years 1990 and 1991.

(b) AVAILABILITY TO STATES.—Any amounts paid to a State under section 2501(a) shall remain available to the State until the expiration of the 1-year period beginning on the date on which the State receives such amounts.

PART B—NATIONAL INFORMATION PROGRAMS

SEC. 2521.[300ee–31] AVAILABILITY OF INFORMATION TO GENERAL PUBLIC.

(a) COMPREHENSIVE INFORMATION PLAN.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall annually prepare a comprehensive plan, including a budget, for a National Acquired Immune Deficiency Syndrome Information Program. The plan shall contain provisions to implement the provisions of this title. The Director shall submit such plan to the Secretary. The authority established in this subsection may not be construed to be the exclusive authority for the Director to carry out information activities with respect to acquired immune deficiency syndrome.

(b) CLEARINGHOUSE.—

(1) The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may establish a clearinghouse to make information concerning acquired immune de-

ficiency syndrome available to Federal agencies, States, public and private entities, and the general public.

(2) The clearinghouse may conduct or support programs—

(A) to develop and obtain educational materials, model curricula, and methods directed toward reducing the transmission of the etiologic agent for acquired immune deficiency syndrome;

(B) to provide instruction and support for individuals who provide instruction in methods and techniques of education relating to the prevention of acquired immune deficiency syndrome and instruction in the use of the materials and curricula described in subparagraph (A); and

(C) to conduct, or to provide for the conduct of, the materials, curricula, and methods described in paragraph (1) and the efficacy of such materials, curricula, and methods in preventing infection with the the[4] etiologic agent for acquired immune deficiency syndrome.

(c) TOLL-FREE TELEPHONE COMMUNICATIONS.—The Secretary shall provide for the establishment and maintenance of toll-free telephone communications to provide information to, and respond to queries from, the public concerning acquired immune deficiency syndrome. Such communications shall be available on a 24-hour basis.

SEC. 2522.[300ee–32] PUBLIC INFORMATION CAMPAIGNS.

(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make grants to public entities, and to nonprofit private entities concerned with acquired immune deficiency syndrome, and shall enter into contracts with public and private entities, for the development and delivery of public service announcements and paid advertising messages that warn individuals about activities which place them at risk of infection with the etiologic agent for such syndrome.

(b) REQUIREMENT OF APPLICATION.—The Secretary may not provide financial assistance under subsection (a) unless—

(1) an application for such assistance is submitted to the Secretary;

(2) with respect to carrying out the purpose for which the assistance is to be provided, the application provides assurances of compliance satisfactory to the Secretary; and

(3) the application otherwise is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

SEC. 2523.[300ee–33] PROVISION OF INFORMATION TO UNDERSERVED POPULATIONS.

(a) IN GENERAL.—The Secretary may make grants to public entities, to migrant health centers (as defined in section 329(a)[5]), to community health centers (as defined in section 330(a)), and to nonprofit private entities concerned with acquired immune deficiency syndrome, for the purpose of assisting grantees in providing services to populations of individuals that are underserved with re-

[4] So in law. The word "the" appears twice.
[5] See footnote for section 217(a).

spect to programs providing information on the prevention of exposure to, and the transmission of, the etiologic agent for acquired immune deficiency syndrome.

(b) PREFERENCES IN MAKING GRANTS.—In making grants under subsection (a), the Secretary shall give preference to any applicant for such a grant that has the ability to disseminate rapidly the information described in subsection (a) (including any national organization with such ability).

SEC. 2524.[300ee–34] AUTHORIZATION OF APPROPRIATIONS.

(a) IN GENERAL.—For the purpose of carrying out sections 2521 through 2523, there are authorized to be appropriated $105,000,000 for fiscal year 1989 and such sums as may be necessary for each of the fiscal years 1990 and 1991.

(b) ALLOCATIONS.—

(1) Of the amounts appropriated pursuant to subsection (a), the Secretary shall make available $45,000,000 to carry out section 2522 and $30,000,000 to carry out this part through financial assistance to minority entities for the provision of services to minority populations.

(2) After consultation with the Director of the Office of Minority Health and with the Indian Health Service, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall, not later than 90 days after the date of the enactment of the AIDS Amendments of 1988,[6] publish guidelines to provide procedures for applications for funding pursuant to paragraph (1) and for public comment.

[6] Enacted on November 4, 1988.

PUBLIC HEALTH SERVICE ACT

As Amended Through P.L. 112–240, Enacted January 2, 2013

TITLE XXVI—HIV HEALTH CARE SERVICES PROGRAM [1]

PART A—EMERGENCY RELIEF FOR AREAS WITH SUBSTANTIAL NEED FOR SERVICES [2]

Subpart I—General Grant Provisions

SEC. 2601.[300ff–11] ESTABLISHMENT OF PROGRAM OF GRANTS.

(a) ELIGIBLE AREAS.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall, subject to subsections (b) through (c), make grants in accordance with section 2603 for the purpose of assisting in the provision of the services specified in section 2604 in any metropolitan area for which there has been reported to and confirmed by the Director of the Centers for Disease Control and Prevention a cumulative total of more than 2,000 cases of AIDS during the most recent period of 5 calendar years for which such data are available.

(b) CONTINUED STATUS AS ELIGIBLE AREA.—Notwithstanding any other provision of this section, a metropolitan area that is an eligible area for a fiscal year continues to be an eligible area until the metropolitan area fails, for three consecutive fiscal years—

(1) to meet the requirements of subsection (a); and

(2) to have a cumulative total of 3,000 or more living cases of AIDS (reported to and confirmed by the Director of the Centers for Disease Control and Prevention) as of December 31 of the most recent calendar year for which such data is available.

(c) BOUNDARIES.—For purposes of determining eligibility under this subpart—

(1) with respect to a metropolitan area that received funding under this subpart in fiscal year 2006, the boundaries of

[1] This title was added by Public Law 101–381. Section 2 of that Public Law provides as follows: "It is the purpose of this Act to provide emergency assistance to localities that are disproportionately affected by the Human Immunodeficiency Virus epidemic and to make financial assistance available to States and other public or private nonprofit entities to provide for the development, organization, coordination and operation of more effective and cost efficient systems for the delivery of essential services to individuals and families with HIV disease.".

[2] Section 502 of Public Law 106–345 (114 Stat. 1353) relates to the development of reliable and affordable tests for HIV disease that can rapidly be administered and whose results can rapidly be obtained.

With respect to information for determining formula grants under parts A and B, section 501(a) of Public Law 106–345 (114 Stat. 1352) provides for a study of State surveillance systems regarding cases of infection with the human immunodeficiency virus. Section 501(d)(1) of such Law requires that a report of the findings of the study be submitted not later than 3 years after the date of the enactment of the Law, which was enacted October 20, 2000.

such metropolitan area shall be the boundaries that were in effect for such area for fiscal year 1994; or

(2) with respect to a metropolitan area that becomes eligible to receive funding under this subpart in any fiscal year after fiscal year 2006, the boundaries of such metropolitan area shall be the boundaries that are in effect for such area when such area initially receives funding under this subpart.

SEC. 2602.[300ff–12] ADMINISTRATION AND PLANNING COUNCIL.

(a) ADMINISTRATION.—

(1) IN GENERAL.—Assistance made available under grants awarded under this subpart shall be directed to the chief elected official of the city or urban county that administers the public health agency that provides outpatient and ambulatory services to the greatest number of individuals with AIDS, as reported to and confirmed by the Centers for Disease Control and Prevention, in the eligible area that is awarded such a grant.

(2) REQUIREMENTS.—

(A) IN GENERAL.—To receive assistance under section 2601(a), the chief elected official of the eligible area involved shall—

(i) establish, through intergovernmental agreements with the chief elected officials of the political subdivisions described in subparagraph (B), an administrative mechanism to allocate funds and services based on—

(I) the number of AIDS cases in such subdivisions;

(II) the severity of need for outpatient and ambulatory care services in such subdivisions; and

(III) the health and support services personnel needs of such subdivisions; and

(ii) establish an HIV health services planning council in accordance with subsection (b).

(B) LOCAL POLITICAL SUBDIVISION.—The political subdivisions referred to in subparagraph (A) are those political subdivisions in the eligible area—

(i) that provide HIV-related health services; and

(ii) for which the number of cases reported for purposes of section 2601(a) constitutes not less than 10 percent of the number of such cases reported for the eligible area.

(b) HIV HEALTH SERVICES PLANNING COUNCIL.—

(1) ESTABLISHMENT.—To be eligible for assistance under this subpart, the chief elected official described in subsection (a)(1) shall establish or designate an HIV health services planning council that shall reflect in its composition the demographics of the population of individuals with HIV/AIDS in the eligible area involved, with particular consideration given to disproportionately affected and historically underserved groups and subpopulations. Nominations for membership on the council shall be identified through an open process and candidates shall be selected based on locally delineated and publicized cri-

teria. Such criteria shall include a conflict-of-interest standard that is in accordance with paragraph (5).

(2) REPRESENTATION.—The HIV health services planning council shall include representatives of—

(A) health care providers, including federally qualified health centers;

(B) community-based organizations serving affected populations and AIDS service organizations;

(C) social service providers, including providers of housing and homeless services;

(D) mental health and substance abuse providers;

(E) local public health agencies;

(F) hospital planning agencies or health care planning agencies;

(G) affected communities, including people with HIV/AIDS, members of a Federally recognized Indian tribe as represented in the population, individuals co-infected with hepatitis B or C and historically underserved groups and subpopulations;

(H) nonelected community leaders;

(I) State government (including the State medicaid agency and the agency administering the program under part B);

(J) grantees under subpart II of part C;

(K) grantees under section 2671, or, if none are operating in the area, representatives of organizations with a history of serving children, youth, women, and families living with HIV and operating in the area;

(L) grantees under other Federal HIV programs, including but not limited to providers of HIV prevention services; and

(M) representatives of individuals who formerly were Federal, State, or local prisoners, were released from the custody of the penal system during the preceding 3 years, and had HIV/AIDS as of the date on which the individuals were so released.

(3) METHOD OF PROVIDING FOR COUNCIL.—

(A) IN GENERAL.—In providing for a council for purposes of paragraph (1), a chief elected official receiving a grant under section 2601(a) may establish the council directly or designate an existing entity to serve as the council, subject to subparagraph (B).

(B) CONSIDERATION REGARDING DESIGNATION OF COUNCIL.—In making a determination of whether to establish or designate a council under subparagraph (A), a chief elected official receiving a grant under section 2601(a) shall give priority to the designation of an existing entity that has demonstrated experience in planning for the HIV health care service needs within the eligible area and in the implementation of such plans in addressing those needs. Any existing entity so designated shall be expanded to include a broad representation of the full range of entities that provide such services within the geographic area to be served.

(4) DUTIES.—The planning council established or designated under paragraph (1) shall—

(A) determine the size and demographics of the population of individuals with HIV/AIDS, as well as the size and demographics of the estimated population of individuals with HIV/AIDS who are unaware of their HIV status;

(B) determine the needs of such population, with particular attention to—

(i) individuals with HIV/AIDS who know their HIV status and are not receiving HIV-related services;

(ii) disparities in access and services among affected subpopulations and historically underserved communities; and

(iii) individuals with HIV/AIDS who do not know their HIV status;

(C) establish priorities for the allocation of funds within the eligible area, including how best to meet each such priority and additional factors that a grantee should consider in allocating funds under a grant based on the—

(i) size and demographics of the population of individuals with HIV/AIDS (as determined under subparagraph (A)) and the needs of such population (as determined under subparagraph (B));

(ii) demonstrated (or probable) cost effectiveness and outcome effectiveness of proposed strategies and interventions, to the extent that data are reasonably available;

(iii) priorities of the communities with HIV/AIDS for whom the services are intended;

(iv) coordination in the provision of services to such individuals with programs for HIV prevention and for the prevention and treatment of substance abuse, including programs that provide comprehensive treatment for such abuse;

(v) availability of other governmental and nongovernmental resources, including the State medicaid plan under title XIX of the Social Security Act and the State Children's Health Insurance Program under title XXI of such Act to cover health care costs of eligible individuals and families with HIV/AIDS; and

(vi) capacity development needs resulting from disparities in the availability of HIV-related services in historically underserved communities;

(D) develop a comprehensive plan for the organization and delivery of health and support services described in section 2604 that—

(i) includes a strategy for identifying individuals who know their HIV status and are not receiving such services and for informing the individuals of and enabling the individuals to utilize the services, giving particular attention to eliminating disparities in access and services among affected subpopulations and historically underserved communities, and including dis-

crete goals, a timetable, and an appropriate allocation of funds;

(ii) includes a strategy to coordinate the provision of such services with programs for HIV prevention (including outreach and early intervention) and for the prevention and treatment of substance abuse (including programs that provide comprehensive treatment services for such abuse);

(iii) is compatible with any State or local plan for the provision of services to individuals with HIV/AIDS; and

(iv) includes a strategy, coordinated as appropriate with other community strategies and efforts, including discrete goals, a timetable, and appropriate funding, for identifying individuals with HIV/AIDS who do not know their HIV status, making such individuals aware of such status, and enabling such individuals to use the health and support services described in section 2604, with particular attention to reducing barriers to routine testing and disparities in access and services among affected subpopulations and historically underserved communities;

(E) assess the efficiency of the administrative mechanism in rapidly allocating funds to the areas of greatest need within the eligible area, and at the discretion of the planning council, assess the effectiveness, either directly or through contractual arrangements, of the services offered in meeting the identified needs;

(F) participate in the development of the statewide coordinated statement of need initiated by the State public health agency responsible for administering grants under part B;

(G) establish methods for obtaining input on community needs and priorities which may include public meetings (in accordance with paragraph (7)), conducting focus groups, and convening ad-hoc panels; and

(H) coordinate with Federal grantees that provide HIV-related services within the eligible area.

(5) CONFLICTS OF INTEREST.—

(A) IN GENERAL.—The planning council under paragraph (1) may not be directly involved in the administration of a grant under section 2601(a). With respect to compliance with the preceding sentence, the planning council may not designate (or otherwise be involved in the selection of) particular entities as recipients of any of the amounts provided in the grant.

(B) REQUIRED AGREEMENTS.—An individual may serve on the planning council under paragraph (1) only if the individual agrees that if the individual has a financial interest in an entity, if the individual is an employee of a public or private entity, or if the individual is a member of a public or private organization, and such entity or organization is seeking amounts from a grant under section 2601(a), the individual will not, with respect to the purpose for which

the entity seeks such amounts, participate (directly or in an advisory capacity) in the process of selecting entities to receive such amounts for such purpose.

(C) COMPOSITION OF COUNCIL.—The following applies regarding the membership of a planning council under paragraph (1):

(i) Not less than 33 percent of the council shall be individuals who are receiving HIV-related services pursuant to a grant under section 2601(a), are not officers, employees, or consultants to any entity that receives amounts from such a grant, and do not represent any such entity, and reflect the demographics of the population of individuals with HIV/AIDS as determined under paragraph (4)(A). For purposes of the preceding sentence, an individual shall be considered to be receiving such services if the individual is a parent of, or a caregiver for, a minor child who is receiving such services.

(ii) With respect to membership on the planning council, clause (i) may not be construed as having any effect on entities that receive funds from grants under any of parts B through F but do not receive funds from grants under section 2601(a), on officers or employees of such entities, or on individuals who represent such entities.

(6) GRIEVANCE PROCEDURES.—A planning council under paragraph (1) shall develop procedures for addressing grievances with respect to funding under this subpart, including procedures for submitting grievances that cannot be resolved to binding arbitration. Such procedures shall be described in the by-laws of the planning council and be consistent with the requirements of subsection (c).

(7) PUBLIC DELIBERATIONS.—With respect to a planning council under paragraph (1), the following applies:

(A) The council may not be chaired solely by an employee of the grantee under section 2601(a).

(B) In accordance with criteria established by the Secretary:

(i) The meetings of the council shall be open to the public and shall be held only after adequate notice to the public.

(ii) The records, reports, transcripts, minutes, agenda, or other documents which were made available to or prepared for or by the council shall be available for public inspection and copying at a single location.

(iii) Detailed minutes of each meeting of the council shall be kept. The accuracy of all minutes shall be certified to by the chair of the council.

(iv) This subparagraph does not apply to any disclosure of information of a personal nature that would constitute a clearly unwarranted invasion of personal privacy, including any disclosure of medical information or personnel matters.

(c)[3] GRIEVANCE PROCEDURES.—

(1) FEDERAL RESPONSIBILITY.—

(A) MODELS.—The Secretary shall, through a process that includes consultations with grantees under this subpart and public and private experts in grievance procedures, arbitration, and mediation, develop model grievance procedures that may be implemented by the planning council under subsection (b)(1) and grantees under this subpart. Such model procedures shall describe the elements that must be addressed in establishing local grievance procedures and provide grantees with flexibility in the design of such local procedures.

(B) REVIEW.—The Secretary shall review grievance procedures established by the planning council and grantees under this subpart to determine if such procedures are adequate. In making such a determination, the Secretary shall assess whether such procedures permit legitimate grievances to be filed, evaluated, and resolved at the local level.

(2) GRANTEES.—To be eligible to receive funds under this subpart, a grantee shall develop grievance procedures that are determined by the Secretary to be consistent with the model procedures developed under paragraph (1)(A). Such procedures shall include a process for submitting grievances to binding arbitration.

(d) PROCESS FOR ESTABLISHING ALLOCATION PRIORITIES.—Promptly after the date of the submission of the report required in section 501(b) of the Ryan White CARE Act Amendments of 2000[4] (relating to the relationship between epidemiological measures and health care for certain individuals with HIV/AIDS), the Secretary, in consultation with planning councils and entities that receive amounts from grants under section 2601(a) or 2611, shall develop epidemiologic measures—

(1) for establishing the number of individuals living with HIV/AIDS who are not receiving HIV-related health services; and

(2) for carrying out the duties under subsection (b)(4) and section 2617(b).

(e) TRAINING GUIDANCE AND MATERIALS.—The Secretary shall provide to each chief elected official receiving a grant under section 2601(a) guidelines and materials for training members of the planning council under paragraph (1) regarding the duties of the council.

SEC. 2603.[300ff–13] TYPE AND DISTRIBUTION OF GRANTS.

(a) GRANTS BASED ON RELATIVE NEED OF AREA.—

(1) IN GENERAL.—In carrying out section 2601(a), the Secretary shall make a grant for each eligible area for which an application under section 2605(a) has been approved. Each

[3] Subsection (c) was added by an amendment to subsection (b). Section 3(b)(1)(F) of Public Law 104–146 (110 Stat. 1348) provided that subsection (b) of section 2602 is amended "by adding at the end thereof the following:", and then added paragraphs (5) and (6) and subsection (c).

[4] Public Law 106–345 (114 Stat. 1352). Section 501(d)(2) of such Law requires that the report be submitted not later than 2 years after the date of the enactment of the Law, which was enacted October 20, 2000.

such grant shall be made in an amount determined in accordance with paragraph (3).

(2) EXPEDITED DISTRIBUTION.—Not later than 60 days after an appropriation becomes available to carry out this subpart for a fiscal year, the Secretary shall, except in the case of waivers granted under section 2605(c), disburse 66⅔ percent of the amount made available under section 2610(b) for carrying out this subpart for such fiscal year through grants to eligible areas under section 2601(a), in accordance with paragraphs (3) and (4).

(3) AMOUNT OF GRANT.—

(A) IN GENERAL.—Subject to the extent of amounts made available in appropriations Acts, a grant made for purposes of this paragraph to an eligible area shall be made in an amount equal to the product of—

(i) an amount equal to the amount available for distribution under paragraph (2) for the fiscal year involved; and

(ii) the percentage constituted by the ratio of the distribution factor for the eligible area to the sum of the respective distribution factors for all eligible areas;

which product shall then, as applicable, be increased under paragraph (4).

(B) DISTRIBUTION FACTOR.—For purposes of subparagraph (A)(ii), the term "distribution factor" means an amount equal to the estimated number of living cases of AIDS[5] in the eligible area involved, as determined under subparagraph (C).

(C) LIVING CASES OF HIV/AIDS.—

(i) REQUIREMENT OF NAMES-BASED REPORTING.—Except as provided in clause (ii), the number determined under this subparagraph for an eligible area for a fiscal year for purposes of subparagraph (B) is the number of living names-based cases of HIV/AIDS that, as of December 31 of the most recent calendar year for which such data is available, have been reported to and confirmed by the Director of the Centers for Disease Control and Prevention.

(ii) TRANSITION PERIOD; EXEMPTION REGARDING NON-AIDS CASES.—For each of the fiscal years 2007 through 2012, an eligible area is, subject to clauses (iii) through (v), exempt from the requirement under clause (i) that living names-based non-AIDS cases of HIV be reported unless—

(I) a system was in operation as of December 31, 2005, that provides sufficiently accurate and reliable names-based reporting of such cases

[5] Section 102(b)(1) of Public Law 109–415 provides as follows:

(1) in subparagraph (B), by striking "estimated living cases of acquired immune deficiency syndrome" and inserting "living cases of HIV/AIDS (reported to and confirmed by the Director of the Centers for Disease Control and Prevention)"; and

Such amendment could not be executed because the words "number of" probably should appear before "living cases" in the matter purported to be struck.

throughout the State in which the area is located, subject to clause (viii); or

(II) no later than the beginning of fiscal year 2008 or a subsequent fiscal year through fiscal year 2012, the Secretary, in consultation with the chief executive of the State in which the area is located, determines that a system has become operational in the State that provides sufficiently accurate and reliable names-based reporting of such cases throughout the State.

(iii) REQUIREMENTS FOR EXEMPTION FOR FISCAL YEAR 2007.—For fiscal year 2007, an exemption under clause (ii) for an eligible area applies only if, by October 1, 2006—

(I)(aa) the State in which the area is located had submitted to the Secretary a plan for making the transition to sufficiently accurate and reliable names-based reporting of living non-AIDS cases of HIV; or

(bb) all statutory changes necessary to provide for sufficiently accurate and reliable reporting of such cases had been made; and

(II) the State had agreed that, by April 1, 2008, the State will begin accurate and reliable names-based reporting of such cases, except that such agreement is not required to provide that, as of such date, the system for such reporting be fully sufficient with respect to accuracy and reliability throughout the area.

(iv) REQUIREMENT FOR EXEMPTION AS OF FISCAL YEAR 2008.—For each of the fiscal years 2008 through 2012, an exemption under clause (ii) for an eligible area applies only if, as of April 1, 2008, the State in which the area is located is substantially in compliance with the agreement under clause (iii)(II).

(v) PROGRESS TOWARD NAMES-BASED REPORTING.—For fiscal year 2009 or a subsequent fiscal year, the Secretary may terminate an exemption under clause (ii) for an eligible area if the State in which the area is located submitted a plan under clause (iii)(I)(aa) and the Secretary determines that the State is not substantially following the plan.

(vi) COUNTING OF CASES IN AREAS WITH EXEMPTIONS.—

(I) IN GENERAL.—With respect to an eligible area that is under a reporting system for living non-AIDS cases of HIV that is not names-based (referred to in this subparagraph as "code-based reporting"), the Secretary shall, for purposes of this subparagraph, modify the number of such cases reported for the eligible area in order to adjust for duplicative reporting in and among systems that use code-based reporting.

(II) ADJUSTMENT RATE.—The adjustment rate under subclause (I) for an eligible area shall be a reduction of 5 percent for fiscal years before fiscal year 2012 (and 6 percent for fiscal year 2012) in the number of living non-AIDS cases of HIV reported for the area.

(III) INCREASED ADJUSTMENT FOR CERTAIN AREAS PREVIOUSLY USING CODE-BASED REPORTING.—For purposes of this subparagraph for each of fiscal years 2010 through 2012, the Secretary shall deem the applicable number of living cases of HIV/AIDS in an area that were reported to and confirmed by the Centers for Disease Control and Prevention to be 3 percent higher than the actual number if—

(aa) for fiscal year 2007, such area was a transitional area;

(bb) fiscal year 2007 was the first year in which the count of living non-AIDS cases of HIV in such area, for purposes of this section, was based on a names-based reporting system; and

(cc) the amount of funding that such area received under this part for fiscal year 2007 was less than 70 percent of the amount of funding (exclusive of funds that were identified as being for purposes of the Minority AIDS Initiative) that such area received under such part for fiscal year 2006.

(vii) MULTIPLE POLITICAL JURISDICTIONS.—With respect to living non-AIDS cases of HIV, if an eligible area is not entirely within one political jurisdiction and as a result is subject to more than one reporting system for purposes of this subparagraph:

(I) Names-based reporting under clause (i) applies in a jurisdictional portion of the area, or an exemption under clause (ii) applies in such portion (subject to applicable provisions of this subparagraph), according to whether names-based reporting or code-based reporting is used in such portion.

(II) If under subclause (I) both names-based reporting and code-based reporting apply in the area, the number of code-based cases shall be reduced under clause (vi).

(viii) LIST OF ELIGIBLE AREAS MEETING STANDARD REGARDING DECEMBER 31, 2005.—

(I) IN GENERAL.—If an eligible area or portion thereof is in a State specified in subclause (II), the eligible area or portion shall be considered to meet the standard described in clause (ii)(I). No other eligible area or portion thereof may be considered to meet such standard.

(II) RELEVANT STATES.—For purposes of subclause (I), the States specified in this subclause are the following: Alaska, Alabama, Arkansas, Arizona, Colorado, Florida, Indiana, Iowa, Idaho, Kansas, Louisiana, Michigan, Minnesota, Missouri, Mississippi, North Carolina, North Dakota, Nebraska, New Jersey, New Mexico, New York, Nevada, Ohio, Oklahoma, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, Wisconsin, West Virginia, Wyoming, Guam, and the Virgin Islands.

(ix) RULES OF CONSTRUCTION REGARDING ACCEPTANCE OF REPORTS.—

(I) CASES OF AIDS.—With respect to an eligible area that is subject to the requirement under clause (i) and is not in compliance with the requirement for names-based reporting of living non-AIDS cases of HIV, the Secretary shall, notwithstanding such noncompliance, accept reports of living cases of AIDS that are in accordance with such clause.

(II) APPLICABILITY OF EXEMPTION REQUIREMENTS.—The provisions of clauses (ii) through (viii) may not be construed as having any legal effect for fiscal year 2013 or any subsequent fiscal year, and accordingly, the status of a State for purposes of such clauses may not be considered after fiscal year 2012.

(x) PROGRAM FOR DETECTING INACCURATE OR FRAUDULENT COUNTING.—The Secretary shall carry out a program to monitor the reporting of names-based cases for purposes of this subparagraph and to detect instances of inaccurate reporting, including fraudulent reporting.

(xi) FUTURE FISCAL YEARS.—For fiscal years beginning with fiscal year 2013, determinations under this paragraph shall be based only on living names-based cases of HIV/AIDS with respect to the area involved.

(D) CODE-BASED AREAS; LIMITATION ON INCREASE IN GRANT.—

(i) IN GENERAL.—For each of the fiscal years 2007 through 2012, if code-based reporting (within the meaning of subparagraph (C)(vi)) applies in an eligible area or any portion thereof as of the beginning of the fiscal year involved, then notwithstanding any other provision of this paragraph, the amount of the grant pursuant to this paragraph for such area for such fiscal year may not—

(I) for fiscal year 2007, exceed by more than 5 percent the amount of the grant for the area that would have been made pursuant to this paragraph and paragraph (4) for fiscal year 2006 (as such paragraphs were in effect for such fiscal year) if paragraph (2) (as so in effect) had been

applied by substituting "66⅔ percent" for "50 percent"; and

(II) for each of the fiscal years 2008 through 2012, exceed by more than 5 percent the amount of the grant pursuant to this paragraph and paragraph (4) for the area for the preceding fiscal year.

(ii) USE OF AMOUNTS INVOLVED.—For each of the fiscal years 2007 through 2012, amounts available as a result of the limitation under clause (i) shall be made available by the Secretary as additional amounts for grants pursuant to subsection (b) for the fiscal year involved, subject to paragraph (4) and section 2610(d)(2).

(4) INCREASES IN GRANT.—

(A) IN GENERAL.—For each eligible area that received a grant pursuant to this subsection for fiscal year 2009, the Secretary shall, for each of the fiscal years 2010 through 2013, increase the amount of the grant made pursuant to paragraph (3) for the area to ensure that the amount of the grant for the fiscal year involved is not less than the following amount, as applicable to such fiscal year:

(i) For fiscal year 2010, an amount equal to 95 percent of the sum of the amount of the grant made pursuant to paragraph (3) and this paragraph for fiscal year 2009.

(ii) For each of the fiscal years 2011 and 2012, an amount equal to 100 percent of the amount of the grant made pursuant to paragraph (3) and this paragraph for fiscal year 2010.

(iii) For fiscal year 2013, an amount equal to 92.5 percent of the amount of the grant made pursuant to paragraph (3) and this paragraph for fiscal year 2012.

(B) SOURCE OF FUNDS FOR INCREASE.—

(i) IN GENERAL.—From the amounts available for carrying out the single program referred to in section 2609(d)(2)(C) for a fiscal year (relating to supplemental grants), the Secretary shall make available such amounts as may be necessary to comply with subparagraph (A), subject to section 2610(d)(2).

(ii) PRO RATA REDUCTION.—If the amounts referred to in clause (i) for a fiscal year are insufficient to fully comply with subparagraph (A) for the year, the Secretary, in order to provide the additional funds necessary for such compliance, shall reduce on a pro rata basis the amount of each grant pursuant to this subsection for the fiscal year, other than grants for eligible areas for which increases under subparagraph (A) apply. A reduction under the preceding sentence may not be made in an amount that would result in the eligible area involved becoming eligible for such an increase.

(C) LIMITATION.—This paragraph may not be construed as having any applicability after fiscal year 2013.

(b) SUPPLEMENTAL GRANTS.—

(1) IN GENERAL.—Subject to subsection (a)(4)(B)(i) and section 2610(d), the Secretary shall disburse the remainder of amounts not disbursed under section 2603(a)(2) for such fiscal year for the purpose of making grants under section 2601(a) to eligible areas whose application under section 2605(b)—

(A) contains a report concerning the dissemination of emergency relief funds under subsection (a) and the plan for utilization of such funds;

(B) demonstrates the need in such area, on an objective and quantified basis, for supplemental financial assistance to combat the HIV epidemic;

(C) demonstrates the existing commitment of local resources of the area, both financial and in-kind, to combating the HIV epidemic;

(D) demonstrates the ability of the area to utilize such supplemental financial resources in a manner that is immediately responsive and cost effective;

(E) demonstrates that resources will be allocated in accordance with the local demographic incidence of AIDS including appropriate allocations for services for infants, children, youth, women, and families with HIV/AIDS;

(F) demonstrates the inclusiveness of affected communities and individuals with HIV/AIDS;

(G) demonstrates the manner in which the proposed services are consistent with the local needs assessment and the statewide coordinated statement of need;

(H) demonstrates the ability of the applicant to expend funds efficiently by not having had, for the most recent grant year under subsection (a) for which data is available, more than 5 percent of grant funds under such subsection canceled, offset under subsection (c)(4), or covered by any waivers under subsection (c)(3); and

(I) demonstrates success in identifying individuals with HIV/AIDS as described in clauses (i) through (iii) of paragraph (2)(A).

(2) AMOUNT OF GRANT.—

(A) IN GENERAL.—The amount of each grant made for purposes of this subsection shall be determined by the Secretary based on a weighting of factors under paragraph (1), with demonstrated need under subparagraph (B) of such paragraph counting one-third, and demonstrated success in identifying individuals with HIV/AIDS who do not know their HIV status and making them aware of such status counting one-third. In making such determination, the Secretary shall consider—

(i) the number of individuals who have been tested for HIV/AIDS;

(ii) of those individuals described in clause (i), the number of individuals who tested for HIV/AIDS who are made aware of their status, including the number who test positive; and

(iii) of those individuals described in clause (ii), the number who have been referred to appropriate treatment and care.

(B) DEMONSTRATED NEED.—The factors considered by the Secretary in determining whether an eligible area has a demonstrated need for purposes of paragraph (1)(B) may include any or all of the following:

(i) The unmet need for such services, as determined under section 2602(b)(4) or other community input process as defined under section 2609(d)(1)(A).

(ii) An increasing need for HIV/AIDS-related services, including relative rates of increase in the number of cases of HIV/AIDS.

(iii) The relative rates of increase in the number of cases of HIV/AIDS within new or emerging subpopulations.

(iv) The current prevalence of HIV/AIDS.

(v) Relevant factors related to the cost and complexity of delivering health care to individuals with HIV/AIDS in the eligible area.

(vi) The impact of co-morbid factors, including co-occurring conditions, determined relevant by the Secretary.

(vii) The prevalence of homelessness.

(viii) The prevalence of individuals described under section 2602(b)(2)(M).

(ix) The relevant factors that limit access to health care, including geographic variation, adequacy of health insurance coverage, and language barriers.

(x) The impact of a decline in the amount received pursuant to subsection (a) on services available to all individuals with HIV/AIDS identified and eligible under this title.

(C) PRIORITY IN MAKING GRANTS.—The Secretary shall provide funds under this subsection to an eligible area to address the decline or disruption of all EMA-provided services related to the decline in the amounts received pursuant to subsection (a) consistent with the grant award for the eligible area for fiscal year 2006, to the extent that the factor under subparagraph (B)(x) (relating to a decline in funding) applies to the eligible area.

(D) INCREASED ADJUSTMENT FOR CERTAIN AREAS PREVIOUSLY USING CODE-BASED REPORTING.—For purposes of this subsection for each of fiscal years 2010 through 2012, the Secretary shall deem the applicable number of living cases of HIV/AIDS in an area that were reported to and confirmed by the Centers for Disease Control and Prevention to be 3 percent higher than the actual number if the conditions described in items (aa) through (cc) of subsection (a)(3)(C)(vi)(III) are all satisfied.

(3) REMAINDER OF AMOUNTS.—In determining the amount of funds to be obligated under paragraph (1), the Secretary shall include amounts that are not paid to the eligible areas

under expedited procedures under section 2603(a)(2) as a result of—

(A) the failure of any eligible area to submit an application under section 2605(c); or

(B) any eligible area informing the Secretary that such eligible area does not intend to expend the full amount of its grant under such section.

(4) FAILURE TO SUBMIT.—

(A) IN GENERAL.—The failure of an eligible area to submit an application for an expedited grant under section 2603(a)(2) shall not result in such area being ineligible for a grant under this subsection.

(B) APPLICATION.—The application of an eligible area submitted under section 2605(b) shall contain the assurances required under subsection (a) of such section if such eligible area fails to submit an application for an expedited grant under section 2603(a)(2).

(c) TIMEFRAME FOR OBLIGATION AND EXPENDITURE OF GRANT FUNDS.—

(1) OBLIGATION BY END OF GRANT YEAR.—Effective for fiscal year 2007 and subsequent fiscal years, funds from a grant award made pursuant to subsection (a) or (b) for a fiscal year are available for obligation by the eligible area involved through the end of the one-year period beginning on the date in such fiscal year on which funds from the award first become available to the area (referred to in this subsection as the "grant year for the award"), except as provided in paragraph (3)(A).

(2) SUPPLEMENTAL GRANTS; CANCELLATION OF UNOBLIGATED BALANCE OF GRANT AWARD.—Effective for fiscal year 2007 and subsequent fiscal years, if a grant award made pursuant to subsection (b) for an eligible area for a fiscal year has an unobligated balance as of the end of the grant year for the award—

(A) the Secretary shall cancel that unobligated balance of the award, and shall require the eligible area to return any amounts from such balance that have been disbursed to the area; and

(B) the funds involved shall be made available by the Secretary as additional amounts for grants pursuant to subsection (b) for the first fiscal year beginning after the fiscal year in which the Secretary obtains the information necessary for determining that the balance is required under subparagraph (A) to be canceled, except that the availability of the funds for such grants is subject to subsection (a)(4) and section 2610(d)(2) as applied for such year.

(3) FORMULA GRANTS; CANCELLATION OF UNOBLIGATED BALANCE OF GRANT AWARD; WAIVER PERMITTING CARRYOVER.—

(A) IN GENERAL.—Effective for fiscal year 2007 and subsequent fiscal years, if a grant award made pursuant to subsection (a) for an eligible area for a fiscal year has an unobligated balance as of the end of the grant year for the award, the Secretary shall cancel that unobligated bal-

ance of the award, and shall require the eligible area to return any amounts from such balance that have been disbursed to the area, unless—

(i) before the end of the grant year, the chief elected official of the area submits to the Secretary a written application for a waiver of the cancellation, which application includes a description of the purposes for which the area intends to expend the funds involved; and

(ii) the Secretary approves the waiver.

(B) EXPENDITURE BY END OF CARRYOVER YEAR.—With respect to a waiver under subparagraph (A) that is approved for a balance that is unobligated as of the end of a grant year for an award:

(i) The unobligated funds are available for expenditure by the eligible area involved for the one-year period beginning upon the expiration of the grant year (referred to in this subsection as the "carryover year").

(ii) If the funds are not expended by the end of the carryover year, the Secretary shall cancel that unexpended balance of the award, and shall require the eligible area to return any amounts from such balance that have been disbursed to the area.

(C) USE OF CANCELLED BALANCES.—In the case of any balance of a grant award that is cancelled under subparagraph (A) or (B)(ii), the grant funds involved shall be made available by the Secretary as additional amounts for grants pursuant to subsection (b) for the first fiscal year beginning after the fiscal year in which the Secretary obtains the information necessary for determining that the balance is required under such subparagraph to be canceled, except that the availability of the funds for such grants is subject to subsection (a)(4) and section 2610(d)(2) as applied for such year.

(D) CORRESPONDING REDUCTION IN FUTURE GRANT.—

(i) IN GENERAL.—In the case of an eligible area for which a balance from a grant award under subsection (a) is unobligated as of the end of the grant year for the award—

(I) the Secretary shall reduce, by the same amount as such unobligated balance (less any amount of such balance that is the subject of a waiver of cancellation under subparagraph (A)), the amount of the grant under such subsection for the first fiscal year beginning after the fiscal year in which the Secretary obtains the information necessary for determining that such balance was unobligated as of the end of the grant year (which requirement for a reduction applies without regard to whether a waiver under subparagraph (A) has been approved with respect to such balance); and

(II) the grant funds involved in such reduction shall be made available by the Secretary as addi-

tional funds for grants pursuant to subsection (b) for such first fiscal year, subject to subsection (a)(4) and section 2610(d)(2);

except that this clause does not apply to the eligible area if the amount of the unobligated balance was 5 percent or less.

(ii) RELATION TO INCREASES IN GRANT.—A reduction under clause (i) for an eligible area for a fiscal year may not be taken into account in applying subsection (a)(4) with respect to the area for the subsequent fiscal year.

(4) AUTHORITY REGARDING ADMINISTRATION OF PROVISIONS.—In administering paragraphs (2) and (3) with respect to the unobligated balance of an eligible area, the Secretary may elect to reduce the amount of future grants to the area under subsection (a) or (b), as applicable, by the amount of any such unobligated balance in lieu of cancelling such amount as provided for in paragraph (2) or (3)(A). In such case, the Secretary may permit the area to use such unobligated balance for purposes of any such future grant. An amount equal to such reduction shall be available for use as additional amounts for grants pursuant to subsection (b), subject to subsection (a)(4) and section 2610(d)(2). Nothing in this paragraph shall be construed to affect the authority of the Secretary under paragraphs (2) and (3), including the authority to grant waivers under paragraph (3)(A). The reduction in future grants authorized under this paragraph shall be notwithstanding the penalty required under paragraph (3)(D) with respect to unobligated funds.

(d) COMPLIANCE WITH PRIORITIES OF HIV PLANNING COUNCIL.—Notwithstanding any other provision of this subpart, the Secretary, in carrying out section 2601(a), may not make any grant under subsection (a) or (b) to an eligible area unless the application submitted by such area under section 2605 for the grant involved demonstrates that the grants made under subsections (a) and (b) to the area for the preceding fiscal year (if any) were expended in accordance with the priorities applicable to such year that were established, pursuant to section 2602(b)(4)(C), by the planning council serving the area.

(e) REPORT ON THE AWARDING OF SUPPLEMENTAL FUNDS.—Not later than 45 days after the awarding of supplemental funds under this section, the Secretary shall submit to Congress a report concerning such funds. Such report shall include information detailing—

(1) the total amount of supplemental funds available under this section for the year involved;

(2) the amount of supplemental funds used in accordance with the hold harmless provisions of subsection (a)(4);

(3) the amount of supplemental funds disbursed pursuant to subsection (b)(2)(C);

(4) the disbursement of the remainder of the supplemental funds after taking into account the uses described in paragraphs (2) and (3); and

(5) the rationale used for the amount of funds disbursed as described under paragraphs (2), (3), and (4).

SEC. 2604.[300ff–14] USE OF AMOUNTS.

(a) REQUIREMENTS.—The Secretary may not make a grant under section 2601(a) to the chief elected official of an eligible area unless such political subdivision agrees that—

(1) subject to paragraph (2), the allocation of funds and services within the eligible area will be made in accordance with the priorities established, pursuant to section 2602(b)(4)(C), by the HIV health services planning council that serves such eligible area;

(2) funds provided under section 2601 will be expended only for—

(A) core medical services described in subsection (c);

(B) support services described in subsection (d); and

(C) administrative expenses described in subsection (h); and

(3) the use of such funds will comply with the requirements of this section.

(b) DIRECT FINANCIAL ASSISTANCE TO APPROPRIATE ENTITIES.—

(1) IN GENERAL.—The chief elected official of an eligible area shall use amounts from a grant under section 2601 to provide direct financial assistance to entities described in paragraph (2) for the purpose of providing core medical services and support services.

(2) APPROPRIATE ENTITIES.—Direct financial assistance may be provided under paragraph (1) to public or nonprofit private entities, or private for-profit entities if such entities are the only available provider of quality HIV care in the area.

(c) REQUIRED FUNDING FOR CORE MEDICAL SERVICES.—

(1) IN GENERAL.—With respect to a grant under section 2601 for an eligible area for a grant year, the chief elected official of the area shall, of the portion of the grant remaining after reserving amounts for purposes of paragraphs (1) and (5)(B)(i) of subsection (h), use not less than 75 percent to provide core medical services that are needed in the eligible area for individuals with HIV/AIDS who are identified and eligible under this title (including services regarding the co-occurring conditions of the individuals).

(2) WAIVER.—

(A) IN GENERAL.—The Secretary shall waive the application of paragraph (1) with respect to a chief elected official for a grant year if the Secretary determines that, within the eligible area involved—

(i) there are no waiting lists for AIDS Drug Assistance Program services under section 2616; and

(ii) core medical services are available to all individuals with HIV/AIDS identified and eligible under this title.

(B) NOTIFICATION OF WAIVER STATUS.—When informing the chief elected official of an eligible area that a grant under section 2601 is being made for the area for a grant

year, the Secretary shall inform the official whether a waiver under subparagraph (A) is in effect for such year.

(3) CORE MEDICAL SERVICES.—For purposes of this subsection, the term "core medical services", with respect to an individual with HIV/AIDS (including the co-occurring conditions of the individual), means the following services:

(A) Outpatient and ambulatory health services.

(B) AIDS Drug Assistance Program treatments in accordance with section 2616.

(C) AIDS pharmaceutical assistance.

(D) Oral health care.

(E) Early intervention services described in subsection (e).

(F) Health insurance premium and cost sharing assistance for low-income individuals in accordance with section 2615.

(G) Home health care.

(H) Medical nutrition therapy.

(I) Hospice services.

(J) Home and community-based health services as defined under section 2614(c).

(K) Mental health services.

(L) Substance abuse outpatient care.

(M) Medical case management, including treatment adherence services.

(d) SUPPORT SERVICES.—

(1) IN GENERAL.—For purposes of this section, the term "support services" means services, subject to the approval of the Secretary, that are needed for individuals with HIV/AIDS to achieve their medical outcomes (such as respite care for persons caring for individuals with HIV/AIDS, outreach services, medical transportation, linguistic services, and referrals for health care and support services).

(2) MEDICAL OUTCOMES.—In this subsection, the term "medical outcomes" means those outcomes affecting the HIV-related clinical status of an individual with HIV/AIDS.

(e) EARLY INTERVENTION SERVICES.—

(1) IN GENERAL.—For purposes of this section, the term "early intervention services" means HIV/AIDS early intervention services described in section 2651(e), with follow-up referral provided for the purpose of facilitating the access of individuals receiving the services to HIV-related health services. The entities through which such services may be provided under the grant include public health departments, emergency rooms, substance abuse and mental health treatment programs, detoxification centers, detention facilities, clinics regarding sexually transmitted diseases, homeless shelters, HIV/AIDS counseling and testing sites, health care points of entry specified by eligible areas, federally qualified health centers, and entities described in section 2652(a) that constitute a point of access to services by maintaining referral relationships.

(2) CONDITIONS.—With respect to an entity that proposes to provide early intervention services under paragraph (1), such paragraph shall apply only if the entity demonstrates to

the satisfaction of the chief elected official for the eligible area involved that—

(A) Federal, State, or local funds are otherwise inadequate for the early intervention services the entity proposes to provide; and

(B) the entity will expend funds pursuant to such paragraph to supplement and not supplant other funds available to the entity for the provision of early intervention services for the fiscal year involved.

(f) PRIORITY FOR WOMEN, INFANTS, CHILDREN, AND YOUTH.—

(1) IN GENERAL.—For the purpose of providing health and support services to infants, children, youth, and women with HIV/AIDS, including treatment measures to prevent the perinatal transmission of HIV, the chief elected official of an eligible area, in accordance with the established priorities of the planning council, shall for each of such populations in the eligible area use, from the grants made for the area under section 2601(a) for a fiscal year, not less than the percentage constituted by the ratio of the population involved (infants, children, youth, or women in such area) with HIV/AIDS to the general population in such area of individuals with HIV/AIDS.

(2) WAIVER.—With respect to the population involved, the Secretary may provide to the chief elected official of an eligible area a waiver of the requirement of paragraph (1) if such official demonstrates to the satisfaction of the Secretary that the population is receiving HIV-related health services through the State medicaid program under title XIX of the Social Security Act, the State children's health insurance program under title XXI of such Act, or other Federal or State programs.

(g) REQUIREMENT OF STATUS AS MEDICAID PROVIDER.—

(1) PROVISION OF SERVICE.—Subject to paragraph (2), the Secretary may not make a grant under section 2601(a) for the provision of services under this section in a State unless, in the case of any such service that is available pursuant to the State plan approved under title XIX of the Social Security Act for the State—

(A) the political subdivision involved will provide the service directly, and the political subdivision has entered into a participation agreement under the State plan and is qualified to receive payments under such plan; or

(B) the political subdivision will enter into an agreement with a public or nonprofit private entity under which the entity will provide the service, and the entity has entered into such a participation agreement and is qualified to receive such payments.

(2) WAIVER.—

(A) IN GENERAL.—In the case of an entity making an agreement pursuant to paragraph (1)(B) regarding the provision of services, the requirement established in such paragraph shall be waived by the HIV health services planning council for the eligible area if the entity does not, in providing health care services, impose a charge or accept reimbursement available from any third-party payor,

including reimbursement under any insurance policy or under any Federal or State health benefits program.

(B) DETERMINATION.—A determination by the HIV health services planning council of whether an entity referred to in subparagraph (A) meets the criteria for a waiver under such subparagraph shall be made without regard to whether the entity accepts voluntary donations for the purpose of providing services to the public.

(h) ADMINISTRATION.—

(1) LIMITATION.—The chief elected official of an eligible area shall not use in excess of 10 percent of amounts received under a grant under this subpart for administrative expenses.

(2) ALLOCATIONS BY CHIEF ELECTED OFFICIAL.—In the case of entities and subcontractors to which the chief elected official of an eligible area allocates amounts received by the official under a grant under this subpart, the official shall ensure that, of the aggregate amount so allocated, the total of the expenditures by such entities for administrative expenses does not exceed 10 percent (without regard to whether particular entities expend more than 10 percent for such expenses).

(3) ADMINISTRATIVE ACTIVITIES.—For purposes of paragraph (1), amounts may be used for administrative activities that include—

(A) routine grant administration and monitoring activities, including the development of applications for part A funds, the receipt and disbursal of program funds, the development and establishment of reimbursement and accounting systems, the development of a clinical quality management program as described in paragraph (5), the preparation of routine programmatic and financial reports, and compliance with grant conditions and audit requirements; and

(B) all activities associated with the grantee's contract award procedures, including the activities carried out by the HIV health services planning council as established under section 2602(b), the development of requests for proposals, contract proposal review activities, negotiation and awarding of contracts, monitoring of contracts through telephone consultation, written documentation or onsite visits, reporting on contracts, and funding reallocation activities.

(4) SUBCONTRACTOR ADMINISTRATIVE ACTIVITIES.—For the purposes of this subsection, subcontractor administrative activities include—

(A) usual and recognized overhead activities, including established indirect rates for agencies;

(B) management oversight of specific programs funded under this title; and

(C) other types of program support such as quality assurance, quality control, and related activities.

(5) CLINICAL QUALITY MANAGEMENT.—

(A) REQUIREMENT.—The chief elected official of an eligible area that receives a grant under this subpart shall provide for the establishment of a clinical quality manage-

ment program to assess the extent to which HIV health services provided to patients under the grant are consistent with the most recent Public Health Service guidelines for the treatment of HIV/AIDS and related opportunistic infection, and as applicable, to develop strategies for ensuring that such services are consistent with the guidelines for improvement in the access to and quality of HIV health services.

(B) USE OF FUNDS.—

(i) IN GENERAL.—From amounts received under a grant awarded under this subpart for a fiscal year, the chief elected official of an eligible area may use for activities associated with the clinical quality management program required in subparagraph (A) not to exceed the lesser of—

(I) 5 percent of amounts received under the grant; or

(II) $3,000,000.

(ii) RELATION TO LIMITATION ON ADMINISTRATIVE EXPENSES.—The costs of a clinical quality management program under subparagraph (A) may not be considered administrative expenses for purposes of the limitation established in paragraph (1).

(i) CONSTRUCTION.—A chief elected official may not use amounts received under a grant awarded under this subpart to purchase or improve land, or to purchase, construct, or permanently improve (other than minor remodeling) any building or other facility, or to make cash payments to intended recipients of services.

SEC. 2605.[300ff–15] APPLICATION.

(a) IN GENERAL.—To be eligible to receive a grant under section 2601, an eligible area shall prepare and submit to the Secretary an application, in accordance with subsection (c) regarding a single application and grant award, at such time, in such form, and containing such information as the Secretary shall require, including assurances adequate to ensure—

(1)(A) that funds received under a grant awarded under this subpart will be utilized to supplement not supplant State funds made available in the year for which the grant is awarded to provide HIV-related services as described in section 2604(b)(1);

(B) that the political subdivisions within the eligible area will maintain the level of expenditures by such political subdivisions for HIV-related services as described in section 2604(b)(1) at a level that is equal to the level of such expenditures by such political subdivisions for the preceding fiscal year; and

(C) that political subdivisions within the eligible area will not use funds received under a grant awarded under this subpart in maintaining the level of expenditures for HIV-related services as required in subparagraph (B);

(2) that the eligible area has an HIV health services planning council and has entered into intergovernmental agree-

ments pursuant to section 2602, and has developed or will develop the comprehensive plan in accordance with section 2602(b)(3)(B);

(3) that entities within the eligible area that receive funds under a grant under this subpart will maintain appropriate relationships with entities in the eligible area served that constitute key points of access to the health care system for individuals with HIV/AIDS (including emergency rooms, substance abuse treatment programs, detoxification centers, adult and juvenile detention facilities, sexually transmitted disease clinics, HIV counseling and testing sites, mental health programs, and homeless shelters), and other entities under section 2604(b)(3) and 2652(a), for the purpose of facilitating early intervention for individuals newly diagnosed with HIV/AIDS and individuals knowledgeable of their HIV status but not in care;

(4) that the chief elected official of the eligible area will satisfy all requirements under section 2604(c);

(5) that entities within the eligible area that will receive funds under a grant provided under section 2601(a) shall participate in an established HIV community-based continuum of care if such continuum exists within the eligible area;

(6) that funds received under a grant awarded under this subpart will not be utilized to make payments for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to that item or service—

(A) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program (except for a program administered by or providing the services of the Indian Health Service); or

(B) by an entity that provides health services on a prepaid basis;

(7) to the maximum extent practicable, that—

(A) HIV health care and support services provided with assistance made available under this subpart will be provided without regard—

(i) to the ability of the individual to pay for such services; and

(ii) to the current or past health condition of the individual to be served;

(B) such services will be provided in a setting that is accessible to low-income individuals with HIV-disease; and

(C) a program of outreach will be provided to low-income individuals with HIV-disease to inform such individuals of such services;

(8) that the applicant has participated, or will agree to participate, in the statewide coordinated statement of need process where it has been initiated by the State public health agency responsible for administering grants under part B, and ensure that the services provided under the comprehensive plan are consistent with the statewide coordinated statement of need;

(9) that the eligible area has procedures in place to ensure that services provided with funds received under this subpart meet the criteria specified in section 2604(b)(1); and

(10) that the chief elected official will submit to the lead State agency under section 2617(b)(4), audits, consistent with Office of Management and Budget circular A133, regarding funds expended in accordance with this subpart every 2 years and shall include necessary client-based data to compile unmet need calculations and Statewide coordinated statements of need process.

(b) APPLICATION.—An eligible area that desires to receive a grant under section 2603(b) shall prepare and submit to the Secretary an application, in accordance with subsection (c) regarding a single application and grant award, at such time, in such form, and containing such information as the Secretary shall require, including the information required under such subsection and information concerning—

(1) the number of individuals to be served within the eligible area with assistance provided under the grant, including the identification of individuals with HIV/AIDS as described in clauses (i) through (iii) of section 2603(b)(2)(A);

(2) demographic data on the population of such individuals;

(3) the average cost of providing each category of HIV-related health services and the extent to which such cost is paid by third-party payors;

(4) the aggregate amounts expended for each such category of services;

(5) the manner in which the expected expenditures are related to the planning process for States that receive funding under part B (including the planning process described in section 2617(b)); and

(6) the expected expenditures and how those expenditures will improve overall client outcomes, as described under the State plan under section 2617(b), and through additional outcomes measures as identified by the HIV health services planning council under section 2602(b).

(c) SINGLE APPLICATION AND GRANT AWARD.—

(1) APPLICATION.—The Secretary may phase in the use of a single application that meets the requirements of subsections (a) and (b) of section 2603 with respect to an eligible area that desires to receive grants under section 2603 for a fiscal year.

(2) GRANT AWARD.—The Secretary may phase in the awarding of a single grant to an eligible area that submits an approved application under paragraph (1) for a fiscal year.

(d) DATE CERTAIN FOR SUBMISSION.—

(1) REQUIREMENT.—Except as provided in paragraph (2), to be eligible to receive a grant under section 2601(a) for a fiscal year, an application under subsection (a) shall be submitted not later than 45 days after the date on which appropriations are made under section 2677 for the fiscal year.

(2) EXCEPTION.—The Secretary may extend the time for the submission of an application under paragraph (1) for a period of not to exceed 60 days if the Secretary determines that

the eligible area has made a good faith effort to comply with the requirement of such paragraph but has otherwise been unable to submit its application.

(3) DISTRIBUTION BY SECRETARY.—Not later than 45 days after receiving an application that meets the requirements of subsection (a) from an eligible area, the Secretary shall distribute to such eligible area the amounts awarded under the grant for which the application was submitted.

(4) REDISTRIBUTION.—Any amounts appropriated in any fiscal year under this subpart and not obligated to an eligible entity as a result of the failure of such entity to submit an application shall be redistributed by the Secretary to other eligible entities in proportion to the original grants made to such eligible areas under section 2601(a).

(e) REQUIREMENTS REGARDING IMPOSITION OF CHARGES FOR SERVICES.—

(1) IN GENERAL.—The Secretary may not make a grant under section 2601 to an eligible area unless the eligible area provides assurances that in the provision of services with assistance provided under the grant—

(A) in the case of individuals with an income less than or equal to 100 percent of the official poverty line, the provider will not impose charges on any such individual for the provision of services under the grant;

(B) in the case of individuals with an income greater than 100 percent of the official poverty line, the provider—

(i) will impose a charge on each such individual for the provision of such services; and

(ii) will impose the charge according to a schedule of charges that is made available to the public;

(C) in the case of individuals with an income greater than 100 percent of the official poverty line and not exceeding 200 percent of such poverty line, the provider will not, for any calendar year, impose charges in an amount exceeding 5 percent of the annual gross income of the individual involved;

(D) in the case of individuals with an income greater than 200 percent of the official poverty line and not exceeding 300 percent of such poverty line, the provider will not, for any calendar year, impose charges in an amount exceeding 7 percent of the annual gross income of the individual involved; and

(E) in the case of individuals with an income greater than 300 percent of the official poverty line, the provider will not, for any calendar year, impose charges in an amount exceeding 10 percent of the annual gross income of the individual involved.

(2) ASSESSMENT OF CHARGE.—With respect to compliance with the assurance made under paragraph (1), a grantee or entity receiving assistance under this subpart may, in the case of individuals subject to a charge for purposes of such paragraph—

(A) assess the amount of the charge in the discretion of the grantee, including imposing only a nominal charge

for the provision of services, subject to the provisions of such paragraph regarding public schedules and regarding limitations on the maximum amount of charges; and

(B) take into consideration the medical expenses of individuals in assessing the amount of the charge, subject to such provisions.

(3) APPLICABILITY OF LIMITATION ON AMOUNT OF CHARGE.—The Secretary may not make a grant under section 2601 to an eligible area unless the eligible area agrees that the limitations established in subparagraphs (C), (D) and (E) of paragraph (1) regarding the imposition of charges for services applies to the annual aggregate of charges imposed for such services, without regard to whether they are characterized as enrollment fees, premiums, deductibles, cost sharing, copayments, coinsurance, or other charges.

(4) WAIVER REGARDING SECONDARY AGREEMENTS.—The requirements established in paragraphs (1) through (3) shall be waived in accordance with section 2604(d)(2).

SEC. 2606.[300ff–16] TECHNICAL ASSISTANCE.

The Administrator of the Health Resources and Services Administration shall, beginning on the date of enactment of this title, provide technical assistance, including assistance from other grantees, contractors or subcontractors under this title to assist newly eligible metropolitan areas in the establishment of HIV health services planning councils and, to assist entities in complying with the requirements of this subpart in order to make such entities eligible to receive a grant under this subpart. The Administrator may make planning grants available to metropolitan areas, in an amount not to exceed $75,000 for any metropolitan area, projected to be eligible for funding under section 2601 in the following fiscal year. Such grant amounts shall be deducted from the first year formula award to eligible areas accepting such grants. Not to exceed 1 percent of the amount appropriated for a fiscal year under section 2677 for grants under part A may be used to carry out this section.

SEC. 2607.[300ff–17] DEFINITIONS.

For purposes of this subpart:

(1) ELIGIBLE AREA.—The term "eligible area" means a metropolitan area meeting the requirements of section 2601 that are applicable to the area.

(2) METROPOLITAN AREA.—The term "metropolitan area" means an area that is referred to in the HIV/AIDS Surveillance Report of the Centers for Disease Control and Prevention as a metropolitan area, and that has a population of 50,000 or more individuals.

Subpart II—Transitional Grants

SEC. 2609.[300ff–19] ESTABLISHMENT OF PROGRAM.

(a) IN GENERAL.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall make grants for the purpose of providing services described in section 2604 in transitional areas, subject to the same provisions re-

garding the allocation of grant funds as apply under subsection (c) of such section.

(b) TRANSITIONAL AREAS.—For purposes of this section, the term "transitional area" means, subject to subsection (c), a metropolitan area for which there has been reported to and confirmed by the Director of the Centers for Disease Control and Prevention a cumulative total of at least 1,000, but fewer than 2,000, cases of AIDS during the most recent period of 5 calendar years for which such data are available.

(c) CERTAIN ELIGIBILITY RULES.—

(1) FISCAL YEAR 2011.—With respect to grants under subsection (a) for fiscal year 2011, a metropolitan area that received funding under subpart I for fiscal year 2010 but does not for fiscal year 2011 qualify under such subpart as an eligible area and does not qualify under subsection (b) as a transitional area shall, notwithstanding subsection (b), be considered a transitional area.

(2) CONTINUED STATUS AS TRANSITIONAL AREA.—

(A) IN GENERAL.—Notwithstanding subsection (b), a metropolitan area that is a transitional area for a fiscal year continues, except as provided in subparagraph (B), to be a transitional area until the metropolitan area fails, for three consecutive fiscal years—

(i) to qualify under such subsection as a transitional area; and

(ii) subject to subparagraphs (B) and (C), to have a cumulative total of 1,500 or more living cases of AIDS (reported to and confirmed by the Director of the Centers for Disease Control and Prevention) as of December 31 of the most recent calendar year for which such data is available.

(B) PERMITTING MARGIN OF ERROR APPLICABLE TO CERTAIN METROPOLITAN AREAS.—In applying subparagraph (A)(ii) for a fiscal year after fiscal year 2008, in the case of a metropolitan area that has a cumulative total of at least 1,400 (and fewer than 1,500) living cases of AIDS as of December 31 of the most recent calendar year for which such data is available, such area shall be treated as having met the criteria of such subparagraph if not more than 5 percent of the total from grants awarded to such area under this part is unobligated as of the end of the most recent fiscal year for which such data is available.

(C) EXCEPTION REGARDING STATUS AS ELIGIBLE AREA.—Subparagraphs (A) and (B) do not apply for a fiscal year if the metropolitan area involved qualifies under subpart I as an eligible area.

(d) APPLICATION OF CERTAIN PROVISIONS OF SUBPART I.—

(1) ADMINISTRATION; PLANNING COUNCIL.—

(A) IN GENERAL.—The provisions of section 2602 apply with respect to a grant under subsection (a) for a transitional area to the same extent and in the same manner as such provisions apply with respect to a grant under subpart I for an eligible area, except that, subject to subparagraph (B), the chief elected official of the transitional area

may elect not to comply with the provisions of section 2602(b) if the official provides documentation to the Secretary that details the process used to obtain community input (particularly from those with HIV) in the transitional area for formulating the overall plan for priority setting and allocating funds from the grant under subsection (a).

(B) EXCEPTION.—For each of the fiscal years 2007 through 2013, the exception described in subparagraph (A) does not apply if the transitional area involved received funding under subpart I for fiscal year 2006.

(2) TYPE AND DISTRIBUTION OF GRANTS; TIMEFRAME FOR OBLIGATION AND EXPENDITURE OF GRANT FUNDS.—

(A) FORMULA GRANTS; SUPPLEMENTAL GRANTS.—The provisions of section 2603 apply with respect to grants under subsection (a) to the same extent and in the same manner as such provisions apply with respect to grants under subpart I, subject to subparagraphs (B) and (C).

(B) FORMULA GRANTS; INCREASE IN GRANT.—For purposes of subparagraph (A), section 2603(a)(4) does not apply.

(C) SUPPLEMENTAL GRANTS; SINGLE PROGRAM WITH SUBPART I PROGRAM.—With respect to section 2603(b) as applied for purposes of subparagraph (A):

(i) The Secretary shall combine amounts available pursuant to such subparagraph with amounts available for carrying out section 2603(b) and shall administer the two programs as a single program.

(ii) In the single program, the Secretary has discretion in allocating amounts between eligible areas under subpart I and transitional areas under this section, subject to the eligibility criteria that apply under such section, and subject to section 2603(b)(2)(C) (relating to priority in making grants).

(iii) Pursuant to section 2603(b)(1), amounts for the single program are subject to use under sections 2603(a)(4) and 2610(d)(1).

(3) APPLICATION; TECHNICAL ASSISTANCE; DEFINITIONS.—The provisions of sections 2605, 2606, and 2607 apply with respect to grants under subsection (a) to the same extent and in the same manner as such provisions apply with respect to grants under subpart I.

Subpart III—General Provisions

SEC. 2610.[300ff–20] AUTHORIZATION OF APPROPRIATIONS.

(a) IN GENERAL.—For the purpose of carrying out this part, there are authorized to be appropriated $604,000,000 for fiscal year 2007, $626,300,000 for fiscal year 2008, $649,500,000 for fiscal year 2009, $681,975,000 for fiscal year 2010, $716,074,000 for fiscal year 2011, $751,877,000 for fiscal year 2012, and $789,471,000 for fiscal year 2013. Amounts appropriated under the preceding sentence for a fiscal year are available for obligation by the Secretary until the end of the second succeeding fiscal year.

(b) RESERVATION OF AMOUNTS.—

(1) FISCAL YEAR 2007.—Of the amount appropriated under subsection (a) for fiscal year 2007, the Secretary shall reserve—

(A) $458,310,000 for grants under subpart I; and

(B) $145,690,000 for grants under section 2609.

(2) SUBSEQUENT FISCAL YEARS.—Of the amount appropriated under subsection (a) for fiscal year 2008 and each subsequent fiscal year—

(A) the Secretary shall reserve an amount for grants under subpart I; and

(B) the Secretary shall reserve an amount for grants under section 2609.

(c) TRANSFER OF CERTAIN AMOUNTS; CHANGE IN STATUS AS ELIGIBLE AREA OR TRANSITIONAL AREA.—Notwithstanding subsection (b):

(1) If a metropolitan area is an eligible area under subpart I for a fiscal year, but for a subsequent fiscal year ceases to be an eligible area by reason of section 2601(b)—

(A)(i) the amount reserved under paragraph (1)(A) or (2)(A) of subsection (b) of this section for the first such subsequent year of not being an eligible area is deemed to be reduced by an amount equal to the amount of the grant made pursuant to section 2603(a) for the metropolitan area for the preceding fiscal year; and

(ii)(I) if the metropolitan area qualifies for such first subsequent fiscal year as a transitional area under 2609, the amount reserved under paragraph (1)(B) or (2)(B) of subsection (b) for such fiscal year is deemed to be increased by an amount equal to the amount of the reduction under subparagraph (A) for such year; or

(II) if the metropolitan area does not qualify for such first subsequent fiscal year as a transitional area under 2609, an amount equal to the amount of such reduction is, notwithstanding subsection (a), transferred and made available for grants pursuant to section 2618(a)(1), in addition to amounts available for such grants under section 2623; and

(B) if a transfer under subparagraph (A)(ii)(II) is made with respect to the metropolitan area for such first subsequent fiscal year, then—

(i) the amount reserved under paragraph (1)(A) or (2)(A) of subsection (b) of this section for such year is deemed to be reduced by an additional $500,000; and

(ii) an amount equal to the amount of such additional reduction is, notwithstanding subsection (a), transferred and made available for grants pursuant to section 2618(a)(1), in addition to amounts available for such grants under section 2623.

(2) If a metropolitan area is a transitional area under section 2609 for a fiscal year, but for a subsequent fiscal year ceases to be a transitional area by reason of section 2609(c)(2) (and does not qualify for such subsequent fiscal year as an eligible area under subpart I)—

(A) the amount reserved under subsection (b)(2)(B) of this section for the first such subsequent fiscal year of not being a transitional area is deemed to be reduced by an amount equal to the total of—

(i) the amount of the grant that, pursuant to section 2603(a), was made under section 2609(d)(2)(A) for the metropolitan area for the preceding fiscal year; and

(ii) $500,000; and

(B)(i) subject to clause (ii), an amount equal to the amount of the reduction under subparagraph (A) for such year is, notwithstanding subsection (a), transferred and made available for grants pursuant to section 2618(a)(1), in addition to amounts available for such grants under section 2623; and

(ii) for each of fiscal years 2010 through 2013, notwithstanding subsection (a)—

(I) there shall be transferred to the State containing the metropolitan area, for purposes described in section 2612(a), an amount (which shall not be taken into account in applying section 2618(a)(2)(H)) equal to—

(aa) for the first fiscal year of the metropolitan area not being a transitional area, 75 percent of the amount described in subparagraph (A)(i) for such area;

(bb) for the second fiscal year of the metropolitan area not being a transitional area, 50 percent of such amount; and

(cc) for the third fiscal year of the metropolitan area not being a transitional area, 25 percent of such amount; and

(II) there shall be transferred and made available for grants pursuant to section 2618(a)(1) for the fiscal year, in addition to amounts available for such grants under section 2623, an amount equal to the total amount of the reduction for such fiscal year under subparagraph (A), less the amount transferred for such fiscal year under subclause (I).

(3) If a metropolitan area is a transitional area under section 2609 for a fiscal year, but for a subsequent fiscal year qualifies as an eligible area under subpart I—

(A) the amount reserved under subsection (b)(2)(B) of this section for the first such subsequent fiscal year of becoming an eligible area is deemed to be reduced by an amount equal to the amount of the grant that, pursuant to section 2603(a), was made under section 2609(d)(2)(A) for the metropolitan area for the preceding fiscal year; and

(B) the amount reserved under subsection (b)(2)(A) for such fiscal year is deemed to be increased by an amount equal to the amount of the reduction under subparagraph (A) for such year.

(d) CERTAIN TRANSFERS; ALLOCATIONS BETWEEN PROGRAMS UNDER SUBPART I.—With respect to paragraphs (1)(B)(i) and

(2)(A)(ii) of subsection (c), the Secretary shall administer any reductions under such paragraphs for a fiscal year in accordance with the following:

(1) The reductions shall be made from amounts available for the single program referred to in section 2609(d)(2)(C) (relating to supplemental grants).

(2) The reductions shall be made before the amounts referred to in paragraph (1) are used for purposes of section 2603(a)(4).

(3) If the amounts referred to in paragraph (1) are not sufficient for making all the reductions, the reductions shall be reduced until the total amount of the reductions equals the total of the amounts referred to in such paragraph.

(e) RULES OF CONSTRUCTION REGARDING FIRST SUBSEQUENT FISCAL YEAR.—Paragraphs (1) and (2) of subsection (c) apply with respect to each series of fiscal years during which a metropolitan area is an eligible area under subpart I or a transitional area under section 2609 for a fiscal year and then for a subsequent fiscal year ceases to be such an area by reason of section 2601(b) or 2609(c)(2), respectively, rather than applying to a single such series. Paragraph (3) of subsection (c) applies with respect to each series of fiscal years during which a metropolitan area is a transitional area under section 2609 for a fiscal year and then for a subsequent fiscal year becomes an eligible area under subpart I, rather than applying to a single such series.

PART B—CARE GRANT PROGRAM[6]

Subpart I—General Grant Provisions

SEC. 2611.[300ff–21] GRANTS.

The Secretary shall, subject to the availability of appropriations, make grants to States to enable such States to improve the quality, availability and organization of health care and support services for individuals and families with HIV/AIDS. The authority of the Secretary to provide grants under part B is subject to section 2626(e)(2) (relating to the decrease in perinatal transmission of HIV/AIDS).

SEC. 2612.[300ff–22] GENERAL USE OF GRANTS.

(a) IN GENERAL.—A State may use amounts provided under grants made under section 2611 for—

(1) core medical services described in subsection (b);

(2) support services described in subsection (c); and

(3) administrative expenses described in section 2618(b)(3).

(b) REQUIRED FUNDING FOR CORE MEDICAL SERVICES.—

(1) IN GENERAL.—With respect to a grant under section 2611 for a State for a grant year, the State shall, of the portion of the grant remaining after reserving amounts for purposes of subparagraphs (A) and (E)(ii)(I) of section 2618(b)(3), use not less than 75 percent to provide core medical services that are

[6] See footnote at the beginning of part A.

Section 8(a) of Public Law 104–146 (110 Stat. 1372) establishes a condition for the receipt of grants under part B. The condition relates to notification of spouses of HIV-infected patients.

needed in the State for individuals with HIV/AIDS who are identified and eligible under this title (including services regarding the co-occurring conditions of the individuals).

(2) WAIVER.—

(A) IN GENERAL.—The Secretary shall waive the application of paragraph (1) with respect to a State for a grant year if the Secretary determines that, within the State—

(i) there are no waiting lists for AIDS Drug Assistance Program services under section 2616; and

(ii) core medical services are available to all individuals with HIV/AIDS identified and eligible under this title.

(B) NOTIFICATION OF WAIVER STATUS.—When informing a State that a grant under section 2611 is being made to the State for a fiscal year, the Secretary shall inform the State whether a waiver under subparagraph (A) is in effect for the fiscal year.

(3) CORE MEDICAL SERVICES.—For purposes of this subsection, the term "core medical services", with respect to an individual infected with HIV/AIDS (including the co-occurring conditions of the individual) means the following services:

(A) Outpatient and ambulatory health services.

(B) AIDS Drug Assistance Program treatments in accordance with section 2616.

(C) AIDS pharmaceutical assistance.

(D) Oral health care.

(E) Early intervention services described in subsection (d).

(F) Health insurance premium and cost sharing assistance for low-income individuals in accordance with section 2615.

(G) Home health care.

(H) Medical nutrition therapy.

(I) Hospice services.

(J) Home and community-based health services as defined under section 2614(c).

(K) Mental health services.

(L) Substance abuse outpatient care.

(M) Medical case management, including treatment adherence services.

(c) SUPPORT SERVICES.—

(1) IN GENERAL.—For purposes of this subsection, the term "support services" means services, subject to the approval of the Secretary, that are needed for individuals with HIV/AIDS to achieve their medical outcomes (such as respite care for persons caring for individuals with HIV/AIDS, outreach services, medical transportation, linguistic services, and referrals for health care and support services).

(2) DEFINITION OF MEDICAL OUTCOMES.—In this subsection, the term "medical outcomes" means those outcomes affecting the HIV-related clinical status of an individual with HIV/AIDS.

(d) EARLY INTERVENTION SERVICES.—

(1) IN GENERAL.—For purposes of this section, the term "early intervention services" means HIV/AIDS early interven-

tion services described in section 2651(e), with follow-up referral provided for the purpose of facilitating the access of individuals receiving the services to HIV-related health services. The entities through which such services may be provided under the grant include public health departments, emergency rooms, substance abuse and mental health treatment programs, detoxification centers, detention facilities, clinics regarding sexually transmitted diseases, homeless shelters, HIV/AIDS counseling and testing sites, health care points of entry specified by States, federally qualified health centers, and entities described in section 2652(a) that constitute a point of access to services by maintaining referral relationships.

(2) CONDITIONS.—With respect to an entity that proposes to provide early intervention services under paragraph (1), such paragraph shall apply only if the entity demonstrates to the satisfaction of the chief elected official for the State involved that—

(A) Federal, State, or local funds are otherwise inadequate for the early intervention services the entity proposes to provide; and

(B) the entity will expend funds pursuant to such subparagraph to supplement and not supplant other funds available to the entity for the provision of early intervention services for the fiscal year involved.

(e) PRIORITY FOR WOMEN, INFANTS, CHILDREN, AND YOUTH.—

(1) IN GENERAL.—For the purpose of providing health and support services to infants, children, youth, and women with HIV/AIDS, including treatment measures to prevent the perinatal transmission of HIV, a State shall for each of such populations in the eligible area use, from the grants made for the area under section 2601(a) for a fiscal year, not less than the percentage constituted by the ratio of the population involved (infants, children, youth, or women in such area) with HIV/AIDS to the general population in such area of individuals with HIV/AIDS.

(2) WAIVER.—With respect to the population involved, the Secretary may provide to a State a waiver of the requirement of paragraph (1) if such State demonstrates to the satisfaction of the Secretary that the population is receiving HIV-related health services through the State medicaid program under title XIX of the Social Security Act, the State children's health insurance program under title XXI of such Act, or other Federal or State programs.

(f) CONSTRUCTION.—A State may not use amounts received under a grant awarded under section 2611 to purchase or improve land, or to purchase, construct, or permanently improve (other than minor remodeling) any building or other facility, or to make cash payments to intended recipients of services.

SEC. 2613.[300ff–23] GRANTS TO ESTABLISH HIV CARE CONSORTIA.

(a) CONSORTIA.—A State may, subject to subsection (f), use amounts provided under a grant awarded under section 2611 to provide assistance under section 2612(a) to an entity that—

(1) is an association of one or more public, and one or more nonprofit private, (or private for-profit providers or organizations if such entities are the only available providers of quality HIV care in the area) health care and support service providers and community based organizations operating within areas determined by the State to be most affected by HIV/AIDS; and

(2) agrees to use such assistance for the planning, development and delivery, through the direct provision of services or through entering into agreements with other entities for the provision of such services, of comprehensive outpatient health and support services for individuals with HIV disease, that may include—

(A) essential health services such as case management services, medical, nursing, substance abuse treatment, mental health treatment, and dental care, diagnostics, monitoring, prophylactic treatment for opportunistic infections, treatment education to take place in the context of health care delivery, and medical follow-up services, mental health, developmental, and rehabilitation services, home health and hospice care; and

(B) essential support services such as transportation services, attendant care, homemaker services, day or respite care, benefits advocacy, advocacy services provided through public and nonprofit private entities, and services that are incidental to the provision of health care services for individuals with HIV/AIDS including nutrition services, housing referral services, and child welfare and family services (including foster care and adoption services).

An entity or entities of the type described in this subsection shall hereinafter be referred to in this title as a "consortium" or "consortia".

(b) ASSURANCES.—

(1) REQUIREMENT.—To receive assistance from a State under subsection (a), an applicant consortium shall provide the State with assurances that—

(A) within any locality in which such consortium is to operate, the populations and subpopulations of individuals and families with HIV/AIDS have been identified by the consortium, particularly those experiencing disparities in access and services and those who reside in historically underserved communities;

(B) the service plan established under subsection (c)(2) by such consortium is consistent with the comprehensive plan under section 2617(b)(4) and addresses the special care and service needs of the populations and subpopulations identified under subparagraph (A); and

(C) except as provided in paragraph (2), the consortium will be a single coordinating entity that will integrate the delivery of services among the populations and subpopulations identified under subparagraph (A).

(2) EXCEPTION.—Subparagraph (C) of paragraph (1) shall not apply to any applicant consortium that the State determines will operate in a community or locality in which it has been demonstrated by the applicant consortium that—

(A) subpopulations exist within the community to be served that have unique service requirements; and

(B) such unique service requirements cannot be adequately and efficiently addressed by a single consortium serving the entire community or locality.

(c) APPLICATION.—

(1) IN GENERAL.—To receive assistance from the State under subsection (a), a consortium shall prepare and submit to the State, an application that—

(A) demonstrates that the consortium includes agencies and community-based organizations—

(i) with a record of service to populations and subpopulations with HIV/AIDS requiring care within the community to be served; and

(ii) that are representative of populations and subpopulations reflecting the local incidence of HIV and that are located in areas in which such populations reside;

(B) demonstrates that the consortium has carried out an assessment of service needs within the geographic area to be served and, after consultation with the entities described in paragraph (2), has established a plan to ensure the delivery of services to meet such identified needs that shall include—

(i) assurances that service needs will be addressed through the coordination and expansion of existing programs before new programs are created;

(ii) assurances that, in metropolitan areas, the geographic area to be served by the consortium corresponds to the geographic boundaries of local health and support services delivery systems to the extent practicable;

(iii) assurances that, in the case of services for individuals residing in rural areas, the applicant consortium shall deliver case management services that link available community support services to appropriate specialized medical services; and

(iv) assurances that the assessment of service needs and the planning of the delivery of services will include participation by individuals with HIV/AIDS;

(C) demonstrates that adequate planning has occurred to meet the special needs of families with HIV/AIDS, including family centered and youth centered care;

(D) demonstrates that the consortium has created a mechanism to evaluate periodically—

(i) the success of the consortium in responding to identified needs; and

(ii) the cost-effectiveness of the mechanisms employed by the consortium to deliver comprehensive care;

(E) demonstrates that the consortium will report to the State the results of the evaluations described in subparagraph (D) and shall make available to the State or the Secretary, on request, such data and information on the

program methodology that may be required to perform an independent evaluation; and

(F) demonstrates that adequate planning occurred to address disparities in access and services and historically underserved communities.

(2) CONSULTATION.—In establishing the plan required under paragraph (1)(B), the consortium shall consult with—

(A)(i) the public health agency that provides or supports ambulatory and outpatient HIV-related health care services within the geographic area to be served; or

(ii) in the case of a public health agency that does not directly provide such HIV-related health care services such agency shall consult with an entity or entities that directly provide ambulatory and outpatient HIV-related health care services within the geographic area to be served;

(B) not less than one community-based organization that is organized solely for the purpose of providing HIV-related support services to individuals with HIV/AIDS;

(C) grantees under section 2671, or, if none are operating in the area, representatives in the area of organizations with a history of serving children, youth, women, and families living with HIV; and

(D) the types of entities described in section 2602(b)(2).

The organization to be consulted under subparagraph (B) shall be at the discretion of the applicant consortium.

(d) DEFINITION.—As used in section 2611, the term "family centered care" means the system of services described in this section that is targeted specifically to the special needs of infants, children, women, and families. Family centered care shall be based on a partnership between parents, professionals, and the community designed to ensure an integrated, coordinated, culturally sensitive, and community-based continuum of care for children, women, and families with HIV/AIDS.

(e) PRIORITY.—In providing assistance under subsection (a), the State shall, among applicants that meet the requirements of this section, give priority—

(1) first to consortia that are receiving assistance from the Health Resources and Services Administration for adult and pediatric HIV-related care demonstration projects; and then

(2) to any other existing HIV care consortia.

(f) ALLOCATION OF FUNDS; TREATMENT AS SUPPORT SERVICES.—For purposes of the requirement of section 2612(b)(1), expenditures of grants under section 2611 for or through consortia under this section are deemed to be support services, not core medical services. The preceding sentence may not be construed as having any legal effect on the provisions of subsection (a) that relate to authorized expenditures of the grant.

SEC. 2614.[300ff–24] GRANTS FOR HOME- AND COMMUNITY-BASED CARE.

(a) USES.—A State may use amounts provided under a grant awarded under section 2611 to make grants under section 2612(b)(3)(J) to entities to—

(1) provide home- and community-based health services for individuals with HIV/AIDS pursuant to written plans of care prepared by a case management team, that shall include appropriate health care professionals, in such State for providing such services to such individuals;

(2) provide outreach services to individuals with HIV/AIDS, including those individuals in rural areas; and

(3) provide for the coordination of the provision of services under this section with the provision of HIV-related health services, including specialty care and vaccinations for hepatitis co-infection, provided by public and private entities.

(b) PRIORITY.—In awarding grants under subsection (a), a State shall give priority to entities that provide assurances to the State that—

(1) such entities will participate in HIV care consortia if such consortia exist within the State; and

(2) such entities will utilize amounts provided under such grants for the provision of home- and community-based services to low-income individuals with HIV/AIDS.

(c) DEFINITION.—As used in section 2611, the term "home- and community-based health services"—

(1) means, with respect to an individual with HIV/AIDS, skilled health services furnished to the individual in the individual's home pursuant to a written plan of care established by a case management team, that shall include appropriate health care professionals, for the provision of such services and items described in paragraph (2);

(2) includes—

(A) durable medical equipment;

(B) home health aide services and personal care services furnished in the home of the individual;

(C) day treatment or other partial hospitalization services;

(D) home intravenous and aerosolized drug therapy (including prescription drugs administered as part of such therapy);

(E) routine diagnostic testing administered in the home of the individual; and

(F) appropriate mental health, developmental, and rehabilitation services; and

(3) does not include—

(A) inpatient hospital services; and

(B) nursing home and other long term care facilities.

SEC. 2615.[300ff–25] CONTINUUM OF HEALTH INSURANCE COVERAGE.

(a) IN GENERAL.—A State may use amounts received under a grant awarded under section 2611 to establish a program of financial assistance under section 2612(b)(3)(F) to assist eligible low-income individuals with HIV/AIDS in—

(1) maintaining a continuity of health insurance; or

(2) receiving medical benefits under a health insurance program, including risk-pools.

(b) LIMITATIONS.—Assistance shall not be utilized under subsection (a)—

(1) to pay any costs associated with the creation, capitalization, or administration of a liability risk pool (other than those costs paid on behalf of individuals as part of premium contributions to existing liability risk pools); and

(2) to pay any amount expended by a State under title XIX of the Social Security Act.

SEC. 2616.[300ff–26] PROVISION OF TREATMENTS.

(a) IN GENERAL.—A State shall use a portion of the amounts provided under a grant awarded under section 2611 to establish a program under section 2612(b)(3)(B) to provide therapeutics to treat HIV/AIDS or prevent the serious deterioration of health arising from HIV/AIDS in eligible individuals, including measures for the prevention and treatment of opportunistic infections.

(b) ELIGIBLE INDIVIDUAL.—To be eligible to receive assistance from a State under this section an individual shall—

(1) have a medical diagnosis of HIV/AIDS; and

(2) be a low-income individual, as defined by the State.

(c) STATE DUTIES.—In carrying out this section the State shall—

(1) ensure that the therapeutics included on the list of classes of core antiretroviral therapeutics established by the Secretary under subsection (e) are, at a minimum, the treatments provided by the State pursuant to this section;

(2) provide assistance for the purchase of treatments determined to be eligible under paragraph (1), and the provision of such ancillary devices that are essential to administer such treatments;

(3) provide outreach to individuals with HIV/AIDS, and as appropriate to the families of such individuals;

(4) facilitate access to treatments for such individuals;

(5) document the progress made in making therapeutics described in subsection (a) available to individuals eligible for assistance under this section; and

(6) encourage, support, and enhance adherence to and compliance with treatment regimens, including related medical monitoring.

Of the amount reserved by a State for a fiscal year for use under this section, the State may not use more than 5 percent to carry out services under paragraph (6), except that the percentage applicable with respect to such paragraph is 10 percent if the State demonstrates to the Secretary that such additional services are essential and in no way diminish access to the therapeutics described in subsection (a).

(d) DUTIES OF THE SECRETARY.—In carrying out this section, the Secretary shall review the current status of State drug reimbursement programs established under section 2612(2) and assess barriers to the expanded availability of the treatments described in subsection (a). The Secretary shall also examine the extent to which States coordinate with other grantees under this title to reduce barriers to the expanded availability of the treatments described in subsection (a).

(e) LIST OF CLASSES OF CORE ANTIRETROVIRAL THERAPEUTICS.—For purposes of subsection (c)(1), the Secretary shall de-

velop and maintain a list of classes of core antiretroviral therapeutics, which list shall be based on the therapeutics included in the guidelines of the Secretary known as the Clinical Practice Guidelines for Use of HIV/AIDS Drugs, relating to drugs needed to manage symptoms associated with HIV. The preceding sentence does not affect the authority of the Secretary to modify such Guidelines.

(f) USE OF HEALTH INSURANCE AND PLANS.—

(1) IN GENERAL.—In carrying out subsection (a), a State may expend a grant under section 2611 to provide the therapeutics described in such subsection by paying on behalf of individuals with HIV/AIDS the costs of purchasing or maintaining health insurance or plans whose coverage includes a full range of such therapeutics and appropriate primary care services.

(2) LIMITATION.—The authority established in paragraph (1) applies only to the extent that, for the fiscal year involved, the costs of the health insurance or plans to be purchased or maintained under such paragraph do not exceed the costs of otherwise providing therapeutics described in subsection (a).

(g) DRUG REBATE PROGRAM.—A State shall ensure that any drug rebates received on drugs purchased from funds provided pursuant to this section are applied to activities supported under this subpart, with priority given to activities described under this section.

SEC. 2617.[300ff–27] STATE APPLICATION.

(a) IN GENERAL.—The Secretary shall not make a grant to a State under section 2611 for a fiscal year unless the State prepares and submits, to the Secretary, an application at such time, in such form, and containing such agreements, assurances, and information as the Secretary determines to be necessary to carry out section 2611.

(b) DESCRIPTION OF INTENDED USES AND AGREEMENTS.—The application submitted under subsection (a) shall contain—

(1) a detailed description of the HIV-related services provided in the State to individuals and families with HIV/AIDS during the year preceding the year for which the grant is requested, and the number of individuals and families receiving such services, that shall include—

(A) a description of the types of programs operated or funded by the State for the provision of HIV-related services during the year preceding the year for which the grant is requested and the methods utilized by the State to finance such programs;

(B) an accounting of the amount of funds that the State has expended for such services and programs during the year preceding the year for which the grant is requested; and

(C) information concerning—

(i) the number of individuals to be served with assistance provided under the grant;

(ii) demographic data on the population of the individuals to be served;

(iii) the average cost of providing each category of HIV-related health services and the extent to which such cost is paid by third-party payors; and

(iv) the aggregate amounts expended for each such category of services;

(2) a determination of the size and demographics of the population of individuals with HIV/AIDS in the State;

(3) a determination of the needs of such population, with particular attention to—

(A) individuals with HIV/AIDS who know their HIV status and are not receiving HIV-related services; and

(B) disparities in access and services among affected subpopulations and historically underserved communities;

(4) the designation of a lead State agency that shall—

(A) administer all assistance received under section 2611;

(B) conduct the needs assessment and prepare the State plan under paragraph (3);

(C) prepare all applications for assistance under section 2611;

(D) receive notices with respect to programs under this title;

(E) every 2 years, collect and submit to the Secretary all audits, consistent with Office of Management and Budget circular A133, from grantees within the State, including audits regarding funds expended in accordance with section 2611; and

(F) carry out any other duties determined appropriate by the Secretary to facilitate the coordination of programs under this title.

(5) a comprehensive plan that describes the organization and delivery of HIV health care and support services to be funded with assistance received under section 2611 that shall include a description of the purposes for which the State intends to use such assistance, and that—

(A)[7] establishes priorities for the allocation of funds within the State based on—

(i) size and demographics of the population of individuals with HIV/AIDS (as determined under paragraph (2)) and the needs of such population (as determined under paragraph (3));

(ii) availability of other governmental and nongovernmental resources, including the State medicaid plan under title XIX of the Social Security Act and the State Children's Health Insurance Program under title XXI of such Act to cover health care costs of eligible individuals and families with HIV/AIDS;

[7] The placement of subparagraphs (A) through (C) is according to the probable intent of the Congress. Section 205(a)(3) of Public Law 106–345 (114 Stat. 1332, 1333) amended paragraph (4) by redesignating subparagraphs (A) through (C) as subparagraphs (D) through (F), and then instructed that new subparagraphs (A) through (C) be inserted before "subparagraph (C)". The amendment probably should have instructed that the new subparagraphs be inserted before subparagraph (D), as redesignated.

(iii) capacity development needs resulting from disparities in the availability of HIV-related services in historically underserved communities and rural communities; and

(iv) the efficiency of the administrative mechanism of the State for rapidly allocating funds to the areas of greatest need within the State;

(B) includes a strategy for identifying individuals who know their HIV status and are not receiving such services and for informing the individuals of and enabling the individuals to utilize the services, giving particular attention to eliminating disparities in access and services among affected subpopulations and historically underserved communities, and including discrete goals, a timetable, and an appropriate allocation of funds;

(C) includes a strategy to coordinate the provision of such services with programs for HIV prevention (including outreach and early intervention) and for the prevention and treatment of substance abuse (including programs that provide comprehensive treatment services for such abuse);

(D) describes the services and activities to be provided and an explanation of the manner in which the elements of the program to be implemented by the State with such assistance will maximize the quality of health and support services available to individuals with HIV/AIDS throughout the State;

(E) provides a description of the manner in which services funded with assistance provided under section 2611 will be coordinated with other available related services for individuals with HIV/AIDS;

(F) provides a description of how the allocation and utilization of resources are consistent with the statewide coordinated statement of need (including traditionally underserved populations and subpopulations) developed in partnership with other grantees in the State that receive funding under this title; and

(G) includes key outcomes to be measured by all entities in the State receiving assistance under this title; and

(6) an assurance that the public health agency administering the grant for the State will periodically convene a meeting of individuals with HIV/AIDS, members of a Federally recognized Indian tribe as represented in the State, representatives of grantees under each part under this title, providers, and public agency representatives for the purpose of developing a statewide coordinated statement of need;

(7) an assurance by the State that—

(A) the public health agency that is administering the grant for the State engages in a public advisory planning process, including public hearings, that includes the participants under paragraph (6), and the types of entities described in section 2602(b)(2), in developing the comprehensive plan under paragraph (5) and commenting on the implementation of such plan;

(B) the State will—

(i) to the maximum extent practicable, ensure that HIV-related health care and support services delivered pursuant to a program established with assistance provided under section 2611 will be provided without regard to the ability of the individual to pay for such services and without regard to the current or past health condition of the individual with HIV/AIDS;

(ii) ensure that such services will be provided in a setting that is accessible to low-income individuals with HIV/AIDS;

(iii) provide outreach to low-income individuals with HIV/AIDS to inform such individuals of the services available under section 2611; and

(iv) in the case of a State that intends to use amounts provided under the grant for purposes described in 2615[8], submit a plan to the Secretary that demonstrates that the State has established a program that assures that—

(I) such amounts will be targeted to individuals who would not otherwise be able to afford health insurance coverage; and

(II) income, asset, and medical expense criteria will be established and applied by the State to identify those individuals who qualify for assistance under such program, and information concerning such criteria shall be made available to the public;

(C) the State will provide for periodic independent peer review to assess the quality and appropriateness of health and support services provided by entities that receive funds from the State under section 2611;

(D) the State will permit and cooperate with any Federal investigations undertaken regarding programs conducted under section 2611;

(E) the State will maintain HIV-related activities at a level that is equal to not less than the level of such expenditures by the State for the 1-year period preceding the fiscal year for which the State is applying to receive a grant under section 2611;

(F) the State will ensure that grant funds are not utilized to make payments for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to that item or service—

(i) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program; or

(ii) by an entity that provides health services on a prepaid basis (except for a program administered by

[8] The word "section" probably should appear before "2615". Section 12(c)(3) of Public Law 104–146 (110 Stat. 1373) provides that subsection (b)(3)(B)(iv) is amended by inserting "section" before "2615", but the amendment cannot be executed because the term "2615" does not appear in paragraph (3)(B)(iv). The term formerly did appear in such paragraph, but former paragraph (3) was redesignated as paragraph (4) by section 3(c)(4)(B) of such Public Law (110 Stat. 1355).

or providing the services of the Indian Health Service); and

(G) entities within areas in which activities under the grant are carried out will maintain appropriate relationships with entities in the area served that constitute key points of access to the health care system for individuals with HIV/AIDS (including emergency rooms, substance abuse treatment programs, detoxification centers, adult and juvenile detention facilities, sexually transmitted disease clinics, HIV counseling and testing sites, mental health programs, and homeless shelters), and other entities under section 2612(c) and 2652(a), for the purpose of facilitating early intervention for individuals newly diagnosed with HIV/AIDS and individuals knowledgeable of their HIV status but not in care; and

(8) a comprehensive plan—

(A) containing an identification of individuals with HIV/AIDS as described in clauses (i) through (iii) of section 2603(b)(2)(A) and the strategy required under section 2602(b)(4)(D)(iv);

(B) describing the estimated number of individuals within the State with HIV/AIDS who do not know their status;

(C) describing activities undertaken by the State to find the individuals described in subparagraph (A) and to make such individuals aware of their status;

(D) describing the manner in which the State will provide undiagnosed individuals who are made aware of their status with access to medical treatment for their HIV/AIDS; and

(E) describing efforts to remove legal barriers, including State laws and regulations, to routine testing.

(c) REQUIREMENTS REGARDING IMPOSITION OF CHARGES FOR SERVICES.—

(1) IN GENERAL.—The Secretary may not make a grant under section 2611 to a State unless the State provides assurances that in the provision of services with assistance provided under the grant—

(A) in the case of individuals with an income less than or equal to 100 percent of the official poverty line, the provider will not impose charges on any such individual for the provision of services under the grant;

(B) in the case of individuals with an income greater than 100 percent of the official poverty line, the provider—

(i) will impose charges on each such individual for the provision of such services; and

(ii) will impose charges according to a schedule of charges that is made available to the public;

(C) in the case of individuals with an income greater than 100 percent of the official poverty line and not exceeding 200 percent of such poverty line, the provider will not, for any calendar year, impose charges in an amount exceeding 5 percent of the annual gross income of the individual involved;

(D) in the case of individuals with an income greater than 200 percent of the official poverty line and not exceeding 300 percent of such poverty line, the provider will not, for any calendar year, impose charges in an amount exceeding 7 percent of the annual gross income of the individual involved; and

(E) in the case of individuals with an income greater than 300 percent of the official poverty line, the provider will not, for any calendar year, impose charges in an amount exceeding 10 percent of the annual gross income of the individual involved.

(2) ASSESSMENT OF CHARGE.—With respect to compliance with the assurance made under paragraph (1), a grantee under section 2611 may, in the case of individuals subject to a charge for purposes of such paragraph—

(A) assess the amount of the charge in the discretion of the grantee, including imposing only a nominal charge for the provision of services, subject to the provisions of such paragraph regarding public schedules regarding limitation on the maximum amount of charges; and

(B) take into consideration the medical expenses of individuals in assessing the amount of the charge, subject to such provisions.

(3) APPLICABILITY OF LIMITATION ON AMOUNT OF CHARGE.—The Secretary may not make a grant under section 2611 unless the applicant of the grant agrees that the limitations established in subparagraphs (C), (D), and (E) of paragraph (1) regarding the imposition of charges for services applies to the annual aggregate of charges imposed for such services, without regard to whether they are characterized as enrollment fees, premiums, deductibles, cost sharing, copayments, coinsurance, or other charges.

(4) WAIVER.—

(A) IN GENERAL.—The State shall waive the requirements established in paragraphs (1) through (3) in the case of an entity that does not, in providing health care services, impose a charge or accept reimbursement from any third-party payor, including reimbursement under any insurance policy or under any Federal or State health benefits program.

(B) DETERMINATION.—A determination by the State of whether an entity referred to in subparagraph (A) meets the criteria for a waiver under such subparagraph shall be made without regard to whether the entity accepts voluntary donations regarding the provision of services to the public.

(d) REQUIREMENT OF MATCHING FUNDS REGARDING STATE ALLOTMENTS.—

(1) IN GENERAL.—In the case of any State to which the criterion described in paragraph (3) applies, the Secretary may not make a grant under section 2611 unless the State agrees that, with respect to the costs to be incurred by the State in carrying out the program for which the grant was awarded, the State will, subject to subsection (b)(2), make available (directly

or through donations from public or private entities) non-Federal contributions toward such costs in an amount equal to—

(A) for the first fiscal year of payments under the grant, not less than 16⅔ percent of such costs ($1 for each $5 of Federal funds provided in the grant);

(B) for any second fiscal year of such payments, not less than 20 percent of such costs ($1 for each $4 of Federal funds provided in the grant);

(C) for any third fiscal year of such payments, not less than 25 percent of such costs ($1 for each $3 of Federal funds provided in the grant);

(D) for any fourth fiscal year of such payments, not less than 33⅓ percent of such costs ($1 for each $2 of Federal funds provided in the grant); and

(E) for any subsequent fiscal year of such payments, not less than 33⅓ percent of such costs ($1 for each $2 of Federal funds provided in the grant).

(2) DETERMINATION OF AMOUNT OF NON-FEDERAL CONTRIBUTION.—

(A) IN GENERAL.—Non-Federal contributions required in paragraph (1) may be in cash or in kind, fairly evaluated, including plant, equipment, or services. Amounts provided by the Federal Government, and any portion of any service subsidized by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

(B) INCLUSION OF CERTAIN AMOUNTS.—

(i) In making a determination of the amount of non-Federal contributions made by a State for purposes of paragraph (1), the Secretary shall, subject to clause (ii), include any non-Federal contributions provided by the State for HIV-related services, without regard to whether the contributions are made for programs established pursuant to this title;

(ii) In making a determination for purposes of clause (i), the Secretary may not include any non-Federal contributions provided by the State as a condition of receiving Federal funds under any program under this title (except for the program established in section 2611) or under other provisions of law.

(3) APPLICABILITY OF REQUIREMENT.—

(A) NUMBER OF CASES.—A State referred to in paragraph (1) is any State for which the number of cases of HIV/AIDS reported to and confirmed by the Director of the Centers for Disease Control and Prevention for the period described in subparagraph (B) constitutes in excess of 1 percent of the aggregate number of such cases reported to and confirmed by the Director for such period for the United States.

(B) PERIOD OF TIME.—The period referred to in subparagraph (A) is the 2-year period preceding the fiscal year for which the State involved is applying to receive a grant under subsection (a).

(C) PUERTO RICO.—For purposes of paragraph (1), the number of cases of HIV/AIDS reported and confirmed for the Commonwealth of Puerto Rico for any fiscal year shall be deemed to be less than 1 percent.

(4) DIMINISHED STATE CONTRIBUTION.—With respect to a State that does not make available the entire amount of the non-Federal contribution referred to in paragraph (1), the State shall continue to be eligible to receive Federal funds under a grant under section 2611, except that the Secretary in providing Federal funds under the grant shall provide such funds (in accordance with the ratios prescribed in paragraph (1)) only with respect to the amount of funds contributed by such State.

SEC. 2618.[300ff–28] DISTRIBUTION OF FUNDS.

(a) AMOUNT OF GRANT TO STATE.—

(1) MINIMUM ALLOTMENT.—Subject to the extent of amounts made available under section 2623, the amount of a grant to be made under section 2611 for—

(A) each of the 50 States, the District of Columbia, Guam, and the Virgin Islands (referred to in this paragraph as a "covered State") for a fiscal year shall be the greater of—

(i)(I) with respect to a covered State that has less than 90 living cases of AIDS, as determined under paragraph (2)(D), $200,000; or

(II) with respect to a covered State that has 90 or more living cases of AIDS, as determined under paragraph (2)(D), $500,000; and

(ii) an amount determined under paragraph (2) and then, as applicable, increased under paragraph (2)(H); and

(B) each territory other than Guam and the Virgin Islands shall be the greater of $50,000 or an amount determined under paragraph (2).

(2) DETERMINATION.—

(A) FORMULA.—For purposes of paragraph (1), the amount referred to in this paragraph for a State (including a territory) for a fiscal year is, subject to subparagraphs (E) and (F)—

(i) an amount equal to the amount made available under section 2623 for the fiscal year involved for grants pursuant to paragraph (1), subject to subparagraph (F); and

(ii) the percentage constituted by the sum of—

(I) the product of 0.75 and the ratio of the State distribution factor for the State or territory (as determined under subsection (B)) to the sum of the respective State distribution factors for all States or territories;

(II) the product of .20 and the ratio of the non-EMA distribution factor for the State or territory (as determined under subparagraph (C)) to

the sum of the respective non-EMA distribution factors for all States or territories; and

(III) if the State does not for such fiscal year contain any area that is an eligible area under subpart I of part A or any area that is a transitional area under section 2609 (referred to in this subclause as a "no-EMA State"), the product of 0.05 and the ratio of the number of cases that applies for the State under subparagraph (D) to the sum of the respective numbers of cases that so apply for all no-EMA States.

(B) STATE DISTRIBUTION FACTOR.—For purposes of subparagraph (A)(ii)(I), the term "State distribution factor" means an amount equal to the number of living cases of HIV/AIDS in the State involved, as determined under subparagraph (D).

(C) NON-EMA DISTRIBUTION FACTOR.—For purposes of subparagraph (A)(ii)(II), the term "non-ema distribution factor" means an amount equal to the sum of—

(i) the number of living cases of HIV/AIDS in the State involved, as determined under subparagraph (D); less

(ii) a number equal to the sum of—

(I) the total number of living cases of HIV/AIDS that are within areas in such State that are eligible areas under subpart I of part A for the fiscal year involved, which individual number for an area is the number that applies under section 2601 for the area for such fiscal year; and

(II) the total number of such cases that are within areas in such State that are transitional areas under section 2609 for such fiscal year, which individual number for an area is the number that applies under such section for the fiscal year.

(D) LIVING CASES OF HIV/AIDS.—

(i) REQUIREMENT OF NAMES-BASED REPORTING.—Except as provided in clause (ii), the number determined under this subparagraph for a State for a fiscal year for purposes of subparagraph (B) is the number of living names-based cases of HIV/AIDS in the State that, as of December 31 of the most recent calendar year for which such data is available, have been reported to and confirmed by the Director of the Centers for Disease Control and Prevention.

(ii) TRANSITION PERIOD; EXEMPTION REGARDING NON-AIDS CASES.—For each of the fiscal years 2007 through 2012, a State is, subject to clauses (iii) through (v), exempt from the requirement under clause (i) that living non-AIDS names-based cases of HIV be reported unless—

(I) a system was in operation as of December 31, 2005, that provides sufficiently accurate and

reliable names-based reporting of such cases throughout the State, subject to clause (vii); or

(II) no later than the beginning of fiscal year 2008 or a subsequent fiscal year through fiscal year 2012, the Secretary, after consultation with the chief executive of the State, determines that a system has become operational in the State that provides sufficiently accurate and reliable names-based reporting of such cases throughout the State.

(iii) REQUIREMENTS FOR EXEMPTION FOR FISCAL YEAR 2007.—For fiscal year 2007, an exemption under clause (ii) for a State applies only if, by October 1, 2006—

(I)(aa) the State had submitted to the Secretary a plan for making the transition to sufficiently accurate and reliable names-based reporting of living non-AIDS cases of HIV; or

(bb) all statutory changes necessary to provide for sufficiently accurate and reliable reporting of such cases had been made; and

(II) the State had agreed that, by April 1, 2008, the State will begin accurate and reliable names-based reporting of such cases, except that such agreement is not required to provide that, as of such date, the system for such reporting be fully sufficient with respect to accuracy and reliability throughout the area.

(iv) REQUIREMENT FOR EXEMPTION AS OF FISCAL YEAR 2008.—For each of the fiscal years 2008 through 2012, an exemption under clause (ii) for a State applies only if, as of April 1, 2008, the State is substantially in compliance with the agreement under clause (iii)(II).

(v) PROGRESS TOWARD NAMES-BASED REPORTING.—For fiscal year 2009 or a subsequent fiscal year, the Secretary may terminate an exemption under clause (ii) for a State if the State submitted a plan under clause (iii)(I)(aa) and the Secretary determines that the State is not substantially following the plan.

(vi) COUNTING OF CASES IN AREAS WITH EXEMPTIONS.—

(I) IN GENERAL.—With respect to a State that is under a reporting system for living non-AIDS cases of HIV that is not names-based (referred to in this subparagraph as "code-based reporting"), the Secretary shall, for purposes of this subparagraph, modify the number of such cases reported for the State in order to adjust for duplicative reporting in and among systems that use code-based reporting.

(II) ADJUSTMENT RATE.—The adjustment rate under subclause (I) for a State shall be a reduction of 5 percent for fiscal years before fiscal year

2012 (and 6 percent for fiscal year 2012) in the number of living non-AIDS cases of HIV reported for the State.

(III) INCREASED ADJUSTMENT FOR CERTAIN STATES PREVIOUSLY USING CODE-BASED REPORTING.—For purposes of this subparagraph for each of fiscal years 2010 through 2012, the Secretary shall deem the applicable number of living cases of HIV/AIDS in a State that were reported to and confirmed by the Centers for Disease Control and Prevention to be 3 percent higher than the actual number if—

(aa) there is an area in such State that satisfies all of the conditions described in items (aa) through (cc) of section 2603(a)(3)(C)(vi)(III); or

(bb)(AA) fiscal year 2007 was the first year in which the count of living non-AIDS cases of HIV in such area, for purposes of this part, was based on a names-based reporting system; and

(BB) the amount of funding that such State received under this part for fiscal year 2007 was less than 70 percent of the amount of funding that such State received under such part for fiscal year 2006.

(vii) LIST OF STATES MEETING STANDARD REGARDING DECEMBER 31, 2005.—

(I) IN GENERAL.—If a State is specified in subclause (II), the State shall be considered to meet the standard described in clause (ii)(I). No other State may be considered to meet such standard.

(II) RELEVANT STATES.—For purposes of subclause (I), the States specified in this subclause are the following: Alaska, Alabama, Arkansas, Arizona, Colorado, Florida, Indiana, Iowa, Idaho, Kansas, Louisiana, Michigan, Minnesota, Missouri, Mississippi, North Carolina, North Dakota, Nebraska, New Jersey, New Mexico, New York, Nevada, Ohio, Oklahoma, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, Wisconsin, West Virginia, Wyoming, Guam, and the Virgin Islands.

(viii) RULES OF CONSTRUCTION REGARDING ACCEPTANCE OF REPORTS.—

(I) CASES OF AIDS.—With respect to a State that is subject to the requirement under clause (i) and is not in compliance with the requirement for names-based reporting of living non-AIDS cases of HIV, the Secretary shall, notwithstanding such noncompliance, accept reports of living cases of AIDS that are in accordance with such clause.

(II) APPLICABILITY OF EXEMPTION REQUIREMENTS.—The provisions of clauses (ii) through (vii)

may not be construed as having any legal effect for fiscal year 2013 or any subsequent fiscal year, and accordingly, the status of a State for purposes of such clauses may not be considered after fiscal year 2012.

(ix) PROGRAM FOR DETECTING INACCURATE OR FRAUDULENT COUNTING.—The Secretary shall carry out a program to monitor the reporting of names-based cases for purposes of this subparagraph and to detect instances of inaccurate reporting, including fraudulent reporting.

(x) FUTURE FISCAL YEARS.—For fiscal years beginning with fiscal year 2013, determinations under this paragraph shall be based only on living names-based cases of HIV/AIDS with respect to the State involved.

(E) CODE-BASED STATES; LIMITATION ON INCREASE IN GRANT.—

(i) IN GENERAL.—For each of the fiscal years 2007 through 2012, if code-based reporting (within the meaning of subparagraph (D)(vi)) applies in a State as of the beginning of the fiscal year involved, then notwithstanding any other provision of this paragraph, the amount of the grant pursuant to paragraph (1) for the State may not for the fiscal year involved exceed by more than 5 percent the amount of the grant pursuant to this paragraph for the State for the preceding fiscal year, except that the limitation under this clause may not result in a grant pursuant to paragraph (1) for a fiscal year that is less than the minimum amount that applies to the State under such paragraph for such fiscal year.

(ii) USE OF AMOUNTS INVOLVED.—For each of the fiscal years 2007 through 2012, amounts available as a result of the limitation under clause (i) shall be made available by the Secretary as additional amounts for grants pursuant to section 2620, subject to subparagraph (H).

(F)[9] APPROPRIATIONS FOR TREATMENT DRUG PROGRAM.—

(i) FORMULA GRANTS.—With respect to the fiscal year involved, if under section 2623 an appropriations Act provides an amount exclusively for carrying out section 2616, the portion of such amount allocated to a State shall be the product of—

(I)[10] 100 percent of such amount, less the percentage reserved under clause (ii)(V); and

(II) the percentage constituted by the ratio of the State distribution factor for the State (as determined

[9] The amendments made by section 203(c) of Public Law 109–415 to section 2618(a)(2)(G) have been carried out to subparagraph (F), as redesignated by subsection (b)(4) of such Public Law, in order to reflect the probable intent of Congress.

[10] Indentation of subclauses (I) and (II) are so in law. See section 206(e)(1) of Public Law 106–345 (114 Stat. 1336).

under subparagraph (B)) to the sum of the State distribution factors for all States;

which product shall then, as applicable, be increased under subparagraph (H).

(ii) SUPPLEMENTAL TREATMENT DRUG GRANTS.—

(I) IN GENERAL.—From amounts made available under subclause (V), the Secretary shall award supplemental grants to States described in subclause (II) to enable such States to purchase and distribute to eligible individuals under section 2616(b) pharmaceutical therapeutics described under subsections (c)(2) and (e) of such section.

(II) ELIGIBLE STATES.—For purposes of subclause (I), a State shall be an eligible State if the State did not have unobligated funds subject to reallocation under section 2618(d) in the previous fiscal year and, in accordance with criteria established by the Secretary, demonstrates a severe need for a grant under this clause. For purposes of determining severe need, the Secretary shall consider eligibility standards, formulary composition, the number of eligible individuals to whom a State is unable to provide therapeutics described in section 2616(a), and an unanticipated increase of eligible individuals with HIV/AIDS.

(III) STATE REQUIREMENTS.—The Secretary may not make a grant to a State under this clause unless the State agrees that the State will make available (directly or through donations of public or private entities) non-Federal contributions toward the activities to be carried out under the grant in an amount equal to $1 for each $4 of Federal funds provided in the grant, except that the Secretary may waive this subclause if the State has otherwise fully complied with section 2617(d) with respect to the grant year involved. The provisions of this subclause shall apply to States that are not required to comply with such section 2617(d).

(IV) USE AND COORDINATION.—Amounts made available under a grant under this clause shall only be used by the State to provide HIV/AIDS-related medications. The State shall coordinate the use of such amounts with the amounts otherwise provided under section 2616(a) in order to maximize drug coverage.

(V) FUNDING.—For the purpose of making grants under this clause, the Secretary shall each fiscal year reserve 5 percent of the amount referred to in clause (i) with respect to section 2616.

(iii) CODE-BASED STATES; LIMITATION ON INCREASE IN FORMULA GRANT.—The limitation under subparagraph (E)(i) applies to grants pursuant to clause (i) of this subparagraph to the same extent and in the same

manner as such limitation applies to grants pursuant to paragraph (1), except that the reference to minimum grants does not apply for purposes of this clause. Amounts available as a result of the limitation under the preceding sentence shall be made available by the Secretary as additional amounts for grants under clause (ii) of this subparagraph.

(H)[11] INCREASE IN FORMULA GRANTS.—

(i) ASSURANCE OF AMOUNT.—

(I) GENERAL RULE.—For fiscal year 2010, the Secretary shall ensure, subject to clauses (ii) through (iv), that the total for a State of the grant pursuant to paragraph (1) and the grant pursuant to subparagraph (F) is not less than 95 percent of such total for the State for fiscal year 2009.

(II) RULE OF CONSTRUCTION.—With respect to the application of subclause (I), the 95 percent requirement under such subclause shall apply with respect to each grant awarded under paragraph (1) and with respect to each grant awarded under subparagraph (F).

(ii) FISCAL YEARS 2011 AND 2012.—For each of the fiscal years 2011 and 2012, the Secretary shall ensure that the total for a State of the grant pursuant to paragraph (1) and the grant pursuant to subparagraph (F) is not less than 100 percent of such total for the State for fiscal year 2010.

(iii) FISCAL YEAR 2013.—For fiscal year 2013, the Secretary shall ensure that the total for a State of the grant pursuant to paragraph (1) and the grant pursuant to subparagraph (F) is not less than 92.5 percent of such total for the State for fiscal year 2012.

(iv) SOURCE OF FUNDS FOR INCREASE.—

(I) IN GENERAL.—From the amount reserved under section 2623(b)(2) for a fiscal year, and from amounts available for such section pursuant to subsection (d) of this section, the Secretary shall make available such amounts as may be necessary to comply with clause (i).

(II) PRO RATA REDUCTION.—If the amounts referred to in subclause (I) for a fiscal year are insufficient to fully comply with clause (i) for the year, the Secretary, in order to provide the additional funds necessary for such compliance, shall reduce on a pro rata basis the amount of each grant pursuant to paragraph (1) for the fiscal year, other than grants for States for which increases under clause (i) apply and other than States described in paragraph (1)(A)(i)(I). A reduction under the preceding sentence may not be made in an amount that would result in the State involved becoming eligible for such an increase.

[11] So in law. There is no subparagraph (G).

(v) APPLICABILITY.—This paragraph may not be construed as having any applicability after fiscal year 2013.

(b) ALLOCATION OF ASSISTANCE BY STATES.—

(1) ALLOWANCES.—Prior to allocating assistance under this subsection, a State shall consider the unmet needs of those areas that have not received financial assistance under part A.

(2) PLANNING AND EVALUATIONS.—Subject to paragraph (4) and except as provided in paragraph (5), a State may not use more than 10 percent of amounts received under a grant awarded under section 2611 for planning and evaluation activities.

(3) ADMINISTRATION.—

(A) IN GENERAL.—Subject to paragraph (4), and except as provided in paragraph (5), a State may not use more than 10 percent of amounts received under a grant awarded under section 2611 for administration.

(B) ALLOCATIONS.—In the case of entities and subcontractors to which a State allocates amounts received by the State under a grant under section 2611, the State shall ensure that, of the aggregate amount so allocated, the total of the expenditures by such entities for administrative expenses does not exceed 10 percent (without regard to whether particular entities expend more than 10 percent for such expenses).

(C) ADMINISTRATIVE ACTIVITIES.—For the purposes of subparagraph (A), amounts may be used for administrative activities that include routine grant administration and monitoring activities, including a clinical quality management program under subparagraph (E).

(D) SUBCONTRACTOR ADMINISTRATIVE COSTS.—For the purposes of this paragraph, subcontractor administrative activities include—

(i) usual and recognized overhead, including established indirect rates for agencies;

(ii) management oversight of specific programs funded under this title; and

(iii) other types of program support such as quality assurance, quality control, and related activities.

(E) CLINICAL QUALITY MANAGEMENT.—

(i) REQUIREMENT.—Each State that receives a grant under section 2611 shall provide for the establishment of a clinical quality management program to assess the extent to which HIV health services provided to patients under the grant are consistent with the most recent Public Health Service guidelines for the treatment of HIV/AIDS and related opportunistic infection, and as applicable, to develop strategies for ensuring that such services are consistent with the guidelines for improvement in the access to and quality of HIV health services.

(ii) USE OF FUNDS.—

(I) IN GENERAL.—From amounts received under a grant awarded under section 2611 for a

fiscal year, a State may use for activities associated with the clinical quality management program required in clause (i) not to exceed the lesser of—

(aa) 5 percent of amounts received under the grant; or

(bb) $3,000,000.

(II) RELATION TO LIMITATION ON ADMINISTRATIVE EXPENSES.—The costs of a clinical quality management program under clause (i) may not be considered administrative expenses for purposes of the limitation established in subparagraph (A).

(4) LIMITATION ON USE OF FUNDS.—Except as provided in paragraph (5), a State may not use more than a total of 15 percent of amounts received under a grant awarded under section 2611 for the purposes described in paragraphs (2) and (3).

(5) EXCEPTION.—With respect to a State that receives the minimum allotment under subsection (a)(1) for a fiscal year, such State, from the amounts received under a grant awarded under section 2611 for such fiscal year for the activities described in paragraphs (2) and (3), may, notwithstanding paragraphs (2) through (4)[12], use not more than that amount required to support one full-time-equivalent employee.

(6) CONSTRUCTION.—A State may not use amounts received under a grant awarded under section 2611 to purchase or improve land, or to purchase, construct, or permanently improve (other than minor remodeling) any building or other facility, or to make cash payments to intended recipients of services.

(c) EXPEDITED DISTRIBUTION.—

(1) IN GENERAL.—Not less than 75 percent of the amounts received under a grant awarded to a State under section 2611 shall be obligated to specific programs and projects and made available for expenditure not later than—

(A) in the case of the first fiscal year for which amounts are received, 150 days after the receipt of such amounts by the State; and

(B) in the case of succeeding fiscal years, 120 days after the receipt of such amounts by the State.

(2) PUBLIC COMMENT.—Within the time periods referred to in paragraph (1), the State shall invite and receive public comment concerning methods for the utilization of such amounts.

(d) REALLOCATION.—Any portion of a grant made to a State under section 2611 for a fiscal year that has not been obligated as described in subsection (c) ceases to be available to the State and shall be made available by the Secretary for grants under section 2620, in addition to amounts made available for such grants under section 2623(b)(2).

[12] Section 203(e)(5) of Public Law 109–415 (120 Stat. 2795) struck "paragraphs (3)" and all that follows through "(5)," and inserted revised text. There were two references to "paragraphs (3)". The amendment was executed to the first such reference to reflect the probable intent of Congress.

SEC. 2619.[300ff–29] TECHNICAL ASSISTANCE.

The Secretary shall provide technical assistance in administering and coordinating the activities authorized under section 2612, including technical assistance for the development and implementation of statewide coordinated statements of need.

SEC. 2620.[300ff–29a] SUPPLEMENTAL GRANTS.

(a) IN GENERAL.—For the purpose of providing services described in section 2612(a), the Secretary shall make grants to States—

(1) whose applications under section 2617 have demonstrated the need in the State, on an objective and quantified basis, for supplemental financial assistance to provide such services; and

(2) that did not, for the most recent grant year pursuant to section 2618(a)(1) or 2618(a)(2)(F)(i) for which data is available, have more than 5 percent of grant funds under such sections canceled, offset under section 2622(e), or covered by any waivers under section 2622(c).

(b) DEMONSTRATED NEED.—The factors considered by the Secretary in determining whether an eligible area has a demonstrated need for purposes of subsection (a)(1) may include any or all of the following:

(1) The unmet need for such services, as determined under section 2617(b).

(2) An increasing need for HIV/AIDS-related services, including relative rates of increase in the number of cases of HIV/AIDS.

(3) The relative rates of increase in the number of cases of HIV/AIDS within new or emerging subpopulations.

(4) The current prevalence of HIV/AIDS.

(5) Relevant factors related to the cost and complexity of delivering health care to individuals with HIV/AIDS in the eligible area.

(6) The impact of co-morbid factors, including co-occurring conditions, determined relevant by the Secretary.

(7) The prevalence of homelessness.

(8) The prevalence of individuals described under section 2602(b)(2)(M).

(9) The relevant factors that limit access to health care, including geographic variation, adequacy of health insurance coverage, and language barriers.

(10) The impact of a decline in the amount received pursuant to section 2618 on services available to all individuals with HIV/AIDS identified and eligible under this title.

(c) PRIORITY IN MAKING GRANTS.—The Secretary shall provide funds under this section to a State to address the decline in services related to the decline in the amounts received pursuant to section 2618 consistent with the grant award to the State for fiscal year 2006, to the extent that the factor under subsection (b)(10) (relating to a decline in funding) applies to the State.

(d) REPORT ON THE AWARDING OF SUPPLEMENTAL FUNDS.—Not later than 45 days after the awarding of supplemental funds under this section, the Secretary shall submit to Congress a report con-

cerning such funds. Such report shall include information detailing—

(1) the total amount of supplemental funds available under this section for the year involved;

(2) the amount of supplemental funds used in accordance with the hold harmless provisions of section 2618(a)(2);

(3) the amount of supplemental funds disbursed pursuant to subsection (c);

(4) the disbursement of the remainder of the supplemental funds after taking into account the uses described in paragraphs (2) and (3); and

(5) the rationale used for the amount of funds disbursed as described under paragraphs (2), (3), and (4).

(e) CORE MEDICAL SERVICES.—The provisions of section 2612(b) apply with respect to a grant under this section to the same extent and in the same manner as such provisions apply with respect to a grant made pursuant to section 2618(a)(1).

(f) APPLICABILITY OF GRANT AUTHORITY.—The authority to make grants under this section applies beginning with the first fiscal year for which amounts are made available for such grants under section 2623(b)(1).

SEC. 2621.[300ff–30] EMERGING COMMUNITIES.

(a) IN GENERAL.—The Secretary shall award supplemental grants to States determined to be eligible under subsection (b) to enable such States to provide comprehensive services of the type described in section 2612(a) to supplement the services otherwise provided by the State under a grant under this subpart in emerging communities within the State that are not eligible to receive grants under part A.

(b) ELIGIBILITY.—To be eligible to receive a supplemental grant under subsection (a), a State shall—

(1) be eligible to receive a grant under this subpart;

(2) demonstrate the existence in the State of an emerging community as defined in subsection (d)(1);

(3) agree that the grant will be used to provide funds directly to emerging communities in the State, separately from other funds under this title that are provided by the State to such communities; and

(4) submit the information described in subsection (c).

(c) REPORTING REQUIREMENTS.—A State that desires a grant under this section shall, as part of the State application submitted under section 2617, submit a detailed description of the manner in which the State will use amounts received under the grant and of the severity of need. Such description shall include—

(1) a report concerning the dissemination of supplemental funds under this section and the plan for the utilization of such funds in the emerging community;

(2) a demonstration of the existing commitment of local resources, both financial and in-kind;

(3) a demonstration that the State will maintain HIV-related activities at a level that is equal to not less than the level of such activities in the State for the 1-year period preceding

the fiscal year for which the State is applying to receive a grant under section 2611;

(4) a demonstration of the ability of the State to utilize such supplemental financial resources in a manner that is immediately responsive and cost effective;

(5) a demonstration that the resources will be allocated in accordance with the local demographic incidence of AIDS including appropriate allocations for services for infants, children, women, and families with HIV/AIDS;

(6) a demonstration of the inclusiveness of the planning process, with particular emphasis on affected communities and individuals with HIV/AIDS; and

(7) a demonstration of the manner in which the proposed services are consistent with local needs assessments and the statewide coordinated statement of need.

(d) DEFINITIONS OF EMERGING COMMUNITY.—For purposes of this section, the term "emerging community" means a metropolitan area (as defined in section 2607) for which there has been reported to and confirmed by the Director of the Centers for Disease Control and Prevention a cumulative total of at least 500, but fewer than 1,000, cases of AIDS during the most recent period of 5 calendar years for which such data are available.

(e) CONTINUED STATUS AS EMERGING COMMUNITY.—Notwithstanding any other provision of this section, a metropolitan area that is an emerging community for a fiscal year continues to be an emerging community until the metropolitan area fails, for three consecutive fiscal years—

(1) to meet the requirements of subsection (d); and

(2) to have a cumulative total of 750 or more living cases of AIDS (reported to and confirmed by the Director of the Centers for Disease Control and Prevention) as of December 31 of the most recent calendar year for which such data is available.

(f) DISTRIBUTION.—The amount of a grant under subsection (a) for a State for a fiscal year shall be an amount equal to the product of—

(1) the amount available under section 2623(b)(1) for the fiscal year; and

(2) a percentage equal to the ratio constituted by the number of living cases of HIV/AIDS in emerging communities in the State to the sum of the respective numbers of such cases in such communities for all States.

SEC. 2622.[300ff–31a] TIMEFRAME FOR OBLIGATION AND EXPENDITURE OF GRANT FUNDS.

(a) OBLIGATION BY END OF GRANT YEAR.—Effective for fiscal year 2007 and subsequent fiscal years, funds from a grant award made to a State for a fiscal year pursuant to section 2618(a)(1) or 2618(a)(2)(F), or under section 2620 or 2621, are available for obligation by the State through the end of the one-year period beginning on the date in such fiscal year on which funds from the award first become available to the State (referred to in this section as the "grant year for the award"), except as provided in subsection (c)(1).

(b) SUPPLEMENTAL GRANTS; CANCELLATION OF UNOBLIGATED BALANCE OF GRANT AWARD.—Effective for fiscal year 2007 and subsequent fiscal years, if a grant award made to a State for a fiscal

year pursuant to section 2618(a)(2)(F)(ii), or under section 2620 or 2621, has an unobligated balance as of the end of the grant year for the award—

(1) the Secretary shall cancel that unobligated balance of the award, and shall require the State to return any amounts from such balance that have been disbursed to the State; and

(2) the funds involved shall be made available by the Secretary as additional amounts for grants pursuant to section 2620 for the first fiscal year beginning after the fiscal year in which the Secretary obtains the information necessary for determining that the balance is required under paragraph (1) to be canceled, except that the availability of the funds for such grants is subject to section 2618(a)(2)(H) as applied for such year.

(c) FORMULA GRANTS; CANCELLATION OF UNOBLIGATED BALANCE OF GRANT AWARD; WAIVER PERMITTING CARRYOVER.—

(1) IN GENERAL.—Effective for fiscal year 2007 and subsequent fiscal years, if a grant award made to a State for a fiscal year pursuant to section 2618(a)(1) or 2618(a)(2)(F)(i) has an unobligated balance as of the end of the grant year for the award, the Secretary shall cancel that unobligated balance of the award, and shall require the State to return any amounts from such balance that have been disbursed to the State, unless—

(A) before the end of the grant year, the State submits to the Secretary a written application for a waiver of the cancellation, which application includes a description of the purposes for which the State intends to expend the funds involved; and

(B) the Secretary approves the waiver.

(2) EXPENDITURE BY END OF CARRYOVER YEAR.—With respect to a waiver under paragraph (1) that is approved for a balance that is unobligated as of the end of a grant year for an award:

(A) The unobligated funds are available for expenditure by the State involved for the one-year period beginning upon the expiration of the grant year (referred to in this section as the "carryover year").

(B) If the funds are not expended by the end of the carryover year, the Secretary shall cancel that unexpended balance of the award, and shall require the State to return any amounts from such balance that have been disbursed to the State.

(3) USE OF CANCELLED BALANCES.—In the case of any balance of a grant award that is cancelled under paragraph (1) or (2)(B), the grant funds involved shall be made available by the Secretary as additional amounts for grants under section 2620 for the first fiscal year beginning after the fiscal year in which the Secretary obtains the information necessary for determining that the balance is required under such paragraph to be canceled, except that the availability of the funds for such grants is subject to section 2618(a)(2)(H) as applied for such year.

(4) CORRESPONDING REDUCTION IN FUTURE GRANT.—

(A) IN GENERAL.—In the case of a State for which a balance from a grant award made pursuant to section 2618(a)(1) or 2618(a)(2)(F)(i) is unobligated as of the end of the grant year for the award—

(i) the Secretary shall reduce, by the same amount as such unobligated balance (less any amount of such balance that is the subject of a waiver of cancellation under paragraph (1)), the amount of the grant under such section for the first fiscal year beginning after the fiscal year in which the Secretary obtains the information necessary for determining that such balance was unobligated as of the end of the grant year (which requirement for a reduction applies without regard to whether a waiver under paragraph (1) has been approved with respect to such balance); and

(ii) the grant funds involved in such reduction shall be made available by the Secretary as additional funds for grants under section 2620 for such first fiscal year, subject to section 2618(a)(2)(H);

except that this subparagraph does not apply to the State if the amount of the unobligated balance was 5 percent or less.

(B) RELATION TO INCREASES IN GRANT.—A reduction under subparagraph (A) for a State for a fiscal year may not be taken into account in applying section 2618(a)(2)(H) with respect to the State for the subsequent fiscal year.

(d) TREATMENT OF DRUG REBATES.—For purposes of this section, funds that are drug rebates referred to in section 2616(g) may not be considered part of any grant award referred to in subsection (a). If an expenditure of ADAP rebate funds would trigger a penalty under this section or a higher penalty than would otherwise have applied, the State may request that for purposes of this section, the Secretary deem the State's unobligated balance to be reduced by the amount of rebate funds in the proposed expenditure. Notwithstanding 2618(a)(2)(F), any unobligated amount under section 2618(a)(2)(F)(ii)(V) that is returned to the Secretary for reallocation shall be used by the Secretary for—

(1) the ADAP supplemental program if the Secretary determines appropriate; or

(2) for additional amounts for grants pursuant to section 2620.

(e) AUTHORITY REGARDING ADMINISTRATION OF PROVISIONS.—In administering subsections (b) and (c) with respect to the unobligated balance of a State, the Secretary may elect to reduce the amount of future grants to the State under section 2618, 2620, or 2621, as applicable, by the amount of any such unobligated balance in lieu of cancelling such amount as provided for in subsection (b) or (c)(1). In such case, the Secretary may permit the State to use such unobligated balance for purposes of any such future grant. An amount equal to such reduction shall be available for use as additional amounts for grants pursuant to section 2620, subject to section 2618(a)(2)(H). Nothing in this paragraph shall be construed to affect the authority of the Secretary under subsections (b) and (c), including the authority to grant waivers under subsection (c)(1).

The reduction in future grants authorized under this subsection shall be notwithstanding the penalty required under subsection (c)(4) with respect to unobligated funds.

SEC. 2623. AUTHORIZATION OF APPROPRIATIONS.

(a) IN GENERAL.—For the purpose of carrying out this subpart, there are authorized to be appropriated $1,195,500,000 for fiscal year 2007, $1,239,500,000 for fiscal year 2008, $1,285,200,000 for fiscal year 2009, $1,349,460,000 for fiscal year 2010, $1,416,933,000 for fiscal year 2011, $1,487,780,000 for fiscal year 2012, and $1,562,169,000 for fiscal year 2013. Amounts appropriated under the preceding sentence for a fiscal year are available for obligation by the Secretary until the end of the second succeeding fiscal year.

(b) RESERVATION OF AMOUNTS.—

(1) EMERGING COMMUNITIES.—Of the amount appropriated under subsection (a) for a fiscal year, the Secretary shall reserve $5,000,000 for grants under section 2621.

(2) SUPPLEMENTAL GRANTS.—

(A) IN GENERAL.—Of the amount appropriated under subsection (a) for a fiscal year in excess of the 2006 adjusted amount, the Secretary shall reserve ⅓ for grants under section 2620, except that the availability of the reserved funds for such grants is subject to section 2618(a)(2)(H) as applied for such year, and except that any amount appropriated exclusively for carrying out section 2616 (and, accordingly, distributed under section 2618(a)(2)(F)) is not subject to this subparagraph.

(B) 2006 ADJUSTED AMOUNT.—For purposes of subparagraph (A), the term "2006 adjusted amount" means the amount appropriated for fiscal year 2006 under section 2677(b) (as such section was in effect for such fiscal year), excluding any amount appropriated for such year exclusively for carrying out section 2616 (and, accordingly, distributed under section 2618(a)(2)(I), as so in effect).

Subpart II—Provisions Concerning Pregnancy and Perinatal Transmission of HIV

SEC. 2625.[300ff–33] EARLY DIAGNOSIS GRANT PROGRAM.

(a) IN GENERAL.—In the case of States whose laws or regulations are in accordance with subsection (b), the Secretary, acting through the Centers for Disease Control and Prevention, shall make grants to such States for the purposes described in subsection (c).

(b) DESCRIPTION OF COMPLIANT STATES.—For purposes of subsection (a), the laws or regulations of a State are in accordance with this subsection if, under such laws or regulations (including programs carried out pursuant to the discretion of State officials), both of the policies described in paragraph (1) are in effect, or both of the policies described in paragraph (2) are in effect, as follows:

(1)(A) Voluntary opt-out testing of pregnant women.

(B) Universal testing of newborns.

(2)(A) Voluntary opt-out testing of clients at sexually transmitted disease clinics.

(B) Voluntary opt-out testing of clients at substance abuse treatment centers.

The Secretary shall periodically ensure that the applicable policies are being carried out and recertify compliance.

(c) USE OF FUNDS.—A State may use funds provided under subsection (a) for HIV/AIDS testing (including rapid testing), prevention counseling, treatment of newborns exposed to HIV/AIDS, treatment of mothers infected with HIV/AIDS, and costs associated with linking those diagnosed with HIV/AIDS to care and treatment for HIV/AIDS.

(d) APPLICATION.—A State that is eligible for the grant under subsection (a) shall submit an application to the Secretary, in such form, in such manner, and containing such information as the Secretary may require.

(e) LIMITATION ON AMOUNT OF GRANT.—A grant under subsection (a) to a State for a fiscal year may not be made in an amount exceeding $10,000,000.

(f) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to pre-empt State laws regarding HIV/AIDS counseling and testing.

(g) DEFINITIONS.—In this section:

(1) The term "voluntary opt-out testing" means HIV/AIDS testing—

(A) that is administered to an individual seeking other health care services; and

(B) in which—

(i) pre-test counseling is not required but the individual is informed that the individual will receive an HIV/AIDS test and the individual may opt out of such testing; and

(ii) for those individuals with a positive test result, post-test counseling (including referrals for care) is provided and confidentiality is protected.

(2) The term "universal testing of newborns" means HIV/AIDS testing that is administered within 48 hours of delivery to—

(A) all infants born in the State; or

(B) all infants born in the State whose mother's HIV/AIDS status is unknown at the time of delivery.

(h) AUTHORIZATION OF APPROPRIATIONS.—Of the funds appropriated annually to the Centers for Disease Control and Prevention for HIV/AIDS prevention activities, $30,000,000 shall be made available for each of the fiscal years 2007 through 2009 for grants under subsection (a), of which $20,000,000 shall be made available for grants to States with the policies described in subsection (b)(1), and $10,000,000 shall be made available for grants to States with the policies described in subsection (b)(2). Funds provided under this section are available until expended.

SEC. 2626.[300ff–34] PERINATAL TRANSMISSION OF HIV DISEASE; CONTINGENT REQUIREMENT REGARDING STATE GRANTS UNDER THIS PART.

(a) ANNUAL DETERMINATION OF REPORTED CASES.—A State shall annually determine the rate of reported cases of AIDS as a result of perinatal transmission among residents of the State.

(b) CAUSES OF PERINATAL TRANSMISSION.—In determining the rate under subsection (a), a State shall also determine the possible causes of perinatal transmission. Such causes may include—

(1) the inadequate provision within the State of prenatal counseling and testing in accordance with the guidelines issued by the Centers for Disease Control and Prevention;

(2) the inadequate provision or utilization within the State of appropriate therapy or failure of such therapy to reduce perinatal transmission of HIV, including—

(A) that therapy is not available, accessible or offered to mothers; or

(B) that available therapy is offered but not accepted by mothers; or

(3) other factors (which may include the lack of prenatal care) determined relevant by the State.

(c) CDC REPORTING SYSTEM.—Not later than 4 months after the date of enactment of this subpart, the Director of the Centers for Disease Control and Prevention shall develop and implement a system to be used by States to comply with the requirements of subsections (a) and (b). The Director shall issue guidelines to ensure that the data collected is statistically valid.

SEC. 2627.[300ff–37] STATE HIV TESTING PROGRAMS ESTABLISHED PRIOR TO OR AFTER ENACTMENT.

Nothing in this subpart shall be construed to disqualify a State from receiving grants under this title if such State has established at any time prior to or after the date of enactment of this subpart a program of mandatory HIV testing.

SEC. 2628.[300ff–37a] RECOMMENDATIONS FOR REDUCING INCIDENCE OF PERINATAL TRANSMISSION.

(a) STUDY BY INSTITUTE OF MEDICINE.—

(1) IN GENERAL.—The Secretary shall request the Institute of Medicine to enter into an agreement with the Secretary under which such Institute conducts a study to provide the following:

(A) For the most recent fiscal year for which the information is available, a determination of the number of newborn infants with HIV born in the United States with respect to whom the attending obstetrician for the birth did not know the HIV status of the mother.

(B) A determination for each State of any barriers, including legal barriers, that prevent or discourage an obstetrician from making it a routine practice to offer pregnant women an HIV test and a routine practice to test newborn infants for HIV/AIDS in circumstances in which the obstetrician does not know the HIV status of the mother of the infant.

(C) Recommendations for each State for reducing the incidence of cases of the perinatal transmission of HIV, including recommendations on removing the barriers identified under subparagraph (B).

If such Institute declines to conduct the study, the Secretary shall enter into an agreement with another appropriate public or nonprofit private entity to conduct the study.

(2) REPORT.—The Secretary shall ensure that, not later than 18 months after the effective date of this section, the study required in paragraph (1) is completed and a report describing the findings made in the study is submitted to the appropriate committees of the Congress, the Secretary, and the chief public health official of each of the States.

(b) PROGRESS TOWARD RECOMMENDATIONS.—In fiscal year 2004, the Secretary shall collect information from the States describing the actions taken by the States toward meeting the recommendations specified for the States under subsection (a)(1)(C).

(c) SUBMISSION OF REPORTS TO CONGRESS.—The Secretary shall submit to the appropriate committees of the Congress reports describing the information collected under subsection (b).

Subpart III—Certain Partner Notification Programs

SEC. 2631.[300ff–38] GRANTS FOR PARTNER NOTIFICATION PROGRAMS.

(a) IN GENERAL.—In the case of States whose laws or regulations are in accordance with subsection (b), the Secretary, subject to subsection (c)(2), may make grants to the States for carrying out programs to provide partner counseling and referral services.

(b) DESCRIPTION OF COMPLIANT STATE PROGRAMS.—For purposes of subsection (a), the laws or regulations of a State are in accordance with this subsection if under such laws or regulations (including programs carried out pursuant to the discretion of State officials) the following policies are in effect:

(1) The State requires that the public health officer of the State carry out a program of partner notification to inform partners of individuals with HIV/AIDS that the partners may have been exposed to the disease.

(2)(A) In the case of a health entity that provides for the performance on an individual of a test for HIV/AIDS, or that treats the individual for the disease, the State requires, subject to subparagraph (B), that the entity confidentially report the positive test results to the State public health officer in a manner recommended and approved by the Director of the Centers for Disease Control and Prevention, together with such additional information as may be necessary for carrying out such program.

(B) The State may provide that the requirement of subparagraph (A) does not apply to the testing of an individual for HIV/AIDS if the individual underwent the testing through a program designed to perform the test and provide the results to the individual without the individual disclosing his or her identity to the program. This subparagraph may not be construed as affecting the requirement of subparagraph (A) with respect to a health entity that treats an individual for HIV/AIDS.

(3) The program under paragraph (1) is carried out in accordance with the following:

(A) Partners are provided with an appropriate opportunity to learn that the partners have been exposed to HIV/AIDS, subject to subparagraph (B).

(B) The State does not inform partners of the identity of the infected individuals involved.

(C) Counseling and testing for HIV/AIDS are made available to the partners and to infected individuals, and such counseling includes information on modes of transmission for the disease, including information on prenatal and perinatal transmission and preventing transmission.

(D) Counseling of infected individuals and their partners includes the provision of information regarding therapeutic measures for preventing and treating the deterioration of the immune system and conditions arising from the disease, and the provision of other prevention-related information.

(E) Referrals for appropriate services are provided to partners and infected individuals, including referrals for support services and legal aid.

(F) Notifications under subparagraph (A) are provided in person, unless doing so is an unreasonable burden on the State.

(G) There is no criminal or civil penalty on, or civil liability for, an infected individual if the individual chooses not to identify the partners of the individual, or the individual does not otherwise cooperate with such program.

(H) The failure of the State to notify partners is not a basis for the civil liability of any health entity who under the program reported to the State the identity of the infected individual involved.

(I) The State provides that the provisions of the program may not be construed as prohibiting the State from providing a notification under subparagraph (A) without the consent of the infected individual involved.

(4) The State annually reports to the Director of the Centers for Disease Control and Prevention the number of individuals from whom the names of partners have been sought under the program under paragraph (1), the number of such individuals who provided the names of partners, and the number of partners so named who were notified under the program.

(5) The State cooperates with such Director in carrying out a national program of partner notification, including the sharing of information between the public health officers of the States.

(c) REPORTING SYSTEM FOR CASES OF HIV DISEASE; PREFERENCE IN MAKING GRANTS.—In making grants under subsection (a), the Secretary shall give preference to States whose reporting systems for cases of HIV/AIDS produce data on such cases that is sufficiently accurate and reliable for use for purposes of section 2618(a)(2)(D)(i).

(d) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there is authorized to be appropriated $10,000,000 for each of the fiscal years 2007 through 2009.

PART C—EARLY INTERVENTION SERVICES

Subpart I—Categorical Grants

SEC. 2651.[300ff–51] ESTABLISHMENT OF A PROGRAM.

(a) IN GENERAL.—For the purposes described in subsection (b), the Secretary, acting through the Administrator of the Health Resources and Services Administration, may make grants to public and nonprofit private entities specified in section 2652(a).

(b) REQUIREMENTS.—

(1) IN GENERAL.—The Secretary may not make a grant under subsection (a) unless the applicant for the grant agrees to expend the grant only for—

(A) core medical services described in subsection (c);

(B) support services described in subsection (d); and

(C) administrative expenses as described in section 2664(g)(3).

(2) EARLY INTERVENTION SERVICES.—An applicant for a grant under subsection (a) shall expend not less than 50 percent of the amount received under the grant for the services described in subparagraphs (B) through (E) of subsection (e)(1) for individuals with HIV/AIDS.

(c) REQUIRED FUNDING FOR CORE MEDICAL SERVICES.—

(1) IN GENERAL.—With respect to a grant under subsection (a) to an applicant for a fiscal year, the applicant shall, of the portion of the grant remaining after reserving amounts for purposes of paragraphs (3) and (5) of section 2664(g), use not less than 75 percent to provide core medical services that are needed in the area involved for individuals with HIV/AIDS who are identified and eligible under this title (including services regarding the co-occurring conditions of the individuals).

(2) WAIVER.—

(A) The Secretary shall waive the application of paragraph (1) with respect to an applicant for a grant if the Secretary determines that, within the service area of the applicant—

(i) there are no waiting lists for AIDS Drug Assistance Program services under section 2616; and

(ii) core medical services are available to all individuals with HIV/AIDS identified and eligible under this title.

(B) NOTIFICATION OF WAIVER STATUS.—When informing an applicant that a grant under subsection (a) is being made for a fiscal year, the Secretary shall inform the applicant whether a waiver under subparagraph (A) is in effect for the fiscal year.

(3) CORE MEDICAL SERVICES.—For purposes of this subsection, the term "core medical services", with respect to an individual with HIV/AIDS (including the co-occurring conditions of the individual) means the following services:

(A) Outpatient and ambulatory health services.

(B) AIDS Drug Assistance Program treatments under section 2616.

(C) AIDS pharmaceutical assistance.

(D) Oral health care.

(E) Early intervention services described in subsection (e).

(F) Health insurance premium and cost sharing assistance for low-income individuals in accordance with section 2615.

(G) Home health care.

(H) Medical nutrition therapy.

(I) Hospice services.

(J) Home and community-based health services as defined under section 2614(c).

(K) Mental health services.

(L) Substance abuse outpatient care.

(M) Medical case management, including treatment adherence services.

(d) SUPPORT SERVICES.—

(1) IN GENERAL.—For purposes of this section, the term "support services" means services, subject to the approval of the Secretary, that are needed for individuals with HIV/AIDS to achieve their medical outcomes (such as respite care for persons caring for individuals with HIV/AIDS, outreach services, medical transportation, linguistic services, and referrals for health care and support services).

(2) DEFINITION OF MEDICAL OUTCOMES.—In this section, the term "medical outcomes" means those outcomes affecting the HIV-related clinical status of an individual with HIV/AIDS.

(e) SPECIFICATION OF EARLY INTERVENTION SERVICES.—

(1) IN GENERAL.—The early intervention services referred to in this section are—

(A) counseling individuals with respect to HIV/AIDS in accordance with section 2662;

(B) testing individuals with respect to HIV/AIDS, including tests to confirm the presence of the disease, tests to diagnose the extent of the deficiency in the immune system, and tests to provide information on appropriate therapeutic measures for preventing and treating the deterioration of the immune system and for preventing and treating conditions arising from HIV/AIDS;

(C) referrals described in paragraph (2);

(D) other clinical and diagnostic services regarding HIV/AIDS, and periodic medical evaluations of individuals with HIV/AIDS; and

(E) providing the therapeutic measures described in subparagraph (B).

(2) REFERRALS.—The services referred to in paragraph (1)(C) are referrals of individuals with HIV/AIDS to appropriate providers of health and support services, including, as appropriate—

(A) to entities receiving amounts under part A or B for the provision of such services;

(B) to biomedical research facilities of institutions of higher education that offer experimental treatment for such disease, or to community-based organizations or other entities that provide such treatment; or

(C) to grantees under section 2671, in the case of a pregnant woman.

(3) REQUIREMENT OF AVAILABILITY OF ALL EARLY INTERVENTION SERVICES THROUGH EACH GRANTEE.—

(A) IN GENERAL.—The Secretary may not make a grant under subsection (a) unless the applicant for the grant agrees that each of the early intervention services specified in paragraph (2) will be available through the grantee. With respect to compliance with such agreement, such a grantee may expend the grant to provide the early intervention services directly, and may expend the grant to enter into agreements with public or nonprofit private entities, or private for-profit entities if such entities are the only available provider of quality HIV care in the area, under which the entities provide the services.

(B) OTHER REQUIREMENTS.—Grantees described in—

(i) subparagraphs (A), (D), (E), and (F) of section 2652(a)(1) shall use not less than 50 percent of the amount of such a grant to provide the services described in subparagraphs (A), (B), (D), and (E) of paragraph (1) directly and on-site or at sites where other primary care services are rendered; and

(ii) subparagraphs (B) and (C) of section 2652(a)(1) shall ensure the availability of early intervention services through a system of linkages to community-based primary care providers, and to establish mechanisms for the referrals described in paragraph (1)(C), and for follow-up concerning such referrals.

SEC. 2652.[300ff–52] MINIMUM QUALIFICATIONS OF GRANTEES.

(a) ELIGIBLE ENTITIES.—

(1) IN GENERAL.—The entities referred to in section 2651(a) are public entities and nonprofit private entities that are—

(A) federally-qualified health centers under section 1905(l)(2)(B) of the Social Security Act;

(B) grantees under section 1001 (regarding family planning) other than States;

(C) comprehensive hemophilia diagnostic and treatment centers;

(D) rural health clinics;

(E) health facilities operated by or pursuant to a contract with the Indian Health Service;

(F) community-based organizations, clinics, hospitals and other health facilities that provide early intervention services to those persons infected with HIV/AIDS through intravenous drug use; or

(G) nonprofit private entities that provide comprehensive primary care services to populations at risk of HIV/AIDS, including faith-based and community-based organizations.

(2) UNDERSERVED POPULATIONS.—Entities described in paragraph (1) shall serve underserved populations which may include minority populations and Native American populations, ex-offenders, individuals with comorbidities including hepatitis

B or C, mental illness, or substance abuse, low-income populations, inner city populations, and rural populations.[13];

(b) STATUS AS MEDICAID PROVIDER.—

(1) IN GENERAL.—Subject to paragraph (2), the Secretary may not make a grant under section 2651 for the provision of services described in subsection (b) of such section in a State unless, in the case of any such service that is available pursuant to the State plan approved under title XIX of the Social Security Act for the State—

(A) the applicant for the grant will provide the service directly, and the applicant has entered into a participation agreement under the State plan and is qualified to receive payments under such plan; or

(B) the applicant for the grant will enter into an agreement with a public or nonprofit private entity, or a private for-profit entity if such entity is the only available provider of quality HIV care in the area, under which the entity will provide the service, and the entity has entered into such a participation agreement and is qualified to receive such payments.

(2) WAIVER REGARDING CERTAIN SECONDARY AGREEMENTS.—

(A) In the case of an entity making an agreement pursuant to paragraph (1)(B) regarding the provision of services, the requirement established in such paragraph regarding a participation agreement shall be waived by the Secretary if the entity does not, in providing health care services, impose a charge or accept reimbursement available from any third-party payor, including reimbursement under any insurance policy or under any Federal or State health benefits program.

(B) A determination by the Secretary of whether an entity referred to in subparagraph (A) meets the criteria for a waiver under such subparagraph shall be made without regard to whether the entity accepts voluntary donations regarding the provision of services to the public.

SEC. 2653.[300ff–53] PREFERENCES IN MAKING GRANTS.

(a) IN GENERAL.—In making grants under section 2651, the Secretary shall give preference to any qualified applicant experiencing an increase in the burden of providing services regarding HIV/AIDS, as indicated by the factors specified in subsection (b).

(b) SPECIFICATION OF FACTORS.—

(1) IN GENERAL.—In the case of the geographic area with respect to which the entity involved is applying for a grant under section 2651, the factors referred to in subsection (a), as determined for the period specified in paragraph (2), are—

(A) the number of cases of HIV/AIDS;

(B) the rate of increase in such cases;

(C) the lack of availability of early intervention services;

(D) the number of other cases of sexually transmitted diseases, and the number of cases of tuberculosis and of

[13] See footnote for section 217(a).

drug abuse and the number of cases of individuals co-infected with HIV/AIDS and hepatitis B or C;

(E) the rate of increase in each of the cases specified in subparagraph (D);

(F) the lack of availability of primary health services from providers other than such applicant; and

(G) the distance between such area and the nearest community that has an adequate level of availability of appropriate HIV-related services, and the length of time required to travel such distance.

(2) RELEVANT PERIOD OF TIME.—The period referred to in paragraph (1) is the 2-year period preceding the fiscal year for which the entity involved is applying to receive a grant under section 2651.

(c) EQUITABLE ALLOCATIONS.—In providing preferences for purposes of subsection (b), the Secretary shall equitably allocate the preferences among urban and rural areas.

(d) CERTAIN AREAS.—Of the applicants who qualify for preference under this section—

(1) the Secretary shall give preference to applicants that will expend the grant under section 2651 to provide early intervention under such section in rural areas; and

(2) the Secretary shall give preference to areas that are underserved with respect to such services.

SEC. 2654.[300ff–54] MISCELLANEOUS PROVISIONS.

(a) SERVICES FOR INDIVIDUALS WITH HEMOPHILIA.—In making grants under section 2651, the Secretary shall ensure that any such grants made regarding the provision of early intervention services to individuals with hemophilia are made through the network of comprehensive hemophilia diagnostic and treatment centers.

(b) TECHNICAL ASSISTANCE.—The Secretary may, directly or through grants or contracts, provide technical assistance to nonprofit private entities regarding the process of submitting to the Secretary applications for grants under section 2651, and may provide technical assistance with respect to the planning, development, and operation of any program or service carried out pursuant to such section.

(c) PLANNING AND DEVELOPMENT GRANTS.—

(1) IN GENERAL.—The Secretary may provide planning grants to public and nonprofit private entities for purposes of—

(A) enabling such entities to provide early intervention services; and

(B) assisting the entities in expanding their capacity to provide HIV/AIDS-related health services, including early intervention services, in low-income communities and affected subpopulations that are underserved with respect to such services (subject to the condition that a grant pursuant to this subparagraph may not be expended to purchase or improve land, or to purchase, construct, or permanently improve, other than minor remodeling, any building or other facility).

(2) REQUIREMENT.—The Secretary may only award a grant to an entity under paragraph (1) if the Secretary determines that the entity will use such grant to assist the entity in qualifying for a grant under section 2651.

(3) PREFERENCE.—In awarding grants under paragraph (1), the Secretary shall give preference to entities that provide primary care services in rural areas or to underserved populations.

(4) AMOUNT AND DURATION OF GRANTS.—

(A) EARLY INTERVENTION SERVICES.—A grant under paragraph (1)(A) may be made in an amount not to exceed $50,000.

(B) CAPACITY DEVELOPMENT.—

(i) AMOUNT.—A grant under paragraph (1)(B) may be made in an amount not to exceed $150,000.

(ii) DURATION.—The total duration of a grant under paragraph (1)(B), including any renewal, may not exceed 3 years.

(5) LIMITATION.—Not to exceed 5 percent of the amount appropriated for a fiscal year under section 2655 may be used to carry out this section.

SEC. 2655.[300ff–55] AUTHORIZATION OF APPROPRIATIONS.

For the purpose of making grants under section 2651, there are authorized to be appropriated, $218,600,000 for fiscal year 2007, $226,700,000 for fiscal year 2008, $235,100,000 for fiscal year 2009, $246,855,000 for fiscal year 2010, $259,198,000 for fiscal year 2011, $272,158,000 for fiscal year 2012, and $285,766,000 for fiscal year 2013.

Subpart II—General Provisions

SEC. 2661.[300ff–61] CONFIDENTIALITY AND INFORMED CONSENT.

(a) CONFIDENTIALITY.—The Secretary may not make a grant under this part unless, in the case of any entity applying for a grant under section 2651, the entity agrees to ensure that information regarding the receipt of early intervention services pursuant to the grant is maintained confidentially in a manner not inconsistent with applicable law.

(b) INFORMED CONSENT.—The Secretary may not make a grant under this part unless the applicant for the grant agrees that, in testing an individual for HIV/AIDS, the applicant will test an individual only after the individual confirms that the decision of the individual with respect to undergoing such testing is voluntarily made.

SEC. 2662.[300ff–62] PROVISION OF CERTAIN COUNSELING SERVICES.

(a) COUNSELING OF INDIVIDUALS WITH NEGATIVE TEST RESULTS.—The Secretary may not make a grant under this part unless the applicant for the grant agrees that, if the results of testing conducted for HIV/AIDS indicate that an individual does not have such condition, the applicant will provide the individual information, including—

(1) measures for prevention of, exposure to, and transmission of HIV/AIDS, hepatitis B, hepatitis C, and other sexually transmitted diseases;

(2) the accuracy and reliability of results of testing for HIV/AIDS, hepatitis B, and hepatitis C;

(3) the significance of the results of such testing, including the potential for developing AIDS, hepatitis B, or hepatitis C;

(4) the appropriateness of further counseling, testing, and education of the individual regarding HIV/AIDS and other sexually transmitted diseases;

(5) if diagnosed with chronic hepatitis B or hepatitis C coinfection, the potential of developing hepatitis-related liver disease and its impact on HIV/AIDS; and

(6) information regarding the availability of hepatitis B vaccine and information about hepatitis treatments.

(b) COUNSELING OF INDIVIDUALS WITH POSITIVE TEST RESULTS.—The Secretary may not make a grant under this part unless the applicant for the grant agrees that, if the results of testing for HIV/AIDS indicate that the individual has such condition, the applicant will provide to the individual appropriate counseling regarding the condition, including—

(1) information regarding—

(A) measures for prevention of, exposure to, and transmission of HIV/AIDS, hepatitis B, and hepatitis C;

(B) the accuracy and reliability of results of testing for HIV/AIDS, hepatitis B, and hepatitis C; and

(C) the significance of the results of such testing, including the potential for developing AIDS, hepatitis B, or hepatitis C;

(2) reviewing the appropriateness of further counseling, testing, and education of the individual regarding HIV/AIDS and other sexually transmitted diseases; and

(3) providing counseling—

(A) on the availability, through the applicant, of early intervention services;

(B) on the availability in the geographic area of appropriate health care, mental health care, and social and support services, including providing referrals for such services, as appropriate;

(C)(i) that explains the benefits of locating and counseling any individual by whom the infected individual may have been exposed to HIV/AIDS, hepatitis B, or hepatitis C and any individual whom the infected individual may have exposed to HIV/AIDS, hepatitis B, or hepatitis C; and

(ii) that emphasizes it is the duty of infected individuals to disclose their infected status to their sexual partners and their partners in the sharing of hypodermic needles; that provides advice to infected individuals on the manner in which such disclosures can be made; and that emphasizes that it is the continuing duty of the individuals to avoid any behaviors that will expose others to HIV/AIDS, hepatitis B, or hepatitis C; and

(D) on the availability of the services of public health authorities with respect to locating and counseling any individual described in subparagraph (C);

(4) if diagnosed with chronic hepatitis B or hepatitis C co-infection, the potential of developing hepatitis-related liver disease and its impact on HIV/AIDS; and

(5) information regarding the availability of hepatitis B vaccine.

(c) ADDITIONAL REQUIREMENTS REGARDING APPROPRIATE COUNSELING.—The Secretary may not make a grant under this part unless the applicant for the grant agrees that, in counseling individuals with respect to HIV/AIDS, the applicant will ensure that the counseling is provided under conditions appropriate to the needs of the individuals.

(d) COUNSELING OF EMERGENCY RESPONSE EMPLOYEES.—The Secretary may not make a grant under this part to a State unless the State agrees that, in counseling individuals with respect to HIV/AIDS, the State will ensure that, in the case of emergency response employees, the counseling is provided to such employees under conditions appropriate to the needs of the employees regarding the counseling.

(e) RULE OF CONSTRUCTION REGARDING COUNSELING WITHOUT TESTING.—Agreements made pursuant to this section may not be construed to prohibit any grantee under this part from expending the grant for the purpose of providing counseling services described in this section to an individual who does not undergo testing for HIV/AIDS as a result of the grantee or the individual determining that such testing of the individual is not appropriate.

SEC. 2663.[300ff–63] APPLICABILITY OF REQUIREMENTS REGARDING CONFIDENTIALITY, INFORMED CONSENT, AND COUNSELING.

The Secretary may not make a grant under this part unless the applicant for the grant agrees that, with respect to testing for HIV/AIDS, any such testing carried out by the applicant with funds appropriated through this Act will be carried out in accordance with conditions described in sections 2661 and 2662.

SEC. 2664.[300ff–64] ADDITIONAL REQUIRED AGREEMENTS.

(a) REPORTS TO SECRETARY.—The Secretary may not make a grant under this part unless—

(1) the applicant submits to the Secretary—

(A) a specification of the expenditures made by the applicant for early intervention services for the fiscal year preceding the fiscal year for which the applicant is applying to receive the grant;

(B) an estimate of the number of individuals to whom the applicant has provided such services for such fiscal year;

(C) information regarding how the expected expenditures of the grant are related to the planning process for localities funded under part A (including the planning process described in section 2602) and for States funded under part B (including the planning process described in section 2617(b)); and

(D) a specification of the expected expenditures and how those expenditures will improve overall client out-

comes, as described in the State plan under section 2617(b);

(2) the applicant agrees to submit to the Secretary a report providing—

(A) the number of individuals to whom the applicant provides early intervention services pursuant to the grant;

(B) epidemiological and demographic data on the population of such individuals;

(C) the extent to which the costs of HIV-related health care for such individuals are paid by third-party payors;

(D) the average costs of providing each category of early intervention service; and

(E) the aggregate amounts expended for each such category;

(3) the applicant agrees to provide additional documentation to the Secretary regarding the process used to obtain community input into the design and implementation of activities related to such grant; and

(4) the applicant agrees to submit, every 2 years, to the lead State agency under section 2617(b)(4) audits, consistent with Office of Management and Budget circular A133, regarding funds expended in accordance with this title and shall include necessary client level data to complete unmet need calculations and Statewide coordinated statements of need process.

(b) PROVISION OF OPPORTUNITIES FOR ANONYMOUS COUNSELING AND TESTING.—The Secretary may not make a grant under this part unless the applicant for the grant agrees that, to the extent permitted under State law, regulation or rule, the applicant will offer substantial opportunities for an individual—

(1) to undergo counseling and testing regarding HIV/AIDS without being required to provide any information relating to the identity of the individual; and

(2) to undergo such counseling and testing through the use of a pseudonym.

(c) PROHIBITION AGAINST REQUIRING TESTING AS CONDITION OF RECEIVING OTHER HEALTH SERVICES.—The Secretary may not make a grant under this part unless the applicant for the grant agrees that, with respect to an individual seeking health services from the applicant, the applicant will not require the individual to undergo testing for HIV as a condition of receiving any health services unless such testing is medically indicated in the provision of the health services sought by the individual.

(d) MAINTENANCE OF SUPPORT.—The Secretary may not make a grant under this part unless the applicant for the grant agrees to maintain the expenditures of the applicant for early intervention services at a level equal to not less than the level of such expenditures maintained by the State for the fiscal year preceding the fiscal year for which the applicant is applying to receive the grant.

(e) REQUIREMENTS REGARDING IMPOSITION OF CHARGES FOR SERVICES.—

(1) IN GENERAL.—The Secretary may not make a grant under this part unless, subject to paragraph (5), the applicant for the grant agrees that—

(A) in the case of individuals with an income less than or equal to 100 percent of the official poverty line, the applicant will not impose a charge on any such individual for the provision of early intervention services under the grant;

(B) in the case of individuals with an income greater than 100 percent of the official poverty line, the applicant—

(i) will impose a charge on each such individual for the provision of such services; and

(ii) will impose the charge according to a schedule of charges that is made available to the public.

(2) LIMITATION ON CHARGES REGARDING INDIVIDUALS SUBJECT TO CHARGES.—With respect to the imposition of a charge for purposes of paragraph (1)(B)(ii), the Secretary may not make a grant under this part unless, subject to paragraph (5), the applicant for the grant agrees that—

(A) in the case of individuals with an income greater than 100 percent of the official poverty line and not exceeding 200 percent of such poverty line, the applicant will not, for any calendar year, impose charges in an amount exceeding 5 percent of the annual gross income of the individual involved;

(B) in the case of individuals with an income greater than 200 percent of the official poverty line and not exceeding 300 percent of such poverty line, the applicant will not, for any calendar year, impose charges in an amount exceeding 7 percent of the annual gross income of the individual involved; and

(C) in the case of individuals with an income greater than 300 percent of the official poverty line, the applicant will not, for any calendar year, impose charges in an amount exceeding 10 percent of the annual gross income of the individual involved.

(3) ASSESSMENT OF CHARGE.—With respect to compliance with the agreement made under paragraph (1), a grantee under this part may, in the case of individuals subject to a charge for purposes of such paragraph—

(A) assess the amount of the charge in the discretion of the grantee, including imposing only a nominal charge for the provision of services, subject to the provisions of such paragraph regarding public schedules and of paragraph (2) regarding limitations on the maximum amount of charges; and

(B) take into consideration the medical expenses of individuals in assessing the amount of the charge, subject to such provisions.

(4) APPLICABILITY OF LIMITATION ON AMOUNT OF CHARGE.—The Secretary may not make a grant under this part unless the applicant for the grant agrees that the limitations established in paragraph (2) regarding the imposition of charges for services applies to the annual aggregate of charges imposed for such services, without regard to whether they are character-

ized as enrollment fees, premiums, deductibles, cost sharing, copayments, coinsurance, or similar charges.

(5) WAIVER REGARDING CERTAIN SECONDARY AGREEMENTS.—The requirement established in paragraph (1)(B)(i) shall be waived by the Secretary in the case of any entity for whom the Secretary has granted a waiver under section 2652(b)(2).

(f) RELATIONSHIP TO ITEMS AND SERVICES UNDER OTHER PROGRAMS.—

(1) IN GENERAL.—The Secretary may not make a grant under this part unless the applicant for the grant agrees that, subject to paragraph (2), the grant will not be expended by the applicant, or by any entity receiving amounts from the applicant for the provision of early intervention services, to make payment for any such service to the extent that payment has been made, or can reasonably be expected to be made, with respect to such service—

(A) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program (except for a program administered by or providing the services of the Indian Health Service); or

(B) by an entity that provides health services on a prepaid basis.

(2) APPLICABILITY TO CERTAIN SECONDARY AGREEMENTS FOR PROVISION OF SERVICES.—An agreement made under paragraph (1) shall not apply in the case of an entity through which a grantee under this part provides early intervention services if the Secretary has provided a waiver under section 2652(b)(2) regarding the entity.

(g) ADMINISTRATION OF GRANT.—The Secretary may not make a grant under this part unless the applicant for the grant agrees that—

(1) the applicant will not expend amounts received pursuant to this part for any purpose other than the purposes described in the subpart under which the grant involved is made;

(2) the applicant will establish such procedures for fiscal control and fund accounting as may be necessary to ensure proper disbursement and accounting with respect to the grant;

(3) the applicant will not expend more than 10 percent of the grant for administrative expenses with respect to the grant, including planning and evaluation, except that the costs of a clinical quality management program under paragraph (5) may not be considered administrative expenses for purposes of such limitation;

(4) the applicant will submit evidence that the proposed program is consistent with the statewide coordinated statement of need and agree to participate in the ongoing revision of such statement of need; and

(5) the applicant will provide for the establishment of a clinical quality management program—

(A) to assess the extent to which medical services funded under this title that are provided to patients are consistent with the most recent Public Health Service guidelines for the treatment of HIV/AIDS and related op-

portunistic infections, and as applicable, to develop strategies for ensuring that such services are consistent with the guidelines; and

(B) to ensure that improvements in the access to and quality of HIV health services are addressed.

SEC. 2665.[300ff–65] REQUIREMENT OF SUBMISSION OF APPLICATION CONTAINING CERTAIN AGREEMENTS AND ASSURANCES.

The Secretary may not make a grant under this part unless—

(1) an application for the grant is submitted to the Secretary containing agreements and assurances in accordance with this part and containing the information specified in section 2664(a)(1);

(2) with respect to such agreements, the application provides assurances of compliance satisfactory to the Secretary; and

(3) the application otherwise is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this part.

SEC. 2666.[300ff–66] PROVISION BY SECRETARY OF SUPPLIES AND SERVICES IN LIEU OF GRANT FUNDS.

(a) IN GENERAL.—Upon the request of a grantee under this part, the Secretary may, subject to subsection (b), provide supplies, equipment, and services for the purpose of aiding the grantee in providing early intervention services and, for such purpose, may detail to the State any officer or employee of the Department of Health and Human Services.

(b) LIMITATION.—With respect to a request described in subsection (a), the Secretary shall reduce the amount of payments under the grant involved by an amount equal to the costs of detailing personnel and the fair market value of any supplies, equipment, or services provided by the Secretary. The Secretary shall, for the payment of expenses incurred in complying with such request, expend the amounts withheld.

SEC. 2667.[300ff–67] USE OF FUNDS.

Counseling programs carried out under this part—

(1) shall not be designed to promote or encourage, directly, intravenous drug abuse or sexual activity, homosexual or heterosexual;

(2) shall be designed to reduce exposure to and transmission of HIV/AIDS by providing accurate information;

(3) shall provide information on the health risks of promiscuous sexual activity and intravenous drug abuse; amd

(4) shall provide information on the transmission and prevention of hepatitis A, B, and C, including education about the availability of hepatitis A and B vaccines and assisting patients in identifying vaccination sites.

PART D—WOMEN, INFANTS, CHILDREN, AND YOUTH

SEC. 2671.[300ff–71] GRANTS FOR COORDINATED SERVICES AND ACCESS TO RESEARCH FOR WOMEN, INFANTS, CHILDREN, AND YOUTH.

(a) IN GENERAL.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall award grants to public and nonprofit private entities (including a health facility operated by or pursuant to a contract with the Indian Health Service) for the purpose of providing family-centered care involving outpatient or ambulatory care (directly or through contracts or memoranda of understanding) for women, infants, children, and youth with HIV/AIDS.

(b) ADDITIONAL SERVICES FOR PATIENTS AND FAMILIES.—Funds provided under grants awarded under subsection (a) may be used for the following support services:

(1) Family-centered care including case management.

(2) Referrals for additional services including—

(A) referrals for inpatient hospital services, treatment for substance abuse, and mental health services; and

(B) referrals for other social and support services, as appropriate.

(3) Additional services necessary to enable the patient and the family to participate in the program established by the applicant pursuant to such subsection including services designed to recruit and retain youth with HIV.

(4) The provision of information and education on opportunities to participate in HIV/AIDS-related clinical research.

(c) COORDINATION WITH OTHER ENTITIES.—A grant awarded under subsection (a) may be made only if the applicant provides an agreement that includes the following:

(1) The applicant will coordinate activities under the grant with other providers of health care services under this Act, and under title V of the Social Security Act, including programs promoting the reduction and elimination of risk of HIV/AIDS for youth.

(2) The applicant will participate in the statewide coordinated statement of need under part B (where it has been initiated by the public health agency responsible for administering grants under part B) and in revisions of such statement.

(3) The applicant will every 2 years submit to the lead State agency under section 2617(b)(4) audits regarding funds expended in accordance with this title and shall include necessary client-level data to complete unmet need calculations and Statewide coordinated statements of need process.

(d) ADMINISTRATION; APPLICATION.—A grant may only be awarded to an entity under subsection (a) if an application for the grant is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section. Such application shall include the following:

(1) Information regarding how the expected expenditures of the grant are related to the planning process for localities funded under part A (including the planning process outlined in section 2602) and for States funded under part B (including the planning process outlined in section 2617(b)).

(2) A specification of the expected expenditures and how those expenditures will improve overall patient outcomes, as outlined as part of the State plan (under section 2617(b)) or through additional outcome measures.

(e) ANNUAL REVIEW OF PROGRAMS; EVALUATIONS.—

(1) REVIEW REGARDING ACCESS TO AND PARTICIPATION IN PROGRAMS.—With respect to a grant under subsection (a) for an entity for a fiscal year, the Secretary shall, not later than 180 days after the end of the fiscal year, provide for the conduct and completion of a review of the operation during the year of the program carried out under such subsection by the entity. The purpose of such review shall be the development of recommendations, as appropriate, for improvements in the following:

(A) Procedures used by the entity to allocate opportunities and services under subsection (a) among patients of the entity who are women, infants, children, or youth.

(B) Other procedures or policies of the entity regarding the participation of such individuals in such program.

(2) EVALUATIONS.——[14]The Secretary shall, directly or through contracts with public and private entities, provide for evaluations of programs carried out pursuant to subsection (a).

(f) ADMINISTRATIVE EXPENSES.—

(1) LIMITATION.—A grantee may not use more than 10 percent of amounts received under a grant awarded under this section for administrative expenses.

(2) CLINICAL QUALITY MANAGEMENT PROGRAM.—A grantee under this section shall implement a clinical quality management program to assess the extent to which HIV health services provided to patients under the grant are consistent with the most recent Public Health Service guidelines for the treatment of HIV/AIDS and related opportunistic infection, and as applicable, to develop strategies for ensuring that such services are consistent with the guidelines for improvement in the access to and quality of HIV health services.

(g) TRAINING AND TECHNICAL ASSISTANCE.—From the amounts appropriated under subsection (j) for a fiscal year, the Secretary may use not more than 5 percent to provide, directly or through contracts with public and private entities (which may include grantees under subsection (a)), training and technical assistance to assist applicants and grantees under subsection (a) in complying with the requirements of this section.

(h) DEFINITIONS.—In this section:

(1) ADMINISTRATIVE EXPENSES.—The term "administrative expenses" means funds that are to be used by grantees for grant management and monitoring activities, including costs

[14] Dash so in law.

related to any staff or activity unrelated to services or indirect costs.

(2) INDIRECT COSTS.—The term "indirect costs" means costs included in a Federally negotiated indirect rate.

(3) SERVICES.—The term "services" means—

(A) services that are provided to clients to meet the goals and objectives of the program under this section, including the provision of professional, diagnostic, and therapeutic services by a primary care provider or a referral to and provision of specialty care; and

(B) services that sustain program activity and contribute to or help improve services under subparagraph (A).

(i) APPLICATION TO PRIMARY CARE SERVICES.—Nothing in this part shall be construed as requiring funds under this part to be used for primary care services when payments are available for such services from other sources (including under titles XVIII, XIX, and XXI of the Social Security Act).

(j) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated, $71,800,000 for each of the fiscal years 2007 through 2009, $75,390,000 for fiscal year 2010, $79,160,000 for fiscal year 2011, $83,117,000 for fiscal year 2012, and $87,273,000 for fiscal year 2013.

PART E—GENERAL PROVISIONS

SEC. 2681.[300ff–81] COORDINATION.

(a) REQUIREMENT.—The Secretary shall ensure that the Health Resources and Services Administration, the Centers for Disease Control and Prevention, the Substance Abuse and Mental Health Services Administration, and the Centers for Medicare & Medicaid Services coordinate the planning, funding, and implementation of Federal HIV programs (including all minority AIDS initiatives of the Public Health Service, including under section 2693) to enhance the continuity of care and prevention services for individuals with HIV/AIDS or those at risk of such disease. The Secretary shall consult with other Federal agencies, including the Department of Veterans Affairs, as needed and utilize planning information submitted to such agencies by the States and entities eligible for assistance under this title.

(b) REPORT.—The Secretary shall biennially prepare and submit to the appropriate committees of the Congress a report concerning the coordination efforts at the Federal, State, and local levels described in this section, including a description of Federal barriers to HIV program integration and a strategy for eliminating such barriers and enhancing the continuity of care and prevention services for individuals with HIV/AIDS or those at risk of such disease.

(c) INTEGRATION BY STATE.—As a condition of receipt of funds under this title, a State shall provide assurances to the Secretary that health support services funded under this title will be integrated with other such services, that programs will be coordinated with other available programs (including Medicaid), and that the

continuity of care and prevention services of individuals with HIV/AIDS is enhanced.

(d) INTEGRATION BY LOCAL OR PRIVATE ENTITIES.—As a condition of receipt of funds under this title, a local government or private nonprofit entity shall provide assurances to the Secretary that services funded under this title will be integrated with other such services, that programs will be coordinated with other available programs (including Medicaid), and that the continuity of care and prevention services of individuals with HIV is enhanced.

SEC. 2682.[300ff–82] AUDITS.

(a) IN GENERAL.—For fiscal year 2009, and each subsequent fiscal year, the Secretary may reduce the amounts of grants under this title to a State or political subdivision of a State for a fiscal year if, with respect to such grants for the second preceding fiscal year, the State or subdivision fails to prepare audits in accordance with the procedures of section 7502 of title 31, United States Code. The Secretary shall annually select representative samples of such audits, prepare summaries of the selected audits, and submit the summaries to the Congress.

(b) POSTING ON THE INTERNET.—All audits that the Secretary receives from the State lead agency under section 2617(b)(4) shall be posted, in their entirety, on the Internet website of the Health Resources and Services Administration.

SEC. 2683.[300ff–83] PUBLIC HEALTH EMERGENCY.

(a) IN GENERAL.—In an emergency area and during an emergency period, the Secretary shall have the authority to waive such requirements of this title to improve the health and safety of those receiving care under this title and the general public, except that the Secretary may not expend more than 5 percent of the funds allocated under this title for sections 2620 and section 2603(b).

(b) EMERGENCY AREA AND EMERGENCY PERIOD.—In this section:

(1) EMERGENCY AREA.—The term "emergency area" means a geographic area in which there exists—

(A) an emergency or disaster declared by the President pursuant to the National Emergencies Act or the Robert T. Stafford Disaster Relief and Emergency Assistance Act; or

(B) a public health emergency declared by the Secretary pursuant to section 319.

(2) EMERGENCY PERIOD.—The term "emergency period" means the period in which there exists—

(A) an emergency or disaster declared by the President pursuant to the National Emergencies Act or the Robert T. Stafford Disaster Relief and Emergency Assistance Act; or

(B) a public health emergency declared by the Secretary pursuant to section 319.

(c) UNOBLIGATED FUNDS.—If funds under a grant under this section are not expended for an emergency in the fiscal year in which the emergency is declared, such funds shall be returned to the Secretary for reallocation under sections 2603(b) and 2620.

SEC. 2684.[300ff–84] PROHIBITION ON PROMOTION OF CERTAIN ACTIVITIES.

None of the funds appropriated under this title shall be used to fund AIDS programs, or to develop materials, designed to promote or encourage, directly, intravenous drug use or sexual activity, whether homosexual or heterosexual. Funds authorized under this title may be used to provide medical treatment and support services for individuals with HIV.

SEC. 2685.[300ff–85] PRIVACY PROTECTIONS.

(a) IN GENERAL.—The Secretary shall ensure that any information submitted to, or collected by, the Secretary under this title excludes any personally identifiable information.

(b) DEFINITION.—In this section, the term "personally identifiable information" has the meaning given such term under the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996.

SEC. 2686.[300ff–86] GAO REPORT.

The Comptroller General of the Government Accountability Office shall, not less than 1 year after the date of enactment of the Ryan White HIV/AIDS Treatment Extension Act of 2009, submit to the appropriate committees of Congress a report describing Minority AIDS Initiative activities across the Department of Health and Human Services, including programs under this title and programs at the Centers for Disease Control and Prevention, the Substance Abuse and Mental Health Services Administration, and other departmental agencies. Such report shall include a history of program activities within each relevant agency and a description of activities conducted, people served and types of grantees funded, and shall collect and describe best practices in community outreach and capacity-building of community based organizations serving the communities that are disproportionately affected by HIV/AIDS.

SEC. 2687.[300ff–87] SEVERITY OF NEED INDEX.

(a) DEVELOPMENT OF INDEX.—Not later than September 30, 2008, the Secretary shall develop and submit to the appropriate committees of Congress a severity of need index in accordance with subsection (c).

(b) DEFINITION OF SEVERITY OF NEED INDEX.—In this section, the term "severity of need index" means the index of the relative needs of individuals within a State or area, as identified by a number of different factors, and is a factor or set of factors that is multiplied by the number of living HIV/AIDS cases in a State or area, providing different weights to those cases based on needs. Such factors or set of factors may be different for different components of the provisions under this title.

(c) REQUIREMENTS FOR SECRETARIAL SUBMISSION.—When the Secretary submits to the appropriate committees of Congress the severity of need index under subsection (a), the Secretary shall provide the following:

(1) Methodology for and rationale behind developing the severity of need index, including information related to the field testing of the severity of need index.

(2) An independent contractor analysis of activities carried out under paragraph (1).

(3) Information regarding the process by which the Secretary received community input regarding the application and development of the severity of need index.

(d) ANNUAL REPORTS.—If the Secretary fails to submit the severity of need index under subsection (a) in either of fiscal years 2007 or 2008, the Secretary shall prepare and submit to the appropriate committees of Congress a report for such fiscal year—

(1) that updates progress toward having client level data;

(2) that updates the progress toward having a severity of need index, including information related to the methodology and process for obtaining community input; and

(3) that, as applicable, states whether the Secretary could develop a severity of need index before fiscal year 2009.

SEC. 2688.[300ff–87a] NATIONAL HIV/AIDS TESTING GOAL.

(a) IN GENERAL.—Not later than January 1, 2010, the Secretary shall establish a national HIV/AIDS testing goal of 5,000,000 tests for HIV/AIDS annually through federally-supported HIV/AIDS prevention, treatment, and care programs, including programs under this title and other programs administered by the Centers for Disease Control and Prevention.

(b) ANNUAL REPORT.—Not later than January 1, 2011, and annually thereafter, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall submit to Congress a report describing, with regard to the preceding 12-month reporting period—

(1) whether the testing goal described in subsection (a) has been met;

(2) the total number of individuals tested through federally-supported and other HIV/AIDS prevention, treatment, and care programs in each State;

(3) the number of individuals who—

(A) prior to such 12-month period, were unaware of their HIV status; and

(B) through federally-supported and other HIV/AIDS prevention, treatment, and care programs, were diagnosed and referred into treatment and care during such period;

(4) any barriers, including State laws and regulations, that the Secretary determines to be a barrier to meeting the testing goal described in subsection (a);

(5) the amount of funding the Secretary determines necessary to meet the annual testing goal in the following 12 months and the amount of Federal funding expended to meet the testing goal in the prior 12-month period; and

(6) the most cost-effective strategies for identifying and diagnosing individuals who were unaware of their HIV status, including voluntary testing with pre-test counseling, routine screening including opt-out testing, partner counseling and referral services, and mass media campaigns.

(c) REVIEW OF PROGRAM EFFECTIVENESS.—Not later than 1 year after the date of enactment of this section, the Secretary, in consultation with the Director of the Centers for Disease Control and Prevention, shall submit a report to Congress based on a comprehensive review of each of the programs and activities conducted

by the Centers for Disease Control and Prevention as part of the Domestic HIV/AIDS Prevention Activities, including the following:

(1) The amount of funding provided for each program or activity.

(2) The primary purpose of each program or activity.

(3) The annual goals for each program or activity.

(4) The relative effectiveness of each program or activity with relation to the other programs and activities conducted by the Centers for Disease Control and Prevention, based on the—

(A) number of previously undiagnosed individuals with HIV/AIDS made aware of their status and referred into the appropriate treatment;

(B) amount of funding provided for each program or activity compared to the number of undiagnosed individuals with HIV/AIDS made aware of their status;

(C) program's contribution to the National HIV/AIDS testing goal; and

(D) progress made toward the goals described in paragraph (3).

(5) Recommendations if any to Congress on ways to allocate funding for domestic HIV/AIDS prevention activities and programs in order to achieve the National HIV/AIDS testing goal.

(d) COORDINATION WITH OTHER FEDERAL ACTIVITIES.—In pursuing the National HIV/AIDS testing goal, the Secretary, where appropriate, shall consider and coordinate with other national strategies conducted by the Federal Government to address HIV/AIDS.

SEC. 2689.[300ff–88] DEFINITIONS.

For purposes of this title:

(1) AIDS.—The term "AIDS" means acquired immune deficiency syndrome.

(2) CO-OCCURRING CONDITIONS.—The term "co-occurring conditions" means one or more adverse health conditions in an individual with HIV/AIDS, without regard to whether the individual has AIDS and without regard to whether the conditions arise from HIV.

(3) COUNSELING.—The term "counseling" means such counseling provided by an individual trained to provide such counseling.

(4) FAMILY-CENTERED CARE.—The term "family-centered care" means the system of services described in this title that is targeted specifically to the special needs of infants, children, women and families. Family-centered care shall be based on a partnership between parents, professionals, and the community designed to ensure an integrated, coordinated, culturally sensitive, and community-based continuum of care for children, women, and families with HIV/AIDS.

(5) FAMILIES WITH HIV/AIDS.—The term "families with HIV/AIDS" means families in which one or more members have HIV/AIDS.

(6) HIV.—The term "HIV" means infection with the human immunodeficiency virus.

(7) HIV/AIDS.—

(A) IN GENERAL.—The term "HIV/AIDS" means HIV, and includes AIDS and any condition arising from AIDS.

(B) COUNTING OF CASES.—The term "living cases of HIV/AIDS", with respect to the counting of cases in a geographic area during a period of time, means the sum of—

(i) the number of living non-AIDS cases of HIV in the area; and

(ii) the number of living cases of AIDS in the area.

(C) NON-AIDS CASES.—The term "non-AIDS", with respect to a case of HIV, means that the individual involved has HIV but does not have AIDS.

(8) HUMAN IMMUNODEFICIENCY VIRUS.—The term "human immunodeficiency virus" means the etiologic agent for AIDS.

(9) OFFICIAL POVERTY LINE.—The term "official poverty line" means the poverty line established by the Director of the Office of Management and Budget and revised by the Secretary in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1981.

(10) PERSON.—The term "person" includes one or more individuals, governments (including the Federal Government and the governments of the States), governmental agencies, political subdivisions, labor unions, partnerships, associations, corporations, legal representatives, mutual companies, joint-stock companies, trusts, unincorporated organizations, receivers, trustees, and trustees in cases under title 11, United States Code.

(11) STATE.—

(A) IN GENERAL.—The term "State" means each of the 50 States, the District of Columbia, and each of the territories.

(B) TERRITORIES.—The term "territory" means each of American Samoa, Guam, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, the Virgin Islands, the Republic of the Marshall Islands, the Federated States of Micronesia, and Palau.

(12) YOUTH WITH HIV.—The term "youth with HIV" means individuals who are 13 through 24 years old and who have HIV/AIDS.

PART F—DEMONSTRATION AND TRAINING

Subpart I—Special Projects of National Significance

SEC. 2691.[300ff–101] SPECIAL PROJECTS OF NATIONAL SIGNIFICANCE.

(a) IN GENERAL.—Of the amount appropriated under each of parts A, B, C, and D for each fiscal year, the Secretary shall use the greater of $20,000,000 or an amount equal to 3 percent of such amount appropriated under each such part, but not to exceed $25,000,000, to administer special projects of national significance to—

(1) quickly respond to emerging needs of individuals receiving assistance under this title; and

(2) to fund special programs to develop a standard electronic client information data system to improve the ability of grantees under this title to report client-level data to the Secretary.

(b) GRANTS.—The Secretary shall award grants under subsection (a) to entities eligible for funding under parts A, B, C, and D based on—

(1) whether the funding will promote obtaining client level data as it relates to the creation of a severity of need index, including funds to facilitate the purchase and enhance the utilization of qualified health information technology systems;

(2) demonstrated ability to create and maintain a qualified health information technology system;

(3) the potential replicability of the proposed activity in other similar localities or nationally;

(4) the demonstrated reliability of the proposed qualified health information technology system across a variety of providers, geographic regions, and clients; and

(5) the demonstrated ability to maintain a safe and secure qualified health information system; or

(6) newly emerging needs of individuals receiving assistance under this title.

(c) COORDINATION.—The Secretary may not make a grant under this section unless the applicant submits evidence that the proposed program is consistent with the statewide coordinated statement of need, and the applicant agrees to participate in the ongoing revision process of such statement of need.

(d) PRIVACY PROTECTION.—The Secretary may not make a grant under this section for the development of a qualified health information technology system unless the applicant provides assurances to the Secretary that the system will, at a minimum, comply with the privacy regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996.

(e) REPLICATION.—The Secretary shall make information concerning successful models or programs developed under this part available to grantees under this title for the purpose of coordination, replication, and integration. To facilitate efforts under this subsection, the Secretary may provide for peer-based technical assistance for grantees funded under this part.

Subpart II—AIDS Education and Training Centers

SEC. 2692.[300ff–111] HIV/AIDS COMMUNITIES, SCHOOLS, AND CENTERS.

(a) SCHOOLS; CENTERS.—

(1) IN GENERAL.—The Secretary may make grants and enter into contracts to assist public and nonprofit private entities and schools and academic health science centers in meeting the costs of projects—

(A) to train health personnel, including practitioners in programs under this title and other community providers, in the diagnosis, treatment, and prevention of HIV/

AIDS, including the prevention of the perinatal transmission of the disease, including measures for the prevention and treatment of opportunistic infections, and including (as applicable to the type of health professional involved), prenatal and other gynecological care for women with HIV/AIDS;

(B) to train the faculty of schools of, and graduate departments or programs of, medicine, nursing, osteopathic medicine, dentistry, public health, allied health, and mental health practice to teach health professions students to provide for the health care needs of individuals with HIV/AIDS;

(C) to develop and disseminate curricula and resource materials relating to the care and treatment of individuals with such disease and the prevention of the disease among individuals who are at risk of contracting the disease; and

(D) to develop protocols for the medical care of women with HIV/AIDS, including prenatal and other gynecological care for such women.

(2) PREFERENCE IN MAKING GRANTS.—In making grants under paragraph (1), the Secretary shall give preference to qualified projects which will—

(A) train, or result in the training of, health professionals who will provide treatment for minority individuals and Native Americans with HIV/AIDS and other individuals who are at high risk of contracting such disease;

(B) train, or result in the training of, minority health professionals and minority allied health professionals to provide treatment for individuals with such disease; and

(C) train or result in the training of health professionals and allied health professionals to provide treatment for hepatitis B or C co-infected individuals.

(3) APPLICATION.—No grant or contract may be made under paragraph (1) unless an application is submitted to the Secretary in such form, at such time, and containing such information, as the Secretary may prescribe.

(b) DENTAL SCHOOLS.—

(1) IN GENERAL.—

(A) GRANTS.—The Secretary may make grants to dental schools and programs described in subparagraph (B) to assist such schools and programs with respect to oral health care to patients with HIV/AIDS.

(B) ELIGIBLE APPLICANTS.—For purposes of this subsection, the dental schools and programs referred to in this subparagraph are dental schools and programs that were described in section 777(b)(4)(B) as such section was in effect on the day before the date of the enactment of the Health Professions Education Partnerships Act of 1998 (Public Law 105–392) and in addition dental hygiene programs that are accredited by the Commission on Dental Accreditation.

(2) APPLICATION.—Each dental school or program described in section [15] the section referred to in paragraph (1)(B) may annually submit an application documenting the unreimbursed costs of oral health care provided to patients with HIV/AIDS by that school or hospital during the prior year.

(3) DISTRIBUTION.—The Secretary shall distribute the available funds among all eligible applicants, taking into account the number of patients with HIV/AIDS served and the unreimbursed oral health care costs incurred by each institution as compared with the total number of patients served and costs incurred by all eligible applicants.

(4) MAINTENANCE OF EFFORT.—The Secretary shall not make a grant under this subsection if doing so would result in any reduction in State funding allotted for such purposes.

(5) COMMUNITY-BASED CARE.—The Secretary may make grants to dental schools and programs described in paragraph (1)(B) that partner with community-based dentists to provide oral health care to patients with HIV/AIDS in unserved areas. Such partnerships shall permit the training of dental students and residents and the participation of community dentists as adjunct faculty.

(c) AUTHORIZATION OF APPROPRIATIONS.—

(1) SCHOOLS; CENTERS.—For the purpose of awarding grants under subsection (a), there are authorized to be appropriated $34,700,000 for each of the fiscal years 2007 through 2009, $36,535,000 for fiscal year 2010, $38,257,000 for fiscal year 2011, $40,170,000 for fiscal year 2012, and $42,178,000 for fiscal year 2013.

(2) DENTAL SCHOOLS.—For the purpose of awarding grants under subsection (b), there are authorized to be appropriated $13,000,000 for each of the fiscal years 2007 through 2009, $13,650,000 for fiscal year 2010, $14,333,000 for fiscal year 2011, $15,049,000 for fiscal year 2012, and $15,802,000 for fiscal year 2013.

Subpart III—Minority AIDS Initiative

SEC. 2693.[300ff–121] MINORITY AIDS INITIATIVE.

(a) IN GENERAL.—For the purpose of carrying out activities under this section to evaluate and address the disproportionate impact of HIV/AIDS on, and the disparities in access, treatment, care, and outcomes for, racial and ethnic minorities (including African Americans, Alaska Natives, Latinos, American Indians, Asian Americans, Native Hawaiians, and Pacific Islanders), there are authorized to be appropriated $131,200,000 for fiscal year 2007, $135,100,000 for fiscal year 2008, $139,100,000 for fiscal year 2009, $146,055,000 for fiscal year 2010, $153,358,000 for fiscal year 2011, $161,026,000 for fiscal year 2012, and $169,077,000 for fiscal year 2013. The Secretary shall develop a formula for the awarding of grants under subsections (b)(1)(A) and (b)(1)(B) that ensures that funding is provided based on the distribution of populations disproportionately impacted by HIV/AIDS.

[15] So in law. See section 402(b)(2) of Public Law 106–345 (114 Stat. 1349).

(b) CERTAIN ACTIVITIES.—

(1) IN GENERAL.—In carrying out the purpose described in subsection (a), the Secretary shall provide for—

(A) emergency assistance under part A;

(B) care grants under part B;

(C) early intervention services under part C;

(D) services through projects for HIV-related care under part D; and

(E) activities through education and training centers under section 2692.

(2) ALLOCATIONS AMONG ACTIVITIES.—Activities under paragraph (1) shall be carried out by the Secretary in accordance with the following:

(A) For supplemental grants to improve HIV-related health outcomes to reduce existing racial and ethnic health disparities, the Secretary shall, of the amount appropriated under subsection (a) for a fiscal year, reserve the following, as applicable:

(i) For fiscal year 2007, $43,800,000.

(ii) For fiscal year 2008, $45,400,000.

(iii) For fiscal year 2009, $47,100,000.

(iv) For fiscal year 2010, $46,738,000.

(v) For fiscal year 2011, $49,075,000.

(vi) For fiscal year 2012, $51,528,000.

(vii) For fiscal year 2013, $54,105,000.

(B) For grants used for supplemental support education and outreach services to increase the number of eligible racial and ethnic minorities who have access to treatment through the program under section 2616 for therapeutics, the Secretary shall, of the amount appropriated for a fiscal year under subsection (a), reserve the following, as applicable:

(i) For fiscal year 2007, $7,000,000.

(ii) For fiscal year 2008, $7,300,000.

(iii) For fiscal year 2009, $7,500,000.

(iv) For fiscal year 2010, $8,763,000.

(v) For fiscal year 2011, $9,202,000.

(vi) For fiscal year 2012, $9,662,000.

(vii) For fiscal year 2013, $10,145,000.

(C) For planning grants, capacity-building grants, and services grants to health care providers who have a history of providing culturally and linguistically appropriate care and services to racial and ethnic minorities, the Secretary shall, of the amount appropriated for a fiscal year under subsection (a), reserve the following, as applicable:

(i) For fiscal year 2007, $53,400,000.

(ii) For fiscal year 2008, $55,400,000.

(iii) For fiscal year 2009, $57,400,000.

(iv) For fiscal year 2010, $61,343,000.

(v) For fiscal year 2011, $64,410,000.

(vi) For fiscal year 2012, $67,631,000.

(vii) For fiscal year 2013, $71,012,000.

(D) For eliminating racial and ethnic disparities in the delivery of comprehensive, culturally and linguistically ap-

propriate care services for HIV disease for women, infants, children, and youth, the Secretary shall, of the amount appropriated under subsection (a), reserve the following, as applicable:

(i) For fiscal year 2010, $20,448,000.

(ii) For fiscal year 2011, $21,470,000.

(iii) For fiscal year 2012, $22,543,000.

(iv) For fiscal year 2013, $23,671,000.

(E) For increasing the training capacity of centers to expand the number of health care professionals with treatment expertise and knowledge about the most appropriate standards of HIV disease-related treatments and medical care for racial and ethnic minority adults, adolescents, and children with HIV disease, the Secretary shall, of the amount appropriated under subsection (a), reserve the following, as applicable:

(i) For fiscal year 2010, $8,763,000.

(ii) For fiscal year 2011, $9,201,000.

(iii) For fiscal year 2012, $9,662,000.

(iv) For fiscal year 2013, $10,144,000.

(c) CONSISTENCY WITH PRIOR PROGRAM.—With respect to the purpose described in subsection (a), the Secretary shall carry out this section consistent with the activities carried out under this title by the Secretary pursuant to the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2002 (Public Law 107–116).

(d) SYNCHRONIZATION OF MINORITY AIDS INITIATIVE.—For fiscal year 2010 and each subsequent fiscal year, the Secretary shall incorporate and synchronize the schedule of application submissions and funding availability under this section with the schedule of application submissions and funding availability under the corresponding provisions of this title XXVI as follows:

(1) The schedule for carrying out subsection (b)(1)(A) shall be the same as the schedule applicable to emergency assistance under part A.

(2) The schedule for carrying out subsection (b)(1)(B) shall be the same as the schedule applicable to care grants under part B.

(3) The schedule for carrying out subsection (b)(1)(C) shall be the same as the schedule applicable to grants for early intervention services under part C.

(4) The schedule for carrying out subsection (b)(1)(D) shall be the same as the schedule applicable to grants for services through projects for HIV-related care under part D.

(5) The schedule for carrying out subsection (b)(1)(E) shall be the same as the schedule applicable to grants and contracts for activities through education and training centers under section 2692.

PART G—NOTIFICATION OF POSSIBLE EXPOSURE TO INFECTIOUS DISEASES

SEC. 2695.[300ff–131] INFECTIOUS DISEASES AND CIRCUMSTANCES RELEVANT TO NOTIFICATION REQUIREMENTS.

(a) IN GENERAL.—Not later than 180 days after the date of the enactment of this part, the Secretary shall complete the development of—

(1) a list of potentially life-threatening infectious diseases, including emerging infectious diseases, to which emergency response employees may be exposed in responding to emergencies;

(2) guidelines describing the circumstances in which such employees may be exposed to such diseases, taking into account the conditions under which emergency response is provided; and

(3) guidelines describing the manner in which medical facilities should make determinations for purposes of section 2695B(d).

(b) SPECIFICATION OF AIRBORNE INFECTIOUS DISEASES.—The list developed by the Secretary under subsection (a)(1) shall include a specification of those infectious diseases on the list that are routinely transmitted through airborne or aerosolized means.

(c) DISSEMINATION.—The Secretary shall—

(1) transmit to State public health officers copies of the list and guidelines developed by the Secretary under subsection (a) with the request that the officers disseminate such copies as appropriate throughout the States; and

(2) make such copies available to the public.

SEC. 2695A.[300ff–132] ROUTINE NOTIFICATIONS WITH RESPECT TO AIRBORNE INFECTIOUS DISEASES IN VICTIMS ASSISTED.

(a) ROUTINE NOTIFICATION OF DESIGNATED OFFICER.—

(1) DETERMINATION BY TREATING FACILITY.—If a victim of an emergency is transported by emergency response employees to a medical facility and the medical facility makes a determination that the victim has an airborne infectious disease, the medical facility shall notify the designated officer of the emergency response employees who transported the victim to the medical facility of the determination.

(2) DETERMINATION BY FACILITY ASCERTAINING CAUSE OF DEATH.—If a victim of an emergency is transported by emergency response employees to a medical facility and the victim dies at or before reaching the medical facility, the medical facility ascertaining the cause of death shall notify the designated officer of the emergency response employees who transported the victim to the initial medical facility of any determination by the medical facility that the victim had an airborne infectious disease.

(b) REQUIREMENT OF PROMPT NOTIFICATION.—With respect to a determination described in paragraph (1) or (2) of subsection (a), the notification required in each of such paragraphs shall be made as soon as is practicable, but not later than 48 hours after the determination is made.

SEC. 2695B.[300ff–133] REQUEST FOR NOTIFICATION WITH RESPECT TO VICTIMS ASSISTED.

(a) INITIATION OF PROCESS BY EMPLOYEE.—If an emergency response employee believes that the employee may have been exposed to an infectious disease by a victim of an emergency who was transported to a medical facility as a result of the emergency, and if the employee attended, treated, assisted, or transported the victim pursuant to the emergency, then the designated officer of the employee shall, upon the request of the employee, carry out the duties described in subsection (b) regarding a determination of whether the employee may have been exposed to an infectious disease by the victim.

(b) INITIAL DETERMINATION BY DESIGNATED OFFICER.—The duties referred to in subsection (a) are that—

(1) the designated officer involved collect the facts relating to the circumstances under which, for purposes of subsection (a), the employee involved may have been exposed to an infectious disease; and

(2) the designated officer evaluate such facts and make a determination of whether, if the victim involved had any infectious disease included on the list issued under paragraph (1) of section 2695(a), the employee would have been exposed to the disease under such facts, as indicated by the guidelines issued under paragraph (2) of such section.

(c) SUBMISSION OF REQUEST TO MEDICAL FACILITY.—

(1) IN GENERAL.—If a designated officer makes a determination under subsection (b)(2) that an emergency response employee may have been exposed to an infectious disease, the designated officer shall submit to the medical facility to which the victim involved was transported a request for a response under subsection (d) regarding the victim of the emergency involved.

(2) FORM OF REQUEST.—A request under paragraph (1) shall be in writing and be signed by the designated officer involved, and shall contain a statement of the facts collected pursuant to subsection (b)(1).

(d) EVALUATION AND RESPONSE REGARDING REQUEST TO MEDICAL FACILITY.—

(1) IN GENERAL.—If a medical facility receives a request under subsection (c), the medical facility shall evaluate the facts submitted in the request and make a determination of whether, on the basis of the medical information possessed by the facility regarding the victim involved, the emergency response employee was exposed to an infectious disease included on the list issued under paragraph (1) of section 2695(a), as indicated by the guidelines issued under paragraph (2) of such section.

(2) NOTIFICATION OF EXPOSURE.—If a medical facility makes a determination under paragraph (1) that the emergency response employee involved has been exposed to an infectious disease, the medical facility shall, in writing, notify the designated officer who submitted the request under subsection (c) of the determination.

(3) FINDING OF NO EXPOSURE.—If a medical facility makes a determination under paragraph (1) that the emergency response employee involved has not been exposed to an infectious disease, the medical facility shall, in writing, inform the designated officer who submitted the request under subsection (c) of the determination.

(4) INSUFFICIENT INFORMATION.—

(A) If a medical facility finds in evaluating facts for purposes of paragraph (1) that the facts are insufficient to make the determination described in such paragraph, the medical facility shall, in writing, inform the designated officer who submitted the request under subsection (c) of the insufficiency of the facts.

(B)(i) If a medical facility finds in making a determination under paragraph (1) that the facility possesses no information on whether the victim involved has an infectious disease included on the list under section 2695(a), the medical facility shall, in writing, inform the designated officer who submitted the request under subsection (c) of the insufficiency of such medical information.

(ii) If after making a response under clause (i) a medical facility determines that the victim involved has an infectious disease, the medical facility shall make the determination described in paragraph (1) and provide the applicable response specified in this subsection.

(e) TIME FOR MAKING RESPONSE.—After receiving a request under subsection (c) (including any such request resubmitted under subsection (g)(2)), a medical facility shall make the applicable response specified in subsection (d) as soon as is practicable, but not later than 48 hours after receiving the request.

(f) DEATH OF VICTIM OF EMERGENCY.—

(1) FACILITY ASCERTAINING CAUSE OF DEATH.—If a victim described in subsection (a) dies at or before reaching the medical facility involved, and the medical facility receives a request under subsection (c), the medical facility shall provide a copy of the request to the medical facility ascertaining the cause of death of the victim, if such facility is a different medical facility than the facility that received the original request.

(2) RESPONSIBILITY OF FACILITY.—Upon the receipt of a copy of a request for purposes of paragraph (1), the duties otherwise established in this part regarding medical facilities shall apply to the medical facility ascertaining the cause of death of the victim in the same manner and to the same extent as such duties apply to the medical facility originally receiving the request.

(g) ASSISTANCE OF PUBLIC HEALTH OFFICER.—

(1) EVALUATION OF RESPONSE OF MEDICAL FACILITY REGARDING INSUFFICIENT FACTS.—

(A) In the case of a request under subsection (c) to which a medical facility has made the response specified in subsection (d)(4)(A) regarding the insufficiency of facts, the public health officer for the community in which the medical facility is located shall evaluate the request and the response, if the designated officer involved submits such

documents to the officer with the request that the officer make such an evaluation.

(B) As soon as is practicable after a public health officer receives a request under subparagraph (A), but not later than 48 hours after receipt of the request, the public health officer shall complete the evaluation required in such paragraph and inform the designated officer of the results of the evaluation.

(2) FINDINGS OF EVALUATION.—

(A) If an evaluation under paragraph (1)(A) indicates that the facts provided to the medical facility pursuant to subsection (c) were sufficient for purposes of determinations under subsection (d)(1)—

(i) the public health officer shall, on behalf of the designated officer involved, resubmit the request to the medical facility; and

(ii) the medical facility shall provide to the designated officer the applicable response specified in subsection (d).

(B) If an evaluation under paragraph (1)(A) indicates that the facts provided in the request to the medical facility were insufficient for purposes of determinations specified in subsection (c)—

(i) the public health officer shall provide advice to the designated officer regarding the collection and description of appropriate facts; and

(ii) if sufficient facts are obtained by the designated officer—

(I) the public health officer shall, on behalf of the designated officer involved, resubmit the request to the medical facility; and

(II) the medical facility shall provide to the designated officer the appropriate response under subsection (c).

SEC. 2695C.[300ff–134] PROCEDURES FOR NOTIFICATION OF EXPOSURE.

(a) CONTENTS OF NOTIFICATION TO OFFICER.—In making a notification required under section 2695A or section 2695B(d)(2), a medical facility shall provide—

(1) the name of the infectious disease involved; and

(2) the date on which the victim of the emergency involved was transported by emergency response employees to the medical facility involved.

(b) MANNER OF NOTIFICATION.—If a notification under section 2695A or section 2695B(d)(2) is mailed or otherwise indirectly made—

(1) the medical facility sending the notification shall, upon sending the notification, inform the designated officer to whom the notification is sent of the fact that the notification has been sent; and

(2) such designated officer shall, not later than 10 days after being informed by the medical facility that the notification has been sent, inform such medical facility whether the designated officer has received the notification.

SEC. 2695D.[300ff–135] NOTIFICATION OF EMPLOYEE.

(a) IN GENERAL.—After receiving a notification for purposes of section 2695A or 2695B(d)(2), a designated officer of emergency response employees shall, to the extent practicable, immediately notify each of such employees who—

(1) responded to the emergency involved; and

(2) as indicated by guidelines developed by the Secretary, may have been exposed to an infectious disease.

(b) CERTAIN CONTENTS OF NOTIFICATION TO EMPLOYEE.—A notification under this subsection to an emergency response employee shall inform the employee of—

(1) the fact that the employee may have been exposed to an infectious disease and the name of the disease involved;

(2) any action by the employee that, as indicated by guidelines developed by the Secretary, is medically appropriate; and

(3) if medically appropriate under such criteria, the date of such emergency.

(c) RESPONSES OTHER THAN NOTIFICATION OF EXPOSURE.—After receiving a response under paragraph (3) or (4) of subsection (d) of section 2695B, or a response under subsection (g)(1) of such section, the designated officer for the employee shall, to the extent practicable, immediately inform the employee of the response.

SEC. 2695E.[300ff–136] SELECTION OF DESIGNATED OFFICERS.

(a) IN GENERAL.—For the purposes of receiving notifications and responses and making requests under this part on behalf of emergency response employees, the public health officer of each State shall designate 1 official or officer of each employer of emergency response employees in the State.

(b) PREFERENCE IN MAKING DESIGNATIONS.—In making the designations required in subsection (a), a public health officer shall give preference to individuals who are trained in the provision of health care or in the control of infectious diseases.

SEC. 2695F.[300ff–137] LIMITATION WITH RESPECT TO DUTIES OF MEDICAL FACILITIES.

The duties established in this part for a medical facility—

(1) shall apply only to medical information possessed by the facility during the period in which the facility is treating the victim for conditions arising from the emergency, or during the 60-day period beginning on the date on which the victim is transported by emergency response employees to the facility, whichever period expires first; and

(2) shall not apply to any extent after the expiration of the 30-day period beginning on the expiration of the applicable period referred to in paragraph (1), except that such duties shall apply with respect to any request under section 2695B(c) received by a medical facility before the expiration of such 30-day period.

SEC. 2695G.[300ff–138] MISCELLANEOUS PROVISIONS.

(a) LIABILITY OF MEDICAL FACILITIES, DESIGNATED OFFICERS, PUBLIC HEALTH OFFICERS, AND GOVERNING ENTITIES.—This part may not be construed to authorize any cause of action for damages or any civil penalty against any medical facility, any designated officer, any other public health officer, or any governing entity of

such facility or officer for failure to comply with the duties established in this part.

(b) TESTING.—This part may not, with respect to victims of emergencies, be construed to authorize or require a medical facility to test any such victim for any infectious disease.

(c) CONFIDENTIALITY.—This part may not be construed to authorize or require any medical facility, any designated officer of emergency response employees, or any such employee, to disclose identifying information with respect to a victim of an emergency or with respect to an emergency response employee.

(d) FAILURE TO PROVIDE EMERGENCY SERVICES.—This part may not be construed to authorize any emergency response employee to fail to respond, or to deny services, to any victim of an emergency.

(e) NOTIFICATION AND REPORTING DEADLINES.—In any case in which the Secretary determines that, wholly or partially as a result of a public health emergency that has been determined pursuant to section 319(a), individuals or public or private entities are unable to comply with the requirements of this part, the Secretary may, notwithstanding any other provision of law, temporarily suspend, in whole or in part, the requirements of this part as the circumstances reasonably require. Before or promptly after such a suspension, the Secretary shall notify the Congress of such action and publish in the Federal Register a notice of the suspension.

(f) CONTINUED APPLICATION OF STATE AND LOCAL LAW.—Nothing in this part shall be construed to limit the application of State or local laws that require the provision of data to public health authorities.

SEC. 2695H.[300ff–139] INJUNCTIONS REGARDING VIOLATION OF PROHIBITION.

(a) IN GENERAL.—The Secretary may, in any court of competent jurisdiction, commence a civil action for the purpose of obtaining temporary or permanent injunctive relief with respect to any violation of this part.

(b) FACILITATION OF INFORMATION ON VIOLATIONS.—The Secretary shall establish an administrative process for encouraging emergency response employees to provide information to the Secretary regarding violations of this part. As appropriate, the Secretary shall investigate alleged such violations and seek appropriate injunctive relief.

SEC. 2695I.[300ff–140] APPLICABILITY OF PART.

This part shall not apply in a State if the chief executive officer of the State certifies to the Secretary that the law of the State is substantially consistent with this part.

December 13, 2013

PUBLIC HEALTH SERVICE ACT

As Amended Through P.L. 112–240, Enacted January 2, 2013

TITLE XXVII—REQUIREMENTS RELATING TO HEALTH INSURANCE COVERAGE

PART A—INDIVIDUAL AND GROUP MARKET REFORMS

[Note: For a version of law of part A, as amended by 1001, 1201, and 1563 (relating to conforming amendments--originally designated as section 1562 and redesignated as section 1563 by section 10107(b)(1)) of Public Law 111–148, see note set out in italic typeface that appears after section 2737 below.**]**

Subpart 1—Portability, Access, and Renewability Requirements

SEC. 2701.[300gg] INCREASED PORTABILITY THROUGH LIMITATION ON PREEXISTING CONDITION EXCLUSIONS.

(a) LIMITATION ON PREEXISTING CONDITION EXCLUSION PERIOD; CREDITING FOR PERIODS OF PREVIOUS COVERAGE.—Subject to subsection (d), a group health plan, and a health insurance issuer offering group health insurance coverage, may, with respect to a participant or beneficiary, impose a preexisting condition exclusion only if—

(1) such exclusion relates to a condition (whether physical or mental), regardless of the cause of the condition, for which medical advice, diagnosis, care, or treatment was recommended or received within the 6-month period ending on the enrollment date;

(2) such exclusion extends for a period of not more than 12 months (or 18 months in the case of a late enrollee) after the enrollment date; and

(3) the period of any such preexisting condition exclusion is reduced by the aggregate of the periods of creditable coverage (if any, as defined in subsection (c)(1)) applicable to the participant or beneficiary as of the enrollment date.

(b) DEFINITIONS.—For purposes of this part—

(1) PREEXISTING CONDITION EXCLUSION.—

(A) IN GENERAL.—The term "preexisting condition exclusion" means, with respect to coverage, a limitation or exclusion of benefits relating to a condition based on the fact that the condition was present before the date of enrollment for such coverage, whether or not any medical advice, diagnosis, care, or treatment was recommended or received before such date.

(B) TREATMENT OF GENETIC INFORMATION.—Genetic information shall not be treated as a condition described in subsection (a)(1) in the absence of a diagnosis of the condition related to such information.

(2) ENROLLMENT DATE.—The term "enrollment date" means, with respect to an individual covered under a group health plan or health insurance coverage, the date of enrollment of the individual in the plan or coverage or, if earlier, the first day of the waiting period for such enrollment.

(3) LATE ENROLLEE.—The term "late enrollee" means, with respect to coverage under a group health plan, a participant or beneficiary who enrolls under the plan other than during—

(A) the first period in which the individual is eligible to enroll under the plan, or

(B) a special enrollment period under subsection (f).

(4) WAITING PERIOD.—The term "waiting period" means, with respect to a group health plan and an individual who is a potential participant or beneficiary in the plan, the period that must pass with respect to the individual before the individual is eligible to be covered for benefits under the terms of the plan.

(c) RULES RELATING TO CREDITING PREVIOUS COVERAGE.—

(1) CREDITABLE COVERAGE DEFINED.—For purposes of this title, the term "creditable coverage" means, with respect to an individual, coverage of the individual under any of the following:

(A) A group health plan.

(B) Health insurance coverage.

(C) Part A or part B of title XVIII of the Social Security Act.

(D) Title XIX of the Social Security Act, other than coverage consisting solely of benefits under section 1928.

(E) Chapter 55 of title 10, United States Code.

(F) A medical care program of the Indian Health Service or of a tribal organization.

(G) A State health benefits risk pool.

(H) A health plan offered under chapter 89 of title 5, United States Code.

(I) A public health plan (as defined in regulations).

(J) A health benefit plan under section 5(e) of the Peace Corps Act (22 U.S.C. 2504(e)).

Such term does not include coverage consisting solely of coverage of excepted benefits (as defined in section 2791(c)).

(2) NOT COUNTING PERIODS BEFORE SIGNIFICANT BREAKS IN COVERAGE.—

(A) IN GENERAL.—A period of creditable coverage shall not be counted, with respect to enrollment of an individual under a group health plan, if, after such period and before the enrollment date, there was a 63-day period during all of which the individual was not covered under any creditable coverage.

(B) WAITING PERIOD NOT TREATED AS A BREAK IN COVERAGE.—For purposes of subparagraph (A) and subsection (d)(4), any period that an individual is in a waiting period

for any coverage under a group health plan (or for group health insurance coverage) or is in an affiliation period (as defined in subsection (g)(2)) shall not be taken into account in determining the continuous period under subparagraph (A).

(C) TAA-ELIGIBLE INDIVIDUALS.—In the case of plan years beginning before January 1, 2014—

(i) TAA PRE-CERTIFICATION PERIOD RULE.—In the case of a TAA-eligible individual, the period beginning on the date the individual has a TAA-related loss of coverage and ending on the date that is 7 days after the date of the issuance by the Secretary (or by any person or entity designated by the Secretary) of a qualified health insurance costs credit eligibility certificate for such individual for purposes of section 7527 of the Internal Revenue Code of 1986 shall not be taken into account in determining the continuous period under subparagraph (A).

(ii) DEFINITIONS.—The terms "TAA-eligible individual" and "TAA-related loss of coverage" have the meanings given such terms in section 2205(b)(4).

(3) METHOD OF CREDITING COVERAGE.—

(A) STANDARD METHOD.—Except as otherwise provided under subparagraph (B), for purposes of applying subsection (a)(3), a group health plan, and a health insurance issuer offering group health insurance coverage, shall count a period of creditable coverage without regard to the specific benefits covered during the period.

(B) ELECTION OF ALTERNATIVE METHOD.—A group health plan, or a health insurance issuer offering group health insurance, may elect to apply subsection (a)(3) based on coverage of benefits within each of several classes or categories of benefits specified in regulations rather than as provided under subparagraph (A). Such election shall be made on a uniform basis for all participants and beneficiaries. Under such election a group health plan or issuer shall count a period of creditable coverage with respect to any class or category of benefits if any level of benefits is covered within such class or category.

(C) PLAN NOTICE.—In the case of an election with respect to a group health plan under subparagraph (B) (whether or not health insurance coverage is provided in connection with such plan), the plan shall—

(i) prominently state in any disclosure statements concerning the plan, and state to each enrollee at the time of enrollment under the plan, that the plan has made such election, and

(ii) include in such statements a description of the effect of this election.

(D) ISSUER NOTICE.—In the case of an election under subparagraph (B) with respect to health insurance coverage offered by an issuer in the small or large group market, the issuer—

(i) shall prominently state in any disclosure statements concerning the coverage, and to each employer at the time of the offer or sale of the coverage, that the issuer has made such election, and

(ii) shall include in such statements a description of the effect of such election.

(4) ESTABLISHMENT OF PERIOD.—Periods of creditable coverage with respect to an individual shall be established through presentation of certifications described in subsection (e) or in such other manner as may be specified in regulations.

(d) EXCEPTIONS.—

(1) EXCLUSION NOT APPLICABLE TO CERTAIN NEWBORNS.—Subject to paragraph (4), a group health plan, and a health insurance issuer offering group health insurance coverage, may not impose any preexisting condition exclusion in the case of an individual who, as of the last day of the 30-day period beginning with the date of birth, is covered under creditable coverage.

(2) EXCLUSION NOT APPLICABLE TO CERTAIN ADOPTED CHILDREN.—Subject to paragraph (4), a group health plan, and a health insurance issuer offering group health insurance coverage, may not impose any preexisting condition exclusion in the case of a child who is adopted or placed for adoption before attaining 18 years of age and who, as of the last day of the 30-day period beginning on the date of the adoption or placement for adoption, is covered under creditable coverage. The previous sentence shall not apply to coverage before the date of such adoption or placement for adoption.

(3) EXCLUSION NOT APPLICABLE TO PREGNANCY.—A group health plan, and health insurance issuer offering group health insurance coverage, may not impose any preexisting condition exclusion relating to pregnancy as a preexisting condition.

(4) LOSS IF BREAK IN COVERAGE.—Paragraphs (1) and (2) shall no longer apply to an individual after the end of the first 63-day period during all of which the individual was not covered under any creditable coverage.

(e) CERTIFICATIONS AND DISCLOSURE OF COVERAGE.—

(1) REQUIREMENT FOR CERTIFICATION OF PERIOD OF CREDITABLE COVERAGE.—

(A) IN GENERAL.—A group health plan, and a health insurance issuer offering group health insurance coverage, shall provide the certification described in subparagraph (B)—

(i) at the time an individual ceases to be covered under the plan or otherwise becomes covered under a COBRA continuation provision,

(ii) in the case of an individual becoming covered under such a provision, at the time the individual ceases to be covered under such provision, and

(iii) on the request on behalf of an individual made not later than 24 months after the date of cessation of the coverage described in clause (i) or (ii), whichever is later.

The certification under clause (i) may be provided, to the extent practicable, at a time consistent with notices required under any applicable COBRA continuation provision.

(B) CERTIFICATION.—The certification described in this subparagraph is a written certification of—

(i) the period of creditable coverage of the individual under such plan and the coverage (if any) under such COBRA continuation provision, and

(ii) the waiting period (if any) (and affiliation period, if applicable) imposed with respect to the individual for any coverage under such plan.

(C) ISSUER COMPLIANCE.—To the extent that medical care under a group health plan consists of group health insurance coverage, the plan is deemed to have satisfied the certification requirement under this paragraph if the health insurance issuer offering the coverage provides for such certification in accordance with this paragraph.

(2) DISCLOSURE OF INFORMATION ON PREVIOUS BENEFITS.—In the case of an election described in subsection (c)(3)(B) by a group health plan or health insurance issuer, if the plan or issuer enrolls an individual for coverage under the plan and the individual provides a certification of coverage of the individual under paragraph (1)—

(A) upon request of such plan or issuer, the entity which issued the certification provided by the individual shall promptly disclose to such requesting plan or issuer information on coverage of classes and categories of health benefits available under such entity's plan or coverage, and

(B) such entity may charge the requesting plan or issuer for the reasonable cost of disclosing such information.

(3) REGULATIONS.—The Secretary shall establish rules to prevent an entity's failure to provide information under paragraph (1) or (2) with respect to previous coverage of an individual from adversely affecting any subsequent coverage of the individual under another group health plan or health insurance coverage.

(f) SPECIAL ENROLLMENT PERIODS.—

(1) INDIVIDUALS LOSING OTHER COVERAGE.—A group health plan, and a health insurance issuer offering group health insurance coverage in connection with a group health plan, shall permit an employee who is eligible, but not enrolled, for coverage under the terms of the plan (or a dependent of such an employee if the dependent is eligible, but not enrolled, for coverage under such terms) to enroll for coverage under the terms of the plan if each of the following conditions is met:

(A) The employee or dependent was covered under a group health plan or had health insurance coverage at the time coverage was previously offered to the employee or dependent.

(B) The employee stated in writing at such time that coverage under a group health plan or health insurance

coverage was the reason for declining enrollment, but only if the plan sponsor or issuer (if applicable) required such a statement at such time and provided the employee with notice of such requirement (and the consequences of such requirement) at such time.

(C) The employee's or dependent's coverage described in subparagraph (A)—

(i) was under a COBRA continuation provision and the coverage under such provision was exhausted; or

(ii) was not under such a provision and either the coverage was terminated as a result of loss of eligibility for the coverage (including as a result of legal separation, divorce, death, termination of employment, or reduction in the number of hours of employment) or employer contributions toward such coverage were terminated.

(D) Under the terms of the plan, the employee requests such enrollment not later than 30 days after the date of exhaustion of coverage described in subparagraph (C)(i) or termination of coverage or employer contribution described in subparagraph (C)(ii).

(2) FOR DEPENDENT BENEFICIARIES.—

(A) IN GENERAL.—If—

(i) a group health plan makes coverage available with respect to a dependent of an individual,

(ii) the individual is a participant under the plan (or has met any waiting period applicable to becoming a participant under the plan and is eligible to be enrolled under the plan but for a failure to enroll during a previous enrollment period), and

(iii) a person becomes such a dependent of the individual through marriage, birth, or adoption or placement for adoption,

the group health plan shall provide for a dependent special enrollment period described in subparagraph (B) during which the person (or, if not otherwise enrolled, the individual) may be enrolled under the plan as a dependent of the individual, and in the case of the birth or adoption of a child, the spouse of the individual may be enrolled as a dependent of the individual if such spouse is otherwise eligible for coverage.

(B) DEPENDENT SPECIAL ENROLLMENT PERIOD.—A dependent special enrollment period under this subparagraph shall be a period of not less than 30 days and shall begin on the later of—

(i) the date dependent coverage is made available, or

(ii) the date of the marriage, birth, or adoption or placement for adoption (as the case may be) described in subparagraph (A)(iii).

(C) NO WAITING PERIOD.—If an individual seeks to enroll a dependent during the first 30 days of such a depend-

ent special enrollment period, the coverage of the dependent shall become effective—

(i) in the case of marriage, not later than the first day of the first month beginning after the date the completed request for enrollment is received;

(ii) in the case of a dependent's birth, as of the date of such birth; or

(iii) in the case of a dependent's adoption or placement for adoption, the date of such adoption or placement for adoption.

(3) SPECIAL RULES FOR APPLICATION IN CASE OF MEDICAID AND CHIP.—

(A) IN GENERAL.—A group health plan, and a health insurance issuer offering group health insurance coverage in connection with a group health plan, shall permit an employee who is eligible, but not enrolled, for coverage under the terms of the plan (or a dependent of such an employee if the dependent is eligible, but not enrolled, for coverage under such terms) to enroll for coverage under the terms of the plan if either of the following conditions is met:

(i) TERMINATION OF MEDICAID OR CHIP COVERAGE.—The employee or dependent is covered under a Medicaid plan under title XIX of the Social Security Act or under a State child health plan under title XXI of such Act and coverage of the employee or dependent under such a plan is terminated as a result of loss of eligibility for such coverage and the employee requests coverage under the group health plan (or health insurance coverage) not later than 60 days after the date of termination of such coverage.

(ii) ELIGIBILITY FOR EMPLOYMENT ASSISTANCE UNDER MEDICAID OR CHIP.—The employee or dependent becomes eligible for assistance, with respect to coverage under the group health plan or health insurance coverage, under such Medicaid plan or State child health plan (including under any waiver or demonstration project conducted under or in relation to such a plan), if the employee requests coverage under the group health plan or health insurance coverage not later than 60 days after the date the employee or dependent is determined to be eligible for such assistance.

(B) COORDINATION WITH MEDICAID AND CHIP.—

(i) OUTREACH TO EMPLOYEES REGARDING AVAILABILITY OF MEDICAID AND CHIP COVERAGE.—

(I) IN GENERAL.—Each employer that maintains a group health plan in a State that provides medical assistance under a State Medicaid plan under title XIX of the Social Security Act, or child health assistance under a State child health plan under title XXI of such Act, in the form of premium assistance for the purchase of coverage under a group health plan, shall provide to each

employee a written notice informing the employee of potential opportunities then currently available in the State in which the employee resides for premium assistance under such plans for health coverage of the employee or the employee's dependents. For purposes of compliance with this subclause, the employer may use any State-specific model notice developed in accordance with section 701(f)(3)(B)(i)(II) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1181(f)(3)(B)(i)(II)).

(II) OPTION TO PROVIDE CONCURRENT WITH PROVISION OF PLAN MATERIALS TO EMPLOYEE.—An employer may provide the model notice applicable to the State in which an employee resides concurrent with the furnishing of materials notifying the employee of health plan eligibility, concurrent with materials provided to the employee in connection with an open season or election process conducted under the plan, or concurrent with the furnishing of the summary plan description as provided in section 104(b) of the Employee Retirement Income Security Act of 1974.

(ii) DISCLOSURE ABOUT GROUP HEALTH PLAN BENEFITS TO STATES FOR MEDICAID AND CHIP ELIGIBLE INDIVIDUALS.—In the case of an enrollee in a group health plan who is covered under a Medicaid plan of a State under title XIX of the Social Security Act or under a State child health plan under title XXI of such Act, the plan administrator of the group health plan shall disclose to the State, upon request, information about the benefits available under the group health plan in sufficient specificity, as determined under regulations of the Secretary of Health and Human Services in consultation with the Secretary that require use of the model coverage coordination disclosure form developed under section 311(b)(1)(C) of the Children's Health Insurance Reauthorization Act of 2009, so as to permit the State to make a determination (under paragraph (2)(B), (3), or (10) of section 2105(c) of the Social Security Act or otherwise) concerning the cost-effectiveness of the State providing medical or child health assistance through premium assistance for the purchase of coverage under such group health plan and in order for the State to provide supplemental benefits required under paragraph (10)(E) of such section or other authority.

(g) USE OF AFFILIATION PERIOD BY HMOS AS ALTERNATIVE TO PREEXISTING CONDITION EXCLUSION.—

(1) IN GENERAL.—A health maintenance organization which offers health insurance coverage in connection with a group health plan and which does not impose any preexisting condition exclusion allowed under subsection (a) with respect

to any particular coverage option may impose an affiliation period for such coverage option, but only if—

(A) such period is applied uniformly without regard to any health status-related factors; and

(B) such period does not exceed 2 months (or 3 months in the case of a late enrollee).

(2) AFFILIATION PERIOD.—

(A) DEFINED.—For purposes of this title, the term "affiliation period" means a period which, under the terms of the health insurance coverage offered by the health maintenance organization, must expire before the health insurance coverage becomes effective. The organization is not required to provide health care services or benefits during such period and no premium shall be charged to the participant or beneficiary for any coverage during the period.

(B) BEGINNING.—Such period shall begin on the enrollment date.

(C) RUNS CONCURRENTLY WITH WAITING PERIODS.—An affiliation period under a plan shall run concurrently with any waiting period under the plan.

(3) ALTERNATIVE METHODS.—A health maintenance organization described in paragraph (1) may use alternative methods, from those described in such paragraph, to address adverse selection as approved by the State insurance commissioner or official or officials designated by the State to enforce the requirements of this part for the State involved with respect to such issuer.

SEC. 2702.[300gg–1] PROHIBITING DISCRIMINATION AGAINST INDIVIDUAL PARTICIPANTS AND BENEFICIARIES BASED ON HEALTH STATUS.

(a) IN ELIGIBILITY TO ENROLL.—

(1) IN GENERAL.—Subject to paragraph (2), a group health plan, and a health insurance issuer offering group health insurance coverage in connection with a group health plan, may not establish rules for eligibility (including continued eligibility) of any individual to enroll under the terms of the plan based on any of the following health status-related factors in relation to the individual or a dependent of the individual:

(A) Health status.

(B) Medical condition (including both physical and mental illnesses).

(C) Claims experience.

(D) Receipt of health care.

(E) Medical history.

(F) Genetic information.

(G) Evidence of insurability (including conditions arising out of acts of domestic violence).

(H) Disability.

(2) NO APPLICATION TO BENEFITS OR EXCLUSIONS.—To the extent consistent with section 701, paragraph (1) shall not be construed—

(A) to require a group health plan, or group health insurance coverage, to provide particular benefits other than

those provided under the terms of such plan or coverage, or

(B) to prevent such a plan or coverage from establishing limitations or restrictions on the amount, level, extent, or nature of the benefits or coverage for similarly situated individuals enrolled in the plan or coverage.

(3) CONSTRUCTION.—For purposes of paragraph (1), rules for eligibility to enroll under a plan include rules defining any applicable waiting periods for such enrollment.

(b) IN PREMIUM CONTRIBUTIONS.—

(1) IN GENERAL.—A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, may not require any individual (as a condition of enrollment or continued enrollment under the plan) to pay a premium or contribution which is greater than such premium or contribution for a similarly situated individual enrolled in the plan on the basis of any health status-related factor in relation to the individual or to an individual enrolled under the plan as a dependent of the individual.

(2) CONSTRUCTION.—Nothing in paragraph (1) shall be construed—

(A) to restrict the amount that an employer may be charged for coverage under a group health plan except as provided in paragraph (3); or

(B) to prevent a group health plan, and a health insurance issuer offering group health insurance coverage, from establishing premium discounts or rebates or modifying otherwise applicable copayments or deductibles in return for adherence to programs of health promotion and disease prevention.

(3) NO GROUP-BASED DISCRIMINATION ON BASIS OF GENETIC INFORMATION.—

(A) IN GENERAL.—For purposes of this section, a group health plan, and health insurance issuer offering group health insurance coverage in connection with a group health plan, may not adjust premium or contribution amounts for the group covered under such plan on the basis of genetic information.

(B) RULE OF CONSTRUCTION.—Nothing in subparagraph (A) or in paragraphs (1) and (2) of subsection (d) shall be construed to limit the ability of a health insurance issuer offering health insurance coverage in connection with a group health plan to increase the premium for an employer based on the manifestation of a disease or disorder of an individual who is enrolled in the plan. In such case, the manifestation of a disease or disorder in one individual cannot also be used as genetic information about other group members and to further increase the premium for the employer.

(c) GENETIC TESTING.—

(1) LIMITATION ON REQUESTING OR REQUIRING GENETIC TESTING.—A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group

health plan, shall not request or require an individual or a family member of such individual to undergo a genetic test.

(2) RULE OF CONSTRUCTION.—Paragraph (1) shall not be construed to limit the authority of a health care professional who is providing health care services to an individual to request that such individual undergo a genetic test.

(3) RULE OF CONSTRUCTION REGARDING PAYMENT.—

(A) IN GENERAL.—Nothing in paragraph (1) shall be construed to preclude a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, from obtaining and using the results of a genetic test in making a determination regarding payment (as such term is defined for the purposes of applying the regulations promulgated by the Secretary under part C of title XI of the Social Security Act and section 264 of the Health Insurance Portability and Accountability Act of 1996, as may be revised from time to time) consistent with subsection (a).

(B) LIMITATION.—For purposes of subparagraph (A), a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, may request only the minimum amount of information necessary to accomplish the intended purpose.

(4) RESEARCH EXCEPTION.—Notwithstanding paragraph (1), a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, may request, but not require, that a participant or beneficiary undergo a genetic test if each of the following conditions is met:

(A) The request is made pursuant to research that complies with part 46 of title 45, Code of Federal Regulations, or equivalent Federal regulations, and any applicable State or local law or regulations for the protection of human subjects in research.

(B) The plan or issuer clearly indicates to each participant or beneficiary, or in the case of a minor child, to the legal guardian of such beneficiary, to whom the request is made that—

(i) compliance with the request is voluntary; and

(ii) non-compliance will have no effect on enrollment status or premium or contribution amounts.

(C) No genetic information collected or acquired under this paragraph shall be used for underwriting purposes.

(D) The plan or issuer notifies the Secretary in writing that the plan or issuer is conducting activities pursuant to the exception provided for under this paragraph, including a description of the activities conducted.

(E) The plan or issuer complies with such other conditions as the Secretary may by regulation require for activities conducted under this paragraph.

(d) PROHIBITION ON COLLECTION OF GENETIC INFORMATION.—

(1) IN GENERAL.—A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, shall not request, require, or pur-

chase genetic information for underwriting purposes (as defined in section 2791).

(2) PROHIBITION ON COLLECTION OF GENETIC INFORMATION PRIOR TO ENROLLMENT.—A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, shall not request, require, or purchase genetic information with respect to any individual prior to such individual's enrollment under the plan or coverage in connection with such enrollment.

(3) INCIDENTAL COLLECTION.—If a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, obtains genetic information incidental to the requesting, requiring, or purchasing of other information concerning any individual, such request, requirement, or purchase shall not be considered a violation of paragraph (2) if such request, requirement, or purchase is not in violation of paragraph (1).

(e) APPLICATION TO ALL PLANS.—The provisions of subsections (a)(1)(F), (b)(3), (c), and (d) and subsection (b)(1) and section 2701 with respect to genetic information, shall apply to group health plans and health insurance issuers without regard to section 2721(a).

(f) GENETIC INFORMATION OF A FETUS OR EMBRYO.—Any reference in this part to genetic information concerning an individual or family member of an individual shall—

(1) with respect to such an individual or family member of an individual who is a pregnant woman, include genetic information of any fetus carried by such pregnant woman; and

(2) with respect to an individual or family member utilizing an assisted reproductive technology, include genetic information of any embryo legally held by the individual or family member.

Subpart II—Improving Coverage

SEC. 2711.[300gg–11] NO LIFETIME OR ANNUAL LIMITS.

(a) PROHIBITION.—

(1) IN GENERAL.—A group health plan and a health insurance issuer offering group or individual health insurance coverage may not establish—

(A) lifetime limits on the dollar value of benefits for any participant or beneficiary; or

(B) except as provided in paragraph (2), annual limits on the dollar value of benefits for any participant or beneficiary.

(2) ANNUAL LIMITS PRIOR TO 2014.—With respect to plan years beginning prior to January 1, 2014, a group health plan and a health insurance issuer offering group or individual health insurance coverage may only establish a restricted annual limit on the dollar value of benefits for any participant or beneficiary with respect to the scope of benefits that are essential health benefits under section 1302(b) of the Patient Protection and Affordable Care Act, as determined by the Secretary. In defining the term "restricted annual limit" for purposes of

the preceding sentence, the Secretary shall ensure that access to needed services is made available with a minimal impact on premiums.

(b) PER BENEFICIARY LIMITS.—Subsection (a) shall not be construed to prevent a group health plan or health insurance coverage from placing annual or lifetime per beneficiary limits on specific covered benefits that are not essential health benefits under section 1302(b) of the Patient Protection and Affordable Care Act, to the extent that such limits are otherwise permitted under Federal or State law.

SEC. 2712.[300gg–12] PROHIBITION ON RESCISSIONS.

A group health plan and a health insurance issuer offering group or individual health insurance coverage shall not rescind such plan or coverage with respect to an enrollee once the enrollee is covered under such plan or coverage involved, except that this section shall not apply to a covered individual who has performed an act or practice that constitutes fraud or makes an intentional misrepresentation of material fact as prohibited by the terms of the plan or coverage. Such plan or coverage may not be cancelled except with prior notice to the enrollee, and only as permitted under section 2702(c) or 2742(b).

SEC. 2713.[300gg–13] COVERAGE OF PREVENTIVE HEALTH SERVICES.

(a) IN GENERAL.—A group health plan and a health insurance issuer offering group or individual health insurance coverage shall, at a minimum provide coverage for and shall not impose any cost sharing requirements for—

(1) evidence-based items or services that have in effect a rating of "A" or "B" in the current recommendations of the United States Preventive Services Task Force;

(2) immunizations that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved; and

(3) with respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in the comprehensive guidelines supported by the Health Resources and Services Administration.

(4) with respect to women, such additional preventive care and screenings not described in paragraph (1) as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of this paragraph.

(5) for the purposes of this Act, and for the purposes of any other provision of law, the current recommendations of the United States Preventive Service Task Force regarding breast cancer screening, mammography, and prevention shall be considered the most current other than those issued in or around November 2009.

Nothing in this subsection shall be construed to prohibit a plan or issuer from providing coverage for services in addition to those recommended by United States Preventive Services Task Force or to deny coverage for services that are not recommended by such Task Force.

(b) INTERVAL.—

(1) IN GENERAL.—The Secretary shall establish a minimum interval between the date on which a recommendation described in subsection (a)(1) or (a)(2) or a guideline under subsection (a)(3) is issued and the plan year with respect to which the requirement described in subsection (a) is effective with respect to the service described in such recommendation or guideline.

(2) MINIMUM.—The interval described in paragraph (1) shall not be less than 1 year.

(c) VALUE-BASED INSURANCE DESIGN.—The Secretary may develop guidelines to permit a group health plan and a health insurance issuer offering group or individual health insurance coverage to utilize value-based insurance designs.

SEC. 2714.[300gg–14] EXTENSION OF DEPENDENT COVERAGE.

(a) IN GENERAL.—A group health plan and a health insurance issuer offering group or individual health insurance coverage that provides dependent coverage of children shall continue to make such coverage available for an adult child until the child turns 26 years of age. Nothing in this section shall require a health plan or a health insurance issuer described in the preceding sentence to make coverage available for a child of a child receiving dependent coverage.

(b) REGULATIONS.—The Secretary shall promulgate regulations to define the dependents to which coverage shall be made available under subsection (a).

(c) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to modify the definition of "dependent" as used in the Internal Revenue Code of 1986 with respect to the tax treatment of the cost of coverage.

SEC. 2715.[300gg–15] DEVELOPMENT AND UTILIZATION OF UNIFORM EXPLANATION OF COVERAGE DOCUMENTS AND STANDARDIZED DEFINITIONS.

(a) IN GENERAL.—Not later than 12 months after the date of enactment of the Patient Protection and Affordable Care Act, the Secretary shall develop standards for use by a group health plan and a health insurance issuer offering group or individual health insurance coverage, in compiling and providing to applicants, enrollees, and policyholders or certificate holders a summary of benefits and coverage explanation that accurately describes the benefits and coverage under the applicable plan or coverage. In developing such standards, the Secretary shall consult with the National Association of Insurance Commissioners (referred to in this section as the "NAIC"), a working group composed of representatives of health insurance-related consumer advocacy organizations, health insurance issuers, health care professionals, patient advocates including those representing individuals with limited English proficiency, and other qualified individuals.

(b) REQUIREMENTS.—The standards for the summary of benefits and coverage developed under subsection (a) shall provide for the following:

(1) APPEARANCE.—The standards shall ensure that the summary of benefits and coverage is presented in a uniform

format that does not exceed 4 pages in length and does not include print smaller than 12-point font.

(2) LANGUAGE.—The standards shall ensure that the summary is presented in a culturally and linguistically appropriate manner and utilizes terminology understandable by the average plan enrollee.

(3) CONTENTS.—The standards shall ensure that the summary of benefits and coverage includes—

(A) uniform definitions of standard insurance terms and medical terms (consistent with subsection (g)) so that consumers may compare health insurance coverage and understand the terms of coverage (or exception to such coverage);

(B) a description of the coverage, including cost sharing for—

(i) each of the categories of the essential health benefits described in subparagraphs (A) through (J) of section 1302(b)(1) of the Patient Protection and Affordable Care Act; and

(ii) other benefits, as identified by the Secretary;

(C) the exceptions, reductions, and limitations on coverage;

(D) the cost-sharing provisions, including deductible, coinsurance, and co-payment obligations;

(E) the renewability and continuation of coverage provisions;

(F) a coverage facts label that includes examples to illustrate common benefits scenarios, including pregnancy and serious or chronic medical conditions and related cost sharing, such scenarios to be based on recognized clinical practice guidelines;

(G) a statement of whether the plan or coverage—

(i) provides minimum essential coverage (as defined under section 5000A(f) of the Internal Revenue Code 1986); and

(ii) ensures that the plan or coverage share of the total allowed costs of benefits provided under the plan or coverage is not less than 60 percent of such costs;

(H) a statement that the outline is a summary of the policy or certificate and that the coverage document itself should be consulted to determine the governing contractual provisions; and

(I) a contact number for the consumer to call with additional questions and an Internet web address where a copy of the actual individual coverage policy or group certificate of coverage can be reviewed and obtained.

(c) PERIODIC REVIEW AND UPDATING.—The Secretary shall periodically review and update, as appropriate, the standards developed under this section.

(d) REQUIREMENT TO PROVIDE.—

(1) IN GENERAL.—Not later than 24 months after the date of enactment of the Patient Protection and Affordable Care Act, each entity described in paragraph (3) shall provide, prior to any enrollment restriction, a summary of benefits and cov-

erage explanation pursuant to the standards developed by the Secretary under subsection (a) to—

(A) an applicant at the time of application;

(B) an enrollee prior to the time of enrollment or re-enrollment, as applicable; and

(C) a policyholder or certificate holder at the time of issuance of the policy or delivery of the certificate.

(2) COMPLIANCE.—An entity described in paragraph (3) is deemed to be in compliance with this section if the summary of benefits and coverage described in subsection (a) is provided in paper or electronic form.

(3) ENTITIES IN GENERAL.—An entity described in this paragraph is—

(A) a health insurance issuer (including a group health plan that is not a self-insured plan) offering health insurance coverage within the United States; or

(B) in the case of a self-insured group health plan, the plan sponsor or designated administrator of the plan (as such terms are defined in section 3(16) of the Employee Retirement Income Security Act of 1974).

(4) NOTICE OF MODIFICATIONS.—If a group health plan or health insurance issuer makes any material modification in any of the terms of the plan or coverage involved (as defined for purposes of section 102 of the Employee Retirement Income Security Act of 1974) that is not reflected in the most recently provided summary of benefits and coverage, the plan or issuer shall provide notice of such modification to enrollees not later than 60 days prior to the date on which such modification will become effective.

(e) PREEMPTION.—The standards developed under subsection (a) shall preempt any related State standards that require a summary of benefits and coverage that provides less information to consumers than that required to be provided under this section, as determined by the Secretary.

(f) FAILURE TO PROVIDE.—An entity described in subsection (d)(3) that willfully fails to provide the information required under this section shall be subject to a fine of not more than $1,000 for each such failure. Such failure with respect to each enrollee shall constitute a separate offense for purposes of this subsection.

(g) DEVELOPMENT OF STANDARD DEFINITIONS.—

(1) IN GENERAL.—The Secretary shall, by regulation, provide for the development of standards for the definitions of terms used in health insurance coverage, including the insurance-related terms described in paragraph (2) and the medical terms described in paragraph (3).

(2) INSURANCE-RELATED TERMS.—The insurance-related terms described in this paragraph are premium, deductible, co-insurance, co-payment, out-of-pocket limit, preferred provider, non-preferred provider, out-of-network co-payments, UCR (usual, customary and reasonable) fees, excluded services, grievance and appeals, and such other terms as the Secretary determines are important to define so that consumers may compare health insurance coverage and understand the terms of their coverage.

(3) MEDICAL TERMS.—The medical terms described in this paragraph are hospitalization, hospital outpatient care, emergency room care, physician services, prescription drug coverage, durable medical equipment, home health care, skilled nursing care, rehabilitation services, hospice services, emergency medical transportation, and such other terms as the Secretary determines are important to define so that consumers may compare the medical benefits offered by health insurance and understand the extent of those medical benefits (or exceptions to those benefits).

SEC. 2715A.[300gg–15a] PROVISION OF ADDITIONAL INFORMATION.

A group health plan and a health insurance issuer offering group or individual health insurance coverage shall comply with the provisions of section 1311(e)(3) of the Patient Protection and Affordable Care Act, except that a plan or coverage that is not offered through an Exchange shall only be required to submit the information required to the Secretary and the State insurance commissioner, and make such information available to the public.

SEC. 2716.[300gg–16] PROHIBITION ON DISCRIMINATION IN FAVOR OF HIGHLY COMPENSATED INDIVIDUALS.

(a) IN GENERAL.—A group health plan (other than a self-insured plan) shall satisfy the requirements of section 105(h)(2) of the Internal Revenue Code of 1986 (relating to prohibition on discrimination in favor of highly compensated individuals).

(b) RULES AND DEFINITIONS.—For purposes of this section—

(1) CERTAIN RULES TO APPLY.—Rules similar to the rules contained in paragraphs (3), (4), and (8) of section 105(h) of such Code shall apply.

(2) HIGHLY COMPENSATED INDIVIDUAL.—The term "highly compensated individual" has the meaning given such term by section 105(h)(5) of such Code.

SEC. 2717.[300gg–17] ENSURING THE QUALITY OF CARE.

(a) QUALITY REPORTING.—

(1) IN GENERAL.—Not later than 2 years after the date of enactment of the Patient Protection and Affordable Care Act, the Secretary, in consultation with experts in health care quality and stakeholders, shall develop reporting requirements for use by a group health plan, and a health insurance issuer offering group or individual health insurance coverage, with respect to plan or coverage benefits and health care provider reimbursement structures that—

(A) improve health outcomes through the implementation of activities such as quality reporting, effective case management, care coordination, chronic disease management, and medication and care compliance initiatives, including through the use of the medical homes model as defined for purposes of section 3602 of the Patient Protection and Affordable Care Act, for treatment or services under the plan or coverage;

(B) implement activities to prevent hospital readmissions through a comprehensive program for hospital discharge that includes patient-centered education and counseling, comprehensive discharge planning, and post dis-

charge reinforcement by an appropriate health care professional;

(C) implement activities to improve patient safety and reduce medical errors through the appropriate use of best clinical practices, evidence based medicine, and health information technology under the plan or coverage; and

(D) implement wellness and health promotion activities.

(2) REPORTING REQUIREMENTS.—

(A) IN GENERAL.—A group health plan and a health insurance issuer offering group or individual health insurance coverage shall annually submit to the Secretary, and to enrollees under the plan or coverage, a report on whether the benefits under the plan or coverage satisfy the elements described in subparagraphs (A) through (D) of paragraph (1).

(B) TIMING OF REPORTS.—A report under subparagraph (A) shall be made available to an enrollee under the plan or coverage during each open enrollment period.

(C) AVAILABILITY OF REPORTS.—The Secretary shall make reports submitted under subparagraph (A) available to the public through an Internet website.

(D) PENALTIES.—In developing the reporting requirements under paragraph (1), the Secretary may develop and impose appropriate penalties for non-compliance with such requirements.

(E) EXCEPTIONS.—In developing the reporting requirements under paragraph (1), the Secretary may provide for exceptions to such requirements for group health plans and health insurance issuers that substantially meet the goals of this section.

(b) WELLNESS AND PREVENTION PROGRAMS.—For purposes of subsection (a)(1)(D), wellness and health promotion activities may include personalized wellness and prevention services, which are coordinated, maintained or delivered by a health care provider, a wellness and prevention plan manager, or a health, wellness or prevention services organization that conducts health risk assessments or offers ongoing face-to-face, telephonic or web-based intervention efforts for each of the program's participants, and which may include the following wellness and prevention efforts:

(1) Smoking cessation.

(2) Weight management.

(3) Stress management.

(4) Physical fitness.

(5) Nutrition.

(6) Heart disease prevention.

(7) Healthy lifestyle support.

(8) Diabetes prevention.

(c) PROTECTION OF SECOND AMENDMENT GUN RIGHTS.—

(1) WELLNESS AND PREVENTION PROGRAMS.—A wellness and health promotion activity implemented under subsection (a)(1)(D) may not require the disclosure or collection of any information relating to—

(A) the presence or storage of a lawfully-possessed firearm or ammunition in the residence or on the property of an individual; or

(B) the lawful use, possession, or storage of a firearm or ammunition by an individual.

(2) LIMITATION ON DATA COLLECTION.—None of the authorities provided to the Secretary under the Patient Protection and Affordable Care Act or an amendment made by that Act shall be construed to authorize or may be used for the collection of any information relating to—

(A) the lawful ownership or possession of a firearm or ammunition;

(B) the lawful use of a firearm or ammunition; or

(C) the lawful storage of a firearm or ammunition.

(3) LIMITATION ON DATABASES OR DATA BANKS.—None of the authorities provided to the Secretary under the Patient Protection and Affordable Care Act or an amendment made by that Act shall be construed to authorize or may be used to maintain records of individual ownership or possession of a firearm or ammunition.

(4) LIMITATION ON DETERMINATION OF PREMIUM RATES OR ELIGIBILITY FOR HEALTH INSURANCE.—A premium rate may not be increased, health insurance coverage may not be denied, and a discount, rebate, or reward offered for participation in a wellness program may not be reduced or withheld under any health benefit plan issued pursuant to or in accordance with the Patient Protection and Affordable Care Act or an amendment made by that Act on the basis of, or on reliance upon—

(A) the lawful ownership or possession of a firearm or ammunition; or

(B) the lawful use or storage of a firearm or ammunition.

(5) LIMITATION ON DATA COLLECTION REQUIREMENTS FOR INDIVIDUALS.—No individual shall be required to disclose any information under any data collection activity authorized under the Patient Protection and Affordable Care Act or an amendment made by that Act relating to—

(A) the lawful ownership or possession of a firearm or ammunition; or

(B) the lawful use, possession, or storage of a firearm or ammunition.

(d) REGULATIONS.—Not later than 2 years after the date of enactment of the Patient Protection and Affordable Care Act, the Secretary shall promulgate regulations that provide criteria for determining whether a reimbursement structure is described in subsection (a).

(e) STUDY AND REPORT.—Not later than 180 days after the date on which regulations are promulgated under subsection (c), the Government Accountability Office shall review such regulations and conduct a study and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report regarding the impact the activities under this section have had on the quality and cost of health care.

SEC. 2718.[300gg–18] BRINGING DOWN THE COST OF HEALTH CARE COVERAGE.

(a) CLEAR ACCOUNTING FOR COSTS.—A health insurance issuer offering group or individual health insurance coverage (including a grandfathered health plan) shall, with respect to each plan year, submit to the Secretary a report concerning the ratio of the incurred loss (or incurred claims) plus the loss adjustment expense (or change in contract reserves) to earned premiums. Such report shall include the percentage of total premium revenue, after accounting for collections or receipts for risk adjustment and risk corridors and payments of reinsurance, that such coverage expends—

(1) on reimbursement for clinical services provided to enrollees under such coverage;

(2) for activities that improve health care quality; and

(3) on all other non-claims costs, including an explanation of the nature of such costs, and excluding Federal and State taxes and licensing or regulatory fees.

The Secretary shall make reports received under this section available to the public on the Internet website of the Department of Health and Human Services.

(b) ENSURING THAT CONSUMERS RECEIVE VALUE FOR THEIR PREMIUM PAYMENTS.—

(1) REQUIREMENT TO PROVIDE VALUE FOR PREMIUM PAYMENTS.—

(A) REQUIREMENT.—Beginning not later than January 1, 2011, a health insurance issuer offering group or individual health insurance coverage (including a grandfathered health plan) shall, with respect to each plan year, provide an annual rebate to each enrollee under such coverage, on a pro rata basis, if the ratio of the amount of premium revenue expended by the issuer on costs described in paragraphs (1) and (2) of subsection (a) to the total amount of premium revenue (excluding Federal and State taxes and licensing or regulatory fees and after accounting for payments or receipts for risk adjustment, risk corridors, and reinsurance under sections 1341, 1342, and 1343 of the Patient Protection and Affordable Care Act) for the plan year (except as provided in subparagraph (B)(ii)), is less than—

(i) with respect to a health insurance issuer offering coverage in the large group market, 85 percent, or such higher percentage as a State may by regulation determine; or

(ii) with respect to a health insurance issuer offering coverage in the small group market or in the individual market, 80 percent, or such higher percentage as a State may by regulation determine, except that the Secretary may adjust such percentage with respect to a State if the Secretary determines that the application of such 80 percent may destabilize the individual market in such State.

(B) REBATE AMOUNT.—

(i) CALCULATION OF AMOUNT.—The total amount of an annual rebate required under this paragraph shall be in an amount equal to the product of—

(I) the amount by which the percentage described in clause (i) or (ii) of subparagraph (A) exceeds the ratio described in such subparagraph; and

(II) the total amount of premium revenue (excluding Federal and State taxes and licensing or regulatory fees and after accounting for payments or receipts for risk adjustment, risk corridors, and reinsurance under sections 1341, 1342, and 1343 of the Patient Protection and Affordable Care Act) for such plan year.

(ii) CALCULATION BASED ON AVERAGE RATIO.—Beginning on January 1, 2014, the determination made under subparagraph (A) for the year involved shall be based on the averages of the premiums expended on the costs described in such subparagraph and total premium revenue for each of the previous 3 years for the plan.

(2) CONSIDERATION IN SETTING PERCENTAGES.—In determining the percentages under paragraph (1), a State shall seek to ensure adequate participation by health insurance issuers, competition in the health insurance market in the State, and value for consumers so that premiums are used for clinical services and quality improvements.

(3) ENFORCEMENT.—The Secretary shall promulgate regulations for enforcing the provisions of this section and may provide for appropriate penalties.

(c) DEFINITIONS.—Not later than December 31, 2010, and subject to the certification of the Secretary, the National Association of Insurance Commissioners shall establish uniform definitions of the activities reported under subsection (a) and standardized methodologies for calculating measures of such activities, including definitions of which activities, and in what regard such activities, constitute activities described in subsection (a)(2). Such methodologies shall be designed to take into account the special circumstances of smaller plans, different types of plans, and newer plans.

(d) ADJUSTMENTS.—The Secretary may adjust the rates described in subsection (b) if the Secretary determines appropriate on account of the volatility of the individual market due to the establishment of State Exchanges.

(e) STANDARD HOSPITAL CHARGES.—Each hospital operating within the United States shall for each year establish (and update) and make public (in accordance with guidelines developed by the Secretary) a list of the hospital's standard charges for items and services provided by the hospital, including for diagnosis-related groups established under section 1886(d)(4) of the Social Security Act.

SEC. 2719.[300gg–19] APPEALS PROCESS.

(a) INTERNAL CLAIMS APPEALS.—

(1) IN GENERAL.—A group health plan and a health insurance issuer offering group or individual health insurance coverage shall implement an effective appeals process for appeals of coverage determinations and claims, under which the plan or issuer shall, at a minimum—

(A) have in effect an internal claims appeal process;

(B) provide notice to enrollees, in a culturally and linguistically appropriate manner, of available internal and external appeals processes, and the availability of any applicable office of health insurance consumer assistance or ombudsman established under section 2793 to assist such enrollees with the appeals processes; and

(C) allow an enrollee to review their file, to present evidence and testimony as part of the appeals process, and to receive continued coverage pending the outcome of the appeals process.

(2) ESTABLISHED PROCESSES.—To comply with paragraph (1)—

(A) a group health plan and a health insurance issuer offering group health coverage shall provide an internal claims and appeals process that initially incorporates the claims and appeals procedures (including urgent claims) set forth at section 2560.503–1 of title 29, Code of Federal Regulations, as published on November 21, 2000 (65 Fed. Reg. 70256), and shall update such process in accordance with any standards established by the Secretary of Labor for such plans and issuers; and

(B) a health insurance issuer offering individual health coverage, and any other issuer not subject to subparagraph (A), shall provide an internal claims and appeals process that initially incorporates the claims and appeals procedures set forth under applicable law (as in existence on the date of enactment of this section), and shall update such process in accordance with any standards established by the Secretary of Health and Human Services for such issuers.

(b) EXTERNAL REVIEW.—A group health plan and a health insurance issuer offering group or individual health insurance coverage—

(1) shall comply with the applicable State external review process for such plans and issuers that, at a minimum, includes the consumer protections set forth in the Uniform External Review Model Act promulgated by the National Association of Insurance Commissioners and is binding on such plans; or

(2) shall implement an effective external review process that meets minimum standards established by the Secretary through guidance and that is similar to the process described under paragraph (1)—

(A) if the applicable State has not established an external review process that meets the requirements of paragraph (1); or

(B) if the plan is a self-insured plan that is not subject to State insurance regulation (including a State law that

establishes an external review process described in paragraph (1)).

(c) SECRETARY AUTHORITY.—The Secretary may deem the external review process of a group health plan or health insurance issuer, in operation as of the date of enactment of this section, to be in compliance with the applicable process established under subsection (b), as determined appropriate by the Secretary.

SEC. 2719A.[300gg–19a] PATIENT PROTECTIONS.

(a) CHOICE OF HEALTH CARE PROFESSIONAL.—If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, requires or provides for designation by a participant, beneficiary, or enrollee of a participating primary care provider, then the plan or issuer shall permit each participant, beneficiary, and enrollee to designate any participating primary care provider who is available to accept such individual.

(b) COVERAGE OF EMERGENCY SERVICES.—

(1) IN GENERAL.—If a group health plan, or a health insurance issuer offering group or individual health insurance issuer, provides or covers any benefits with respect to services in an emergency department of a hospital, the plan or issuer shall cover emergency services (as defined in paragraph (2)(B))—

(A) without the need for any prior authorization determination;

(B) whether the health care provider furnishing such services is a participating provider with respect to such services;

(C) in a manner so that, if such services are provided to a participant, beneficiary, or enrollee—

(i) by a nonparticipating health care provider with or without prior authorization; or

(ii)(I) such services will be provided without imposing any requirement under the plan for prior authorization of services or any limitation on coverage where the provider of services does not have a contractual relationship with the plan for the providing of services that is more restrictive than the requirements or limitations that apply to emergency department services received from providers who do have such a contractual relationship with the plan; and

(II) if such services are provided out-of-network, the cost-sharing requirement (expressed as a copayment amount or coinsurance rate) is the same requirement that would apply if such services were provided in-network;

(D) without regard to any other term or condition of such coverage (other than exclusion or coordination of benefits, or an affiliation or waiting period, permitted under section 2701 of this Act, section 701 of the Employee Retirement Income Security Act of 1974, or section 9801 of the Internal Revenue Code of 1986, and other than applicable cost-sharing).

(2) DEFINITIONS.—In this subsection:

(A) EMERGENCY MEDICAL CONDITION.—The term "emergency medical condition" means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act.

(B) EMERGENCY SERVICES.—The term "emergency services" means, with respect to an emergency medical condition—

(i) a medical screening examination (as required under section 1867 of the Social Security Act) that is within the capability of the emergency department of a hospital, including ancillary services routinely available to the emergency department to evaluate such emergency medical condition, and

(ii) within the capabilities of the staff and facilities available at the hospital, such further medical examination and treatment as are required under section 1867 of such Act to stabilize the patient.

(C) STABILIZE.—The term "to stabilize", with respect to an emergency medical condition (as defined in subparagraph (A)), has the meaning give in section 1867(e)(3) of the Social Security Act (42 U.S.C. 1395dd(e)(3)).

(c) ACCESS TO PEDIATRIC CARE.—

(1) PEDIATRIC CARE.—In the case of a person who has a child who is a participant, beneficiary, or enrollee under a group health plan, or health insurance coverage offered by a health insurance issuer in the group or individual market, if the plan or issuer requires or provides for the designation of a participating primary care provider for the child, the plan or issuer shall permit such person to designate a physician (allopathic or osteopathic) who specializes in pediatrics as the child's primary care provider if such provider participates in the network of the plan or issuer.

(2) CONSTRUCTION.—Nothing in paragraph (1) shall be construed to waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of pediatric care.

(d) PATIENT ACCESS TO OBSTETRICAL AND GYNECOLOGICAL CARE.—

(1) GENERAL RIGHTS.—

(A) DIRECT ACCESS.—A group health plan, or health insurance issuer offering group or individual health insurance coverage, described in paragraph (2) may not require authorization or referral by the plan, issuer, or any person (including a primary care provider described in paragraph (2)(B)) in the case of a female participant, beneficiary, or enrollee who seeks coverage for obstetrical or gynecological care provided by a participating health care professional who specializes in obstetrics or gynecology. Such professional shall agree to otherwise adhere to such plan's or

issuer's policies and procedures, including procedures regarding referrals and obtaining prior authorization and providing services pursuant to a treatment plan (if any) approved by the plan or issuer.

(B) OBSTETRICAL AND GYNECOLOGICAL CARE.—A group health plan or health insurance issuer described in paragraph (2) shall treat the provision of obstetrical and gynecological care, and the ordering of related obstetrical and gynecological items and services, pursuant to the direct access described under subparagraph (A), by a participating health care professional who specializes in obstetrics or gynecology as the authorization of the primary care provider.

(2) APPLICATION OF PARAGRAPH.—A group health plan, or health insurance issuer offering group or individual health insurance coverage, described in this paragraph is a group health plan or coverage that—

(A) provides coverage for obstetric or gynecologic care; and

(B) requires the designation by a participant, beneficiary, or enrollee of a participating primary care provider.

(3) CONSTRUCTION.—Nothing in paragraph (1) shall be construed to—

(A) waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of obstetrical or gynecological care; or

(B) preclude the group health plan or health insurance issuer involved from requiring that the obstetrical or gynecological provider notify the primary care health care professional or the plan or issuer of treatment decisions.

Subpart 2—Other Requirements [1]

SEC. 2725.[300gg–4] STANDARDS RELATING TO BENEFITS FOR MOTHERS AND NEWBORNS.

(a) REQUIREMENTS FOR MINIMUM HOSPITAL STAY FOLLOWING BIRTH.—

(1) IN GENERAL.—A group health plan, and a health insurance issuer offering group health insurance coverage, may not—

(A) except as provided in paragraph (2)—

(i) restrict benefits for any hospital length of stay in connection with childbirth for the mother or newborn child, following a normal vaginal delivery, to less than 48 hours, or

(ii) restrict benefits for any hospital length of stay in connection with childbirth for the mother or newborn child, following a cesarean section, to less than 96 hours, or

[1] Effective January 1, 2014, the probable intent of Congress is to strike both the subpart designation and heading, but the amendment by section 1563 (relating to conforming amendments--originally designated as section 1562 and redesignated as section 1563 by section 10107(b)(1)) of Public Law 111–148, strikes only the "second heading".

(B) require that a provider obtain authorization from the plan or the issuer for prescribing any length of stay required under subparagraph (A) (without regard to paragraph (2)).

(2) EXCEPTION.—Paragraph (1)(A) shall not apply in connection with any group health plan or health insurance issuer in any case in which the decision to discharge the mother or her newborn child prior to the expiration of the minimum length of stay otherwise required under paragraph (1)(A) is made by an attending provider in consultation with the mother.

(b) PROHIBITIONS.—A group health plan, and a health insurance issuer offering group health insurance coverage in connection with a group health plan, may not—

(1) deny to the mother or her newborn child eligibility, or continued eligibility, to enroll or to renew coverage under the terms of the plan, solely for the purpose of avoiding the requirements of this section;

(2) provide monetary payments or rebates to mothers to encourage such mothers to accept less than the minimum protections available under this section;

(3) penalize or otherwise reduce or limit the reimbursement of an attending provider because such provider provided care to an individual participant or beneficiary in accordance with this section;

(4) provide incentives (monetary or otherwise) to an attending provider to induce such provider to provide care to an individual participant or beneficiary in a manner inconsistent with this section; or

(5) subject to subsection (c)(3), restrict benefits for any portion of a period within a hospital length of stay required under subsection (a) in a manner which is less favorable than the benefits provided for any preceding portion of such stay.

(c) RULES OF CONSTRUCTION.—

(1) Nothing in this section shall be construed to require a mother who is a participant or beneficiary—

(A) to give birth in a hospital; or

(B) to stay in the hospital for a fixed period of time following the birth of her child.

(2) This section shall not apply with respect to any group health plan, or any group health insurance coverage offered by a health insurance issuer, which does not provide benefits for hospital lengths of stay in connection with childbirth for a mother or her newborn child.

(3) Nothing in this section shall be construed as preventing a group health plan or issuer from imposing deductibles, coinsurance, or other cost-sharing in relation to benefits for hospital lengths of stay in connection with childbirth for a mother or newborn child under the plan (or under health insurance coverage offered in connection with a group health plan), except that such coinsurance or other cost-sharing for any portion of a period within a hospital length of stay required under subsection (a) may not be greater than such coinsurance or cost-sharing for any preceding portion of such stay.

(d) NOTICE.—A group health plan under this part shall comply with the notice requirement under section 711(d) of the Employee Retirement Income Security Act of 1974 with respect to the requirements of this section as if such section applied to such plan.

(e) LEVEL AND TYPE OF REIMBURSEMENTS.—Nothing in this section shall be construed to prevent a group health plan or a health insurance issuer offering group health insurance coverage from negotiating the level and type of reimbursement with a provider for care provided in accordance with this section.

(f) PREEMPTION; EXCEPTION FOR HEALTH INSURANCE COVERAGE IN CERTAIN STATES.—

(1) IN GENERAL.—The requirements of this section shall not apply with respect to health insurance coverage if there is a State law (as defined in section 2723(d)(1)) for a State that regulates such coverage that is described in any of the following subparagraphs:

(A) Such State law requires such coverage to provide for at least a 48-hour hospital length of stay following a normal vaginal delivery and at least a 96-hour hospital length of stay following a cesarean section.

(B) Such State law requires such coverage to provide for maternity and pediatric care in accordance with guidelines established by the American College of Obstetricians and Gynecologists, the American Academy of Pediatrics, or other established professional medical associations.

(C) Such State law requires, in connection with such coverage for maternity care, that the hospital length of stay for such care is left to the decision of (or required to be made by) the attending provider in consultation with the mother.

(2) CONSTRUCTION.—Section 2723(a)(1) shall not be construed as superseding a State law described in paragraph (1).

SEC. 2726.[300gg–5] PARITY IN MENTAL HEALTH AND SUBSTANCE USE DISORDER BENEFITS.

(a) IN GENERAL.—

(1) AGGREGATE LIFETIME LIMITS.—In the case of a group health plan (or health insurance coverage offered in connection with such a plan) that provides both medical and surgical benefits and mental health or substance use disorder benefits—

(A) NO LIFETIME LIMIT.—If the plan or coverage does not include an aggregate lifetime limit on substantially all medical and surgical benefits, the plan or coverage may not impose any aggregate lifetime limit on mental health or substance use disorder benefits.

(B) LIFETIME LIMIT.—If the plan or coverage includes an aggregate lifetime limit on substantially all medical and surgical benefits (in this paragraph referred to as the "applicable lifetime limit"), the plan or coverage shall either—

(i) apply the applicable lifetime limit both to the medical and surgical benefits to which it otherwise would apply and to mental health and substance use disorder benefits and not distinguish in the application of such limit between such medical and surgical

benefits and mental health and substance use disorder benefits; or

(ii) not include any aggregate lifetime limit on mental health or substance use disorder benefits that is less than the applicable lifetime limit.

(C) RULE IN CASE OF DIFFERENT LIMITS.—In the case of a plan or coverage that is not described in subparagraph (A) or (B) and that includes no or different aggregate lifetime limits on different categories of medical and surgical benefits, the Secretary shall establish rules under which subparagraph (B) is applied to such plan or coverage with respect to mental health and substance use disorder benefits by substituting for the applicable lifetime limit an average aggregate lifetime limit that is computed taking into account the weighted average of the aggregate lifetime limits applicable to such categories.

(2) ANNUAL LIMITS.—In the case of a group health plan (or health insurance coverage offered in connection with such a plan) that provides both medical and surgical benefits and mental health or substance use disorder benefits—

(A) NO ANNUAL LIMIT.—If the plan or coverage does not include an annual limit on substantially all medical and surgical benefits, the plan or coverage may not impose any annual limit on mental health or substance use disorder benefits.

(B) ANNUAL LIMIT.—If the plan or coverage includes an annual limit on substantially all medical and surgical benefits (in this paragraph referred to as the "applicable annual limit"), the plan or coverage shall either—

(i) apply the applicable annual limit both to medical and surgical benefits to which it otherwise would apply and to mental health and substance use disorder benefits and not distinguish in the application of such limit between such medical and surgical benefits and mental health and substance use disorder benefits; or

(ii) not include any annual limit on mental health or substance use disorder benefits that is less than the applicable annual limit.

(C) RULE IN CASE OF DIFFERENT LIMITS.—In the case of a plan or coverage that is not described in subparagraph (A) or (B) and that includes no or different annual limits on different categories of medical and surgical benefits, the Secretary shall establish rules under which subparagraph (B) is applied to such plan or coverage with respect to mental health and substance use disorder benefits by substituting for the applicable annual limit an average annual limit that is computed taking into account the weighted average of the annual limits applicable to such categories.

(3) FINANCIAL REQUIREMENTS AND TREATMENT LIMITATIONS.—

(A) IN GENERAL.—In the case of a group health plan (or health insurance coverage offered in connection with such a plan) that provides both medical and surgical bene-

fits and mental health or substance use disorder benefits, such plan or coverage shall ensure that—

(i) the financial requirements applicable to such mental health or substance use disorder benefits are no more restrictive than the predominant financial requirements applied to substantially all medical and surgical benefits covered by the plan (or coverage), and there are no separate cost sharing requirements that are applicable only with respect to mental health or substance use disorder benefits; and

(ii) the treatment limitations applicable to such mental health or substance use disorder benefits are no more restrictive than the predominant treatment limitations applied to substantially all medical and surgical benefits covered by the plan (or coverage) and there are no separate treatment limitations that are applicable only with respect to mental health or substance use disorder benefits.

(B) DEFINITIONS.—In this paragraph:

(i) FINANCIAL REQUIREMENT.—The term "financial requirement" includes deductibles, copayments, coinsurance, and out-of-pocket expenses, but excludes an aggregate lifetime limit and an annual limit subject to paragraphs (1) and (2).

(ii) PREDOMINANT.—A financial requirement or treatment limit is considered to be predominant if it is the most common or frequent of such type of limit or requirement.

(iii) TREATMENT LIMITATION.—The term "treatment limitation" includes limits on the frequency of treatment, number of visits, days of coverage, or other similar limits on the scope or duration of treatment.

(4) AVAILABILITY OF PLAN INFORMATION.—The criteria for medical necessity determinations made under the plan with respect to mental health or substance use disorder benefits (or the health insurance coverage offered in connection with the plan with respect to such benefits) shall be made available by the plan administrator (or the health insurance issuer offering such coverage) in accordance with regulations to any current or potential participant, beneficiary, or contracting provider upon request. The reason for any denial under the plan (or coverage) of reimbursement or payment for services with respect to mental health or substance use disorder benefits in the case of any participant or beneficiary shall, on request or as otherwise required, be made available by the plan administrator (or the health insurance issuer offering such coverage) to the participant or beneficiary in accordance with regulations.

(5) OUT-OF-NETWORK PROVIDERS.—In the case of a plan or coverage that provides both medical and surgical benefits and mental health or substance use disorder benefits, if the plan or coverage provides coverage for medical or surgical benefits provided by out-of-network providers, the plan or coverage shall provide coverage for mental health or substance use disorder

benefits provided by out-of-network providers in a manner that is consistent with the requirements of this section.

(b) CONSTRUCTION.—Nothing in this section shall be construed—

(1) as requiring a group health plan (or health insurance coverage offered in connection with such a plan) to provide any mental health or substance use disorder benefits; or

(2) in the case of a group health plan (or health insurance coverage offered in connection with such a plan) that provides mental health or substance use disorder benefits, as affecting the terms and conditions of the plan or coverage relating to such benefits under the plan or coverage, except as provided in subsection (a).

(c) EXEMPTIONS.—

(1) SMALL EMPLOYER EXEMPTION.—This section shall not apply to any group health plan (and group health insurance coverage offered in connection with a group health plan) for any plan year of a small employer (as defined in section 2791(e)(4), except that for purposes of this paragraph such term shall include employers with 1 employee in the case of an employer residing in a State that permits small groups to include a single individual).

(2) COST EXEMPTION.—

(A) IN GENERAL.—With respect to a group health plan (or health insurance coverage offered in connection with such a plan), if the application of this section to such plan (or coverage) results in an increase for the plan year involved of the actual total costs of coverage with respect to medical and surgical benefits and mental health and substance use disorder benefits under the plan (as determined and certified under subparagraph (C)) by an amount that exceeds the applicable percentage described in subparagraph (B) of the actual total plan costs, the provisions of this section shall not apply to such plan (or coverage) during the following plan year, and such exemption shall apply to the plan (or coverage) for 1 plan year. An employer may elect to continue to apply mental health and substance use disorder parity pursuant to this section with respect to the group health plan (or coverage) involved regardless of any increase in total costs.

(B) APPLICABLE PERCENTAGE.—With respect to a plan (or coverage), the applicable percentage described in this subparagraph shall be—

(i) 2 percent in the case of the first plan year in which this section is applied; and

(ii) 1 percent in the case of each subsequent plan year.

(C) DETERMINATIONS BY ACTUARIES.—Determinations as to increases in actual costs under a plan (or coverage) for purposes of this section shall be made and certified by a qualified and licensed actuary who is a member in good standing of the American Academy of Actuaries. All such determinations shall be in a written report prepared by the actuary. The report, and all underlying documentation

relied upon by the actuary, shall be maintained by the group health plan or health insurance issuer for a period of 6 years following the notification made under subparagraph (E).

(D) 6-MONTH DETERMINATIONS.—If a group health plan (or a health insurance issuer offering coverage in connection with a group health plan) seeks an exemption under this paragraph, determinations under subparagraph (A) shall be made after such plan (or coverage) has complied with this section for the first 6 months of the plan year involved.

(E) NOTIFICATION.—

(i) IN GENERAL.—A group health plan (or a health insurance issuer offering coverage in connection with a group health plan) that, based upon a certification described under subparagraph (C), qualifies for an exemption under this paragraph, and elects to implement the exemption, shall promptly notify the Secretary, the appropriate State agencies, and participants and beneficiaries in the plan of such election.

(ii) REQUIREMENT.—A notification to the Secretary under clause (i) shall include—

(I) a description of the number of covered lives under the plan (or coverage) involved at the time of the notification, and as applicable, at the time of any prior election of the cost-exemption under this paragraph by such plan (or coverage);

(II) for both the plan year upon which a cost exemption is sought and the year prior, a description of the actual total costs of coverage with respect to medical and surgical benefits and mental health and substance use disorder benefits under the plan; and

(III) for both the plan year upon which a cost exemption is sought and the year prior, the actual total costs of coverage with respect to mental health and substance use disorder benefits under the plan.

(iii) CONFIDENTIALITY.—A notification to the Secretary under clause (i) shall be confidential. The Secretary shall make available, upon request and on not more than an annual basis, an anonymous itemization of such notifications, that includes—

(I) a breakdown of States by the size and type of employers submitting such notification; and

(II) a summary of the data received under clause (ii).

(F) AUDITS BY APPROPRIATE AGENCIES.—To determine compliance with this paragraph, the Secretary may audit the books and records of a group health plan or health insurance issuer relating to an exemption, including any actuarial reports prepared pursuant to subparagraph (C), during the 6 year period following the notification of such exemption under subparagraph (E). A State agency receiv-

ing a notification under subparagraph (E) may also conduct such an audit with respect to an exemption covered by such notification.

(d) SEPARATE APPLICATION TO EACH OPTION OFFERED.—In the case of a group health plan that offers a participant or beneficiary two or more benefit package options under the plan, the requirements of this section shall be applied separately with respect to each such option.

(e) DEFINITIONS.—For purposes of this section—

(1) AGGREGATE LIFETIME LIMIT.—The term "aggregate lifetime limit" means, with respect to benefits under a group health plan or health insurance coverage, a dollar limitation on the total amount that may be paid with respect to such benefits under the plan or health insurance coverage with respect to an individual or other coverage unit.

(2) ANNUAL LIMIT.—The term "annual limit" means, with respect to benefits under a group health plan or health insurance coverage, a dollar limitation on the total amount of benefits that may be paid with respect to such benefits in a 12-month period under the plan or health insurance coverage with respect to an individual or other coverage unit.

(3) MEDICAL OR SURGICAL BENEFITS.—The term "medical or surgical benefits" means benefits with respect to medical or surgical services, as defined under the terms of the plan or coverage (as the case may be), but does not include mental health or substance use disorder benefits.

(4) MENTAL HEALTH BENEFITS.—The term "mental health benefits" means benefits with respect to services for mental health conditions, as defined under the terms of the plan and in accordance with applicable Federal and State law.

(5) SUBSTANCE USE DISORDER BENEFITS.—The term "substance use disorder benefits" means benefits with respect to services for substance use disorders, as defined under the terms of the plan and in accordance with applicable Federal and State law.

SEC. 2727.[300gg–6] REQUIRED COVERAGE FOR RECONSTRUCTIVE SURGERY FOLLOWING MASTECTOMIES.

The provisions of section 713 of the Employee Retirement Income Security Act of 1974 shall apply to group health plans, and health insurance issuers providing health insurance coverage in connection with group health plans, as if included in this subpart.[2]

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[2] Section 2706 was added by subsection (a) of section 903 of the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 1999 (as contained in section 101(f) of division A of Public Law 105–277; 112 Stat. 2681–438). Subsection (c) of such section 903 concerns effective dates, and paragraph (1) of the subsection provides as follows:

"(1) GROUP PLANS.—

"(A) IN GENERAL.—The amendment made by subsection (a) shall apply to group health plans for plan years beginning on or after the date of enactment of this Act.

"(B) SPECIAL RULE FOR COLLECTIVE BARGAINING AGREEMENTS.—In the case of a group health plan maintained pursuant to 1 or more collective bargaining agreements between employee representatives and 1 or more employers, any plan amendment made pursuant to a collective bargaining agreement relating to the plan which amends the plan solely to conform to any requirement added by the amendment made by subsection (a) shall not be treated as a termination of such collective bargaining agreement.".

The Public Law was enacted October 21, 1998.

SEC. 2728.[300gg–7] COVERAGE OF DEPENDENT STUDENTS ON MEDICALLY NECESSARY LEAVE OF ABSENCE.

(a) MEDICALLY NECESSARY LEAVE OF ABSENCE.—In this section, the term "medically necessary leave of absence" means, with respect to a dependent child described in subsection (b)(2) in connection with a group health plan or health insurance coverage offered in connection with such plan, a leave of absence of such child from a postsecondary educational institution (including an institution of higher education as defined in section 102 of the Higher Education Act of 1965), or any other change in enrollment of such child at such an institution, that—

(1) commences while such child is suffering from a serious illness or injury;

(2) is medically necessary; and

(3) causes such child to lose student status for purposes of coverage under the terms of the plan or coverage.

(b) REQUIREMENT TO CONTINUE COVERAGE.—

(1) IN GENERAL.—In the case of a dependent child described in paragraph (2), a group health plan, or a health insurance issuer that provides health insurance coverage in connection with a group health plan, shall not terminate coverage of such child under such plan or health insurance coverage due to a medically necessary leave of absence before the date that is the earlier of—

(A) the date that is 1 year after the first day of the medically necessary leave of absence; or

(B) the date on which such coverage would otherwise terminate under the terms of the plan or health insurance coverage.

(2) DEPENDENT CHILD DESCRIBED.—A dependent child described in this paragraph is, with respect to a group health plan or health insurance coverage offered in connection with the plan, a beneficiary under the plan who—

(A) is a dependent child, under the terms of the plan or coverage, of a participant or beneficiary under the plan or coverage; and

(B) was enrolled in the plan or coverage, on the basis of being a student at a postsecondary educational institution (as described in subsection (a)), immediately before the first day of the medically necessary leave of absence involved.

(3) CERTIFICATION BY PHYSICIAN.—Paragraph (1) shall apply to a group health plan or health insurance coverage offered by an issuer in connection with such plan only if the plan or issuer of the coverage has received written certification by a treating physician of the dependent child which states that the child is suffering from a serious illness or injury and that the leave of absence (or other change of enrollment) described in subsection (a) is medically necessary.

(c) NOTICE.—A group health plan, and a health insurance issuer providing health insurance coverage in connection with a group health plan, shall include, with any notice regarding a requirement for certification of student status for coverage under the plan or coverage, a description of the terms of this section for con-

tinued coverage during medically necessary leaves of absence. Such description shall be in language which is understandable to the typical plan participant.

(d) NO CHANGE IN BENEFITS.—A dependent child whose benefits are continued under this section shall be entitled to the same benefits as if (during the medically necessary leave of absence) the child continued to be a covered student at the institution of higher education and was not on a medically necessary leave of absence.

(e) CONTINUED APPLICATION IN CASE OF CHANGED COVERAGE.—If—

(1) a dependent child of a participant or beneficiary is in a period of coverage under a group health plan or health insurance coverage offered in connection with such a plan, pursuant to a medically necessary leave of absence of the child described in subsection (b);

(2) the manner in which the participant or beneficiary is covered under the plan changes, whether through a change in health insurance coverage or health insurance issuer, a change between health insurance coverage and self-insured coverage, or otherwise; and

(3) the coverage as so changed continues to provide coverage of beneficiaries as dependent children,

this section shall apply to coverage of the child under the changed coverage for the remainder of the period of the medically necessary leave of absence of the dependent child under the plan in the same manner as it would have applied if the changed coverage had been the previous coverage.

Subpart 3—Provisions Applicable Only to Health Insurance Issuers

SEC. 2731.[300gg–11] GUARANTEED AVAILABILITY OF COVERAGE FOR EMPLOYERS IN THE GROUP MARKET.

(a) ISSUANCE OF COVERAGE IN THE SMALL GROUP MARKET.—

(1) IN GENERAL.—Subject to subsections (c) through (f), each health insurance issuer that offers health insurance coverage in the small group market in a State—

(A) must accept every small employer (as defined in section 2791(e)(4)) in the State that applies for such coverage; and

(B) must accept for enrollment under such coverage every eligible individual (as defined in paragraph (2)) who applies for enrollment during the period in which the individual first becomes eligible to enroll under the terms of the group health plan and may not place any restriction which is inconsistent with section 2702 on an eligible individual being a participant or beneficiary.

(2) ELIGIBLE INDIVIDUAL DEFINED.—For purposes of this section, the term "eligible individual" means, with respect to a health insurance issuer that offers health insurance coverage to a small employer in connection with a group health plan in the small group market, such an individual in relation to the employer as shall be determined—

(A) in accordance with the terms of such plan,

(B) as provided by the issuer under rules of the issuer which are uniformly applicable in a State to small employers in the small group market, and

(C) in accordance with all applicable State laws governing such issuer and such market.

(b) ASSURING ACCESS IN THE LARGE GROUP MARKET.—

(1) REPORTS TO HHS.—The Secretary shall request that the chief executive officer of each State submit to the Secretary, by not later December 31, 2000, and every 3 years thereafter a report on—

(A) the access of large employers to health insurance coverage in the State, and

(B) the circumstances for lack of access (if any) of large employers (or one or more classes of such employers) in the State to such coverage.

(2) TRIENNIAL REPORTS TO CONGRESS.—The Secretary, based on the reports submitted under paragraph (1) and such other information as the Secretary may use, shall prepare and submit to Congress, every 3 years, a report describing the extent to which large employers (and classes of such employers) that seek health insurance coverage in the different States are able to obtain access to such coverage. Such report shall include such recommendations as the Secretary determines to be appropriate.

(3) GAO REPORT ON LARGE EMPLOYER ACCESS TO HEALTH INSURANCE COVERAGE.—The Comptroller General shall provide for a study of the extent to which classes of large employers in the different States are able to obtain access to health insurance coverage and the circumstances for lack of access (if any) to such coverage. The Comptroller General shall submit to Congress a report on such study not later than 18 months after the date of the enactment of this title.

(c) SPECIAL RULES FOR NETWORK PLANS.—

(1) IN GENERAL.—In the case of a health insurance issuer that offers health insurance coverage in the small group market through a network plan, the issuer may—

(A) limit the employers that may apply for such coverage to those with eligible individuals who live, work, or reside in the service area for such network plan; and

(B) within the service area of such plan, deny such coverage to such employers if the issuer has demonstrated, if required, to the applicable State authority that—

(i) it will not have the capacity to deliver services adequately to enrollees of any additional groups because of its obligations to existing group contract holders and enrollees, and

(ii) it is applying this paragraph uniformly to all employers without regard to the claims experience of those employers and their employees (and their dependents) or any health status-related factor relating to such employees and dependents.

(2) 180-DAY SUSPENSION UPON DENIAL OF COVERAGE.—An issuer, upon denying health insurance coverage in any service area in accordance with paragraph (1)(B), may not offer cov-

erage in the small group market within such service area for a period of 180 days after the date such coverage is denied.

(d) APPLICATION OF FINANCIAL CAPACITY LIMITS.—

(1) IN GENERAL.—A health insurance issuer may deny health insurance coverage in the small group market if the issuer has demonstrated, if required, to the applicable State authority that—

(A) it does not have the financial reserves necessary to underwrite additional coverage; and

(B) it is applying this paragraph uniformly to all employers in the small group market in the State consistent with applicable State law and without regard to the claims experience of those employers and their employees (and their dependents) or any health status-related factor relating to such employees and dependents.

(2) 180-DAY SUSPENSION UPON DENIAL OF COVERAGE.—A health insurance issuer upon denying health insurance coverage in connection with group health plans in accordance with paragraph (1) in a State may not offer coverage in connection with group health plans in the small group market in the State for a period of 180 days after the date such coverage is denied or until the issuer has demonstrated to the applicable State authority, if required under applicable State law, that the issuer has sufficient financial reserves to underwrite additional coverage, whichever is later. An applicable State authority may provide for the application of this subsection on a service-area-specific basis.

(e) EXCEPTION TO REQUIREMENT FOR FAILURE TO MEET CERTAIN MINIMUM PARTICIPATION OR CONTRIBUTION RULES.—

(1) IN GENERAL.—Subsection (a) shall not be construed to preclude a health insurance issuer from establishing employer contribution rules or group participation rules for the offering of health insurance coverage in connection with a group health plan in the small group market, as allowed under applicable State law.

(2) RULES DEFINED.—For purposes of paragraph (1)—

(A) the term "employer contribution rule" means a requirement relating to the minimum level or amount of employer contribution toward the premium for enrollment of participants and beneficiaries; and

(B) the term "group participation rule" means a requirement relating to the minimum number of participants or beneficiaries that must be enrolled in relation to a specified percentage or number of eligible individuals or employees of an employer.

(f) EXCEPTION FOR COVERAGE OFFERED ONLY TO BONA FIDE ASSOCIATION MEMBERS.—Subsection (a) shall not apply to health insurance coverage offered by a health insurance issuer if such coverage is made available in the small group market only through one or more bona fide associations (as defined in section 2791(d)(3)).

SEC. 2732.[300gg–12] GUARANTEED RENEWABILITY OF COVERAGE FOR EMPLOYERS IN THE GROUP MARKET.

(a) IN GENERAL.—Except as provided in this section, if a health insurance issuer offers health insurance coverage in the small or large group market in connection with a group health plan, the issuer must renew or continue in force such coverage at the option of the plan sponsor of the plan.

(b) GENERAL EXCEPTIONS.—A health insurance issuer may nonrenew or discontinue health insurance coverage offered in connection with a group health plan in the small or large group market based only on one or more of the following:

(1) NONPAYMENT OF PREMIUMS.—The plan sponsor has failed to pay premiums or contributions in accordance with the terms of the health insurance coverage or the issuer has not received timely premium payments.

(2) FRAUD.—The plan sponsor has performed an act or practice that constitutes fraud or made an intentional misrepresentation of material fact under the terms of the coverage.

(3) VIOLATION OF PARTICIPATION OR CONTRIBUTION RULES.—The plan sponsor has failed to comply with a material plan provision relating to employer contribution or group participation rules, as permitted under section 2711(e) in the case of the small group market or pursuant to applicable State law in the case of the large group market.

(4) TERMINATION OF COVERAGE.—The issuer is ceasing to offer coverage in such market in accordance with subsection (c) and applicable State law.

(5) MOVEMENT OUTSIDE SERVICE AREA.—In the case of a health insurance issuer that offers health insurance coverage in the market through a network plan, there is no longer any enrollee in connection with such plan who lives, resides, or works in the service area of the issuer (or in the area for which the issuer is authorized to do business) and, in the case of the small group market, the issuer would deny enrollment with respect to such plan under section 2711(c)(1)(A).

(6) ASSOCIATION MEMBERSHIP CEASES.—In the case of health insurance coverage that is made available in the small or large group market (as the case may be) only through one or more bona fide associations, the membership of an employer in the association (on the basis of which the coverage is provided) ceases but only if such coverage is terminated under this paragraph uniformly without regard to any health status-related factor relating to any covered individual.

(c) REQUIREMENTS FOR UNIFORM TERMINATION OF COVERAGE.—

(1) PARTICULAR TYPE OF COVERAGE NOT OFFERED.—In any case in which an issuer decides to discontinue offering a particular type of group health insurance coverage offered in the small or large group market, coverage of such type may be discontinued by the issuer in accordance with applicable State law in such market only if—

(A) the issuer provides notice to each plan sponsor provided coverage of this type in such market (and participants and beneficiaries covered under such coverage) of

such discontinuation at least 90 days prior to the date of the discontinuation of such coverage;

(B) the issuer offers to each plan sponsor provided coverage of this type in such market, the option to purchase all (or, in the case of the large group market, any) other health insurance coverage currently being offered by the issuer to a group health plan in such market; and

(C) in exercising the option to discontinue coverage of this type and in offering the option of coverage under subparagraph (B), the issuer acts uniformly without regard to the claims experience of those sponsors or any health status-related factor relating to any participants or beneficiaries covered or new participants or beneficiaries who may become eligible for such coverage.

(2) DISCONTINUANCE OF ALL COVERAGE.—

(A) IN GENERAL.—In any case in which a health insurance issuer elects to discontinue offering all health insurance coverage in the small group market or the large group market, or both markets, in a State, health insurance coverage may be discontinued by the issuer only in accordance with applicable State law and if—

(i) the issuer provides notice to the applicable State authority and to each plan sponsor (and participants and beneficiaries covered under such coverage) of such discontinuation at least 180 days prior to the date of the discontinuation of such coverage; and

(ii) all health insurance issued or delivered for issuance in the State in such market (or markets) are discontinued and coverage under such health insurance coverage in such market (or markets) is not renewed.

(B) PROHIBITION ON MARKET REENTRY.—In the case of a discontinuation under subparagraph (A) in a market, the issuer may not provide for the issuance of any health insurance coverage in the market and State involved during the 5-year period beginning on the date of the discontinuation of the last health insurance coverage not so renewed.

(d) EXCEPTION FOR UNIFORM MODIFICATION OF COVERAGE.—At the time of coverage renewal, a health insurance issuer may modify the health insurance coverage for a product offered to a group health plan—

(1) in the large group market; or

(2) in the small group market if, for coverage that is available in such market other than only through one or more bona fide associations, such modification is consistent with State law and effective on a uniform basis among group health plans with that product.

(e) APPLICATION TO COVERAGE OFFERED ONLY THROUGH ASSOCIATIONS.—In applying this section in the case of health insurance coverage that is made available by a health insurance issuer in the small or large group market to employers only through one or more associations, a reference to "plan sponsor" is deemed, with respect to coverage provided to an employer member of the association, to include a reference to such employer.

SEC. 2733.[300gg–13] DISCLOSURE OF INFORMATION.

(a) DISCLOSURE OF INFORMATION BY HEALTH PLAN ISSUERS.—In connection with the offering of any health insurance coverage to a small employer, a health insurance issuer—

(1) shall make a reasonable disclosure to such employer, as part of its solicitation and sales materials, of the availability of information described in subsection (b), and

(2) upon request of such a small employer, provide such information.

(b) INFORMATION DESCRIBED.—

(1) IN GENERAL.—Subject to paragraph (3), with respect to a health insurance issuer offering health insurance coverage to a small employer, information described in this subsection is information concerning—

(A) the provisions of such coverage concerning issuer's right to change premium rates and the factors that may affect changes in premium rates;

(B) the provisions of such coverage relating to renewability of coverage;

(C) the provisions of such coverage relating to any preexisting condition exclusion; and

(D) the benefits and premiums available under all health insurance coverage for which the employer is qualified.

(2) FORM OF INFORMATION.—Information under this subsection shall be provided to small employers in a manner determined to be understandable by the average small employer, and shall be sufficient to reasonably inform small employers of their rights and obligations under the health insurance coverage.

(3) EXCEPTION.—An issuer is not required under this section to disclose any information that is proprietary and trade secret information under applicable law.

Subpart 4—Exclusion of Plans; Enforcement; Preemption

SEC. 2735.[300gg–21] EXCLUSION OF CERTAIN PLANS.

(a) EXCEPTION FOR CERTAIN SMALL GROUP HEALTH PLANS.—The requirements of subparts 1 and 3 shall not apply to any group health plan (and health insurance coverage offered in connection with a group health plan) for any plan year if, on the first day of such plan year, such plan has less than 2 participants who are current employees.

(b) LIMITATION ON APPLICATION OF PROVISIONS RELATING TO GROUP HEALTH PLANS.—

(1) IN GENERAL.—The requirements of subparts 1 through 3 shall apply with respect to group health plans only—

(A) subject to paragraph (2), in the case of a plan that is a nonfederal governmental plan, and

(B) with respect to health insurance coverage offered in connection with a group health plan (including such a plan that is a church plan or a governmental plan).

(2) TREATMENT OF NONFEDERAL GOVERNMENTAL PLANS.—

(A) ELECTION TO BE EXCLUDED.—Except as provided in subparagraph (D), if the plan sponsor of a nonfederal governmental plan which is a group health plan to which the provisions of subparts 1 through 3 otherwise apply makes an election under this subparagraph (in such form and manner as the Secretary may by regulations prescribe), then the requirements of such subparts insofar as they apply directly to group health plans (and not merely to group health insurance coverage) shall not apply to such governmental plans for such period except as provided in this paragraph.

(B) PERIOD OF ELECTION.—An election under subparagraph (A) shall apply—

(i) for a single specified plan year, or

(ii) in the case of a plan provided pursuant to a collective bargaining agreement, for the term of such agreement.

An election under clause (i) may be extended through subsequent elections under this paragraph.

(C) NOTICE TO ENROLLEES.—Under such an election, the plan shall provide for—

(i) notice to enrollees (on an annual basis and at the time of enrollment under the plan) of the fact and consequences of such election, and

(ii) certification and disclosure of creditable coverage under the plan with respect to enrollees in accordance with section 2701(e).

(D) ELECTION NOT APPLICABLE TO REQUIREMENTS CONCERNING GENETIC INFORMATION.—The election described in subparagraph (A) shall not be available with respect to the provisions of subsections (a)(1)(F), (b)(3), (c), and (d) of section 2702 and the provisions of sections 2701 and 2702(b) to the extent that such provisions apply to genetic information.

(c) EXCEPTION FOR CERTAIN BENEFITS.—The requirements of subparts 1 through 3 shall not apply to any group health plan (or group health insurance coverage) in relation to its provision of excepted benefits described in section 2791(c)(1).

(d) EXCEPTION FOR CERTAIN BENEFITS IF CERTAIN CONDITIONS MET.—

(1) LIMITED, EXCEPTED BENEFITS.—The requirements of subparts 1 through 3 shall not apply to any group health plan (and group health insurance coverage offered in connection with a group health plan) in relation to its provision of excepted benefits described in section 2791(c)(2) if the benefits—

(A) are provided under a separate policy, certificate, or contract of insurance; or

(B) are otherwise not an integral part of the plan.

(2) NONCOORDINATED, EXCEPTED BENEFITS.—The requirements of subparts 1 through 3 shall not apply to any group health plan (and group health insurance coverage offered in connection with a group health plan) in relation to its provision of excepted benefits described in section 2791(c)(3) if all of the following conditions are met:

(A) The benefits are provided under a separate policy, certificate, or contract of insurance.

(B) There is no coordination between the provision of such benefits and any exclusion of benefits under any group health plan maintained by the same plan sponsor.

(C) Such benefits are paid with respect to an event without regard to whether benefits are provided with respect to such an event under any group health plan maintained by the same plan sponsor.

(3) SUPPLEMENTAL EXCEPTED BENEFITS.—The requirements of this part shall not apply to any group health plan (and group health insurance coverage) in relation to its provision of excepted benefits described in section 27971(c)(4) if the benefits are provided under a separate policy, certificate, or contract of insurance.

(e) TREATMENT OF PARTNERSHIPS.—For purposes of this part—

(1) TREATMENT AS A GROUP HEALTH PLAN.—Any plan, fund, or program which would not be (but for this subsection) an employee welfare benefit plan and which is established or maintained by a partnership, to the extent that such plan, fund, or program provides medical care (including items and services paid for as medical care) to present or former partners in the partnership or to their dependents (as defined under the terms of the plan, fund, or program), directly or through insurance, reimbursement, or otherwise, shall be treated (subject to paragraph (2)) as an employee welfare benefit plan which is a group health plan.

(2) EMPLOYER.—In the case of a group health plan, the term "employer" also includes the partnership in relation to any partner.

(3) PARTICIPANTS OF GROUP HEALTH PLANS.—In the case of a group health plan, the term "participant" also includes—

(A) in connection with a group health plan maintained by a partnership, an individual who is a partner in relation to the partnership, or

(B) in connection with a group health plan maintained by a self-employed individual (under which one or more employees are participants), the self-employed individual,

if such individual is, or may become, eligible to receive a benefit under the plan or such individual's beneficiaries may be eligible to receive any such benefit.

SEC. 2736.[300gg–22] ENFORCEMENT.

(a) STATE ENFORCEMENT.—

(1) STATE AUTHORITY.—Subject to section 2723, each State may require that health insurance issuers that issue, sell, renew, or offer health insurance coverage in the State in the small or large group markets meet the requirements of this part with respect to such issuers.

(2) FAILURE TO IMPLEMENT PROVISIONS.—In the case of a determination by the Secretary that a State has failed to substantially enforce a provision (or provisions) in this part with respect to health insurance issuers in the State, the Secretary shall enforce such provision (or provisions) under subsection (b)

insofar as they relate to the issuance, sale, renewal, and offering of health insurance coverage in connection with group health plans in such State.

(b) SECRETARIAL ENFORCEMENT AUTHORITY.—

(1) LIMITATION.—The provisions of this subsection shall apply to enforcement of a provision (or provisions) of this part only—

(A) as provided under subsection (a)(2); and

(B) with respect to group health plans that are non-Federal governmental plans.

(2) IMPOSITION OF PENALTIES.—In the cases described in paragraph (1)—

(A) IN GENERAL.—Subject to the succeeding provisions of this subsection, any non-Federal governmental plan that is a group health plan and any health insurance issuer that fails to meet a provision of this part applicable to such plan or issuer is subject to a civil money penalty under this subsection.

(B) LIABILITY FOR PENALTY.—In the case of a failure by—

(i) a health insurance issuer, the issuer is liable for such penalty, or

(ii) a group health plan that is a non-Federal governmental plan which is—

(I) sponsored by 2 or more employers, the plan is liable for such penalty, or

(II) not so sponsored, the employer is liable for such penalty.

(C) AMOUNT OF PENALTY.—

(i) IN GENERAL.—The maximum amount of penalty imposed under this paragraph is $100 for each day for each individual with respect to which such a failure occurs.

(ii) CONSIDERATIONS IN IMPOSITION.—In determining the amount of any penalty to be assessed under this paragraph, the Secretary shall take into account the previous record of compliance of the entity being assessed with the applicable provisions of this part and the gravity of the violation.

(iii) LIMITATIONS.—

(I) PENALTY NOT TO APPLY WHERE FAILURE NOT DISCOVERED EXERCISING REASONABLE DILIGENCE.—No civil money penalty shall be imposed under this paragraph on any failure during any period for which it is established to the satisfaction of the Secretary that none of the entities against whom the penalty would be imposed knew, or exercising reasonable diligence would have known, that such failure existed.

(II) PENALTY NOT TO APPLY TO FAILURES CORRECTED WITHIN 30 DAYS.—No civil money penalty shall be imposed under this paragraph on any failure if such failure was due to reasonable cause and not to willful neglect, and such failure is cor-

rected during the 30-day period beginning on the first day any of the entities against whom the penalty would be imposed knew, or exercising reasonable diligence would have known, that such failure existed.

(D) ADMINISTRATIVE REVIEW.—

(i) OPPORTUNITY FOR HEARING.—The entity assessed shall be afforded an opportunity for hearing by the Secretary upon request made within 30 days after the date of the issuance of a notice of assessment. In such hearing the decision shall be made on the record pursuant to section 554 of title 5, United States Code. If no hearing is requested, the assessment shall constitute a final and unappealable order.

(ii) HEARING PROCEDURE.—If a hearing is requested, the initial agency decision shall be made by an administrative law judge, and such decision shall become the final order unless the Secretary modifies or vacates the decision. Notice of intent to modify or vacate the decision of the administrative law judge shall be issued to the parties within 30 days after the date of the decision of the judge. A final order which takes effect under this paragraph shall be subject to review only as provided under subparagraph (E).

(E) JUDICIAL REVIEW.—

(i) FILING OF ACTION FOR REVIEW.—Any entity against whom an order imposing a civil money penalty has been entered after an agency hearing under this paragraph may obtain review by the United States district court for any district in which such entity is located or the United States District Court for the District of Columbia by filing a notice of appeal in such court within 30 days from the date of such order, and simultaneously sending a copy of such notice by registered mail to the Secretary.

(ii) CERTIFICATION OF ADMINISTRATIVE RECORD.—The Secretary shall promptly certify and file in such court the record upon which the penalty was imposed.

(iii) STANDARD FOR REVIEW.—The findings of the Secretary shall be set aside only if found to be unsupported by substantial evidence as provided by section 706(2)(E) of title 5, United States Code.

(iv) APPEAL.—Any final decision, order, or judgment of the district court concerning such review shall be subject to appeal as provided in chapter 83 of title 28 of such Code.

(F) FAILURE TO PAY ASSESSMENT; MAINTENANCE OF ACTION.—

(i) FAILURE TO PAY ASSESSMENT.—If any entity fails to pay an assessment after it has become a final and unappealable order, or after the court has entered final judgment in favor of the Secretary, the Secretary shall refer the matter to the Attorney General who

shall recover the amount assessed by action in the appropriate United States district court.

(ii) NONREVIEWABILITY.—In such action the validity and appropriateness of the final order imposing the penalty shall not be subject to review.

(G) PAYMENT OF PENALTIES.—Except as otherwise provided, penalties collected under this paragraph shall be paid to the Secretary (or other officer) imposing the penalty and shall be available without appropriation and until expended for the purpose of enforcing the provisions with respect to which the penalty was imposed.

(3) ENFORCEMENT AUTHORITY RELATING TO GENETIC DISCRIMINATION.—

(A) GENERAL RULE.—In the cases described in paragraph (1), notwithstanding the provisions of paragraph (2)(C), the succeeding subparagraphs of this paragraph shall apply with respect to an action under this subsection by the Secretary with respect to any failure of a health insurance issuer in connection with a group health plan, to meet the requirements of subsection (a)(1)(F), (b)(3), (c), or (d) of section 2702 or section 2701 or 2702(b)(1) with respect to genetic information in connection with the plan.

(B) AMOUNT.—

(i) IN GENERAL.—The amount of the penalty imposed under this paragraph shall be $100 for each day in the noncompliance period with respect to each participant or beneficiary to whom such failure relates.

(ii) NONCOMPLIANCE PERIOD.—For purposes of this paragraph, the term "noncompliance period" means, with respect to any failure, the period—

(I) beginning on the date such failure first occurs; and

(II) ending on the date the failure is corrected.

(C) MINIMUM PENALTIES WHERE FAILURE DISCOVERED.—Notwithstanding clauses (i) and (ii) of subparagraph (D):

(i) IN GENERAL.—In the case of 1 or more failures with respect to an individual—

(I) which are not corrected before the date on which the plan receives a notice from the Secretary of such violation; and

(II) which occurred or continued during the period involved;

the amount of penalty imposed by subparagraph (A) by reason of such failures with respect to such individual shall not be less than $2,500.

(ii) HIGHER MINIMUM PENALTY WHERE VIOLATIONS ARE MORE THAN DE MINIMIS.—To the extent violations for which any person is liable under this paragraph for any year are more than de minimis, clause (i) shall be applied by substituting "$15,000" for "$2,500" with respect to such person.

(D) LIMITATIONS.—

(i) PENALTY NOT TO APPLY WHERE FAILURE NOT DISCOVERED EXERCISING REASONABLE DILIGENCE.—No penalty shall be imposed by subparagraph (A) on any failure during any period for which it is established to the satisfaction of the Secretary that the person otherwise liable for such penalty did not know, and exercising reasonable diligence would not have known, that such failure existed.

(ii) PENALTY NOT TO APPLY TO FAILURES CORRECTED WITHIN CERTAIN PERIODS.—No penalty shall be imposed by subparagraph (A) on any failure if—

(I) such failure was due to reasonable cause and not to willful neglect; and

(II) such failure is corrected during the 30-day period beginning on the first date the person otherwise liable for such penalty knew, or exercising reasonable diligence would have known, that such failure existed.

(iii) OVERALL LIMITATION FOR UNINTENTIONAL FAILURES.—In the case of failures which are due to reasonable cause and not to willful neglect, the penalty imposed by subparagraph (A) for failures shall not exceed the amount equal to the lesser of—

(I) 10 percent of the aggregate amount paid or incurred by the employer (or predecessor employer) during the preceding taxable year for group health plans; or

(II) $500,000.

(E) WAIVER BY SECRETARY.—In the case of a failure which is due to reasonable cause and not to willful neglect, the Secretary may waive part or all of the penalty imposed by subparagraph (A) to the extent that the payment of such penalty would be excessive relative to the failure involved.

SEC. 2737.[300gg–23] PREEMPTION; STATE FLEXIBILITY; CONSTRUCTION.

(a) CONTINUED APPLICABILITY OF STATE LAW WITH RESPECT TO HEALTH INSURANCE ISSUERS.—

(1) IN GENERAL.—Subject to paragraph (2) and except as provided in subsection (b), this part and part C insofar as it relates to this part shall not be construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with group health insurance coverage except to the extent that such standard or requirement prevents the application of a requirement of this part.

(2) CONTINUED PREEMPTION WITH RESPECT TO GROUP HEALTH PLANS.—Nothing in this part shall be construed to affect or modify the provisions of section 514 of the Employee Retirement Income Security Act of 1974 with respect to group health plans.

(b) SPECIAL RULES IN CASE OF PORTABILITY REQUIREMENTS.—

(1) IN GENERAL.—Subject to paragraph (2), the provisions of this part relating to health insurance coverage offered by a health insurance issuer supersede any provision of State law which establishes, implements, or continues in effect a standard or requirement applicable to imposition of a preexisting condition exclusion specifically governed by section 701 which differs from the standards or requirements specified in such section.

(2) EXCEPTIONS.—Only in relation to health insurance coverage offered by a health insurance issuer, the provisions of this part do not supersede any provision of State law to the extent that such provision—

(i)[3] substitutes for the reference to "6-month period" in section 2701(a)(1) a reference to any shorter period of time;

(ii) substitutes for the reference to "12 months" and "18 months" in section 2701(a)(2) a reference to any shorter period of time;

(iii) substitutes for the references to "63" days in sections 2701(c)(2)(A) and 2701(d)(4)(A) a reference to any greater number of days;

(iv) substitutes for the reference to "30-day period" in sections 2701(b)(2) and 2701(d)(1) a reference to any greater period;

(v) prohibits the imposition of any preexisting condition exclusion in cases not described in section 2701(d) or expands the exceptions described in such section;

(vi) requires special enrollment periods in addition to those required under section 2701(f); or

(vii) reduces the maximum period permitted in an affiliation period under section 2701(g)(1)(B).

(c) RULES OF CONSTRUCTION.—Nothing in this part (other than section 2704) shall be construed as requiring a group health plan or health insurance coverage to provide specific benefits under the terms of such plan or coverage.

(d) DEFINITIONS.—For purposes of this section—

(1) STATE LAW.—The term "State law" includes all laws, decisions, rules, regulations, or other State action having the effect of law, of any State. A law of the United States applicable only to the District of Columbia shall be treated as a State law rather than a law of the United States.

(2) STATE.—The term "State" includes a State (including the Northern Mariana Islands), any political subdivisions of a State or such Islands, or any agency or instrumentality of either.

[Note: Effective on January 1, 2014, sections 1001, 1201, and 1563 (relating to conforming amendments--originally designated as section 1562 and redesignated as section 1563 by section 10107(b)(1)) of Public Law 111–148 provides for amendments to provisions in part A. The conforming amendments made by section 1563 (as so

[3] Clauses (i) through (vii) probably should be redesignated as subparagraphs (A) through (G). See section 102(a) of Public Law 104–191 (110 Stat. 1971).

redesignated) of such Public Law to part A take effect on date of enactment (March 23, 2010) but have been carried to this version to reflect to probable intent of Congress. Upon such date, part A of title XXVII reads as follows:]

PART A—INDIVIDUAL AND GROUP MARKET REFORMS

Subpart I—General Reform

SEC. 2701.[300gg] FAIR HEALTH INSURANCE PREMIUMS.

(a)[4] *PROHIBITING DISCRIMINATORY PREMIUM RATES.—*

(1) IN GENERAL.—With respect to the premium rate charged by a health insurance issuer for health insurance coverage offered in the individual or small group market—

(A) such rate shall vary with respect to the particular plan or coverage involved only by—

(i) whether such plan or coverage covers an individual or family;

(ii) rating area, as established in accordance with paragraph (2);

(iii) age, except that such rate shall not vary by more than 3 to 1 for adults (consistent with section 2707(c)); and

(iv) tobacco use, except that such rate shall not vary by more than 1.5 to 1; and

(B) such rate shall not vary with respect to the particular plan or coverage involved by any other factor not described in subparagraph (A).

(2) RATING AREA.—

(A) IN GENERAL.—Each State shall establish 1 or more rating areas within that State for purposes of applying the requirements of this title.

(B) SECRETARIAL REVIEW.—The Secretary shall review the rating areas established by each State under subparagraph (A) to ensure the adequacy of such areas for purposes of carrying out the requirements of this title. If the Secretary determines a State's rating areas are not adequate, or that a State does not establish such areas, the Secretary may establish rating areas for that State.

(3) PERMISSIBLE AGE BANDS.—The Secretary, in consultation with the National Association of Insurance Commissioners, shall define the permissible age bands for rating purposes under paragraph (1)(A)(iii).

(4) APPLICATION OF VARIATIONS BASED ON AGE OR TOBACCO USE.—With respect to family coverage under a group health plan or health insurance coverage, the rating variations permitted under clauses (iii) and (iv) of paragraph (1)(A) shall be applied based on the portion of the premium that is attributable to each family member covered under the plan or coverage.

[4] There are no subsections following subsection (a) in section 2701.

(5) SPECIAL RULE FOR LARGE GROUP MARKET.—If a State permits health insurance issuers that offer coverage in the large group market in the State to offer such coverage through the State Exchange (as provided for under section 1312(f)(2)(B) of the Patient Protection and Affordable Care Act), the provisions of this subsection shall apply to all coverage offered in such market (other than self-insured group health plans offered in such market) in the State.

SEC. 2702.[300gg–1] GUARANTEED AVAILABILITY OF COVERAGE.

(a) GUARANTEED ISSUANCE OF COVERAGE IN THE INDIVIDUAL AND GROUP MARKET.—Subject to subsections (b) through (e), each health insurance issuer that offers health insurance coverage in the individual or group market in a State must accept every employer and individual in the State that applies for such coverage.

(b) ENROLLMENT.—

(1) RESTRICTION.—A health insurance issuer described in subsection (a) may restrict enrollment in coverage described in such subsection to open or special enrollment periods.

(2) ESTABLISHMENT.—A health insurance issuer described in subsection (a) shall, in accordance with the regulations promulgated under paragraph (3), establish special enrollment periods for qualifying events (under section 603 of the Employee Retirement Income Security Act of 1974).

(3) REGULATIONS.—The Secretary shall promulgate regulations with respect to enrollment periods under paragraphs (1) and (2).

(c) SPECIAL RULES FOR NETWORK PLANS.—

(1) IN GENERAL.—In the case of a health insurance issuer that offers health insurance coverage in the group and individual market through a network plan, the issuer may—

(A) limit the employers that may apply for such coverage to those with eligible individuals who live, work, or reside in the service area for such network plan; and

(B) within the service area of such plan, deny such coverage to such employers and individuals if the issuer has demonstrated, if required, to the applicable State authority that—

(i) it will not have the capacity to deliver services adequately to enrollees of any additional groups or any additional individuals because of its obligations to existing group contract holders and enrollees, and

(ii) it is applying this paragraph uniformly to all employers and individuals without regard to the claims experience of those individuals, employers and their employees (and their dependents) or any health status-related factor relating to such individuals employees and dependents.

(2) 180-DAY SUSPENSION UPON DENIAL OF COVERAGE.—An issuer, upon denying health insurance coverage in any service area in accordance with paragraph (1)(B), may not offer coverage in the group or individual market within such service area for a period of 180 days after the date such coverage is denied.

(d) APPLICATION OF FINANCIAL CAPACITY LIMITS.—

(1) IN GENERAL.—A health insurance issuer may deny health insurance coverage in the group or individual market if the issuer has demonstrated, if required, to the applicable State authority that—

(A) it does not have the financial reserves necessary to underwrite additional coverage; and

(B) it is applying this paragraph uniformly to all employers and individuals in the group or individual market in the State consistent with applicable State law and without regard to the claims experience of those individuals, employers and their employees (and their dependents) or any health status-related factor relating to such individuals, employees and dependents.

(2) 180-DAY SUSPENSION UPON DENIAL OF COVERAGE.—A health insurance issuer upon denying health insurance coverage in connection with group health plans in accordance with paragraph (1) in a State may not offer coverage in connection with group health plans in the group or individual market in the State for a period of 180 days after the date such coverage is denied or until the issuer has demonstrated to the applicable State authority, if required under applicable State law, that the issuer has sufficient financial reserves to underwrite additional coverage, whichever is later. An applicable State authority may provide for the application of this subsection on a service-area-specific basis.

SEC. 2703.[300gg–2] GUARANTEED RENEWABILITY OF COVERAGE.

(a) IN GENERAL.—Except as provided in this section, if a health insurance issuer offers health insurance coverage in the individual or group market, the issuer must renew or continue in force such coverage at the option of the plan sponsor or the individual, as applicable.

(b) GENERAL EXCEPTIONS.—A health insurance issuer may nonrenew or discontinue health insurance coverage offered in connection with a health insurance coverage offered in the group or individual market based only on one or more of the following:

(1) NONPAYMENT OF PREMIUMS.—The plan sponsor, or individual, as applicable, has failed to pay premiums or contributions in accordance with the terms of the health insurance coverage or the issuer has not received timely premium payments.

(2) FRAUD.—The plan sponsor, or individual, as applicable, has performed an act or practice that constitutes fraud or made an intentional misrepresentation of material fact under the terms of the coverage.

(3) VIOLATION OF PARTICIPATION OR CONTRIBUTION RATES.—In the case of a group health plan, the plan sponsor has failed to comply with a material plan provision relating to employer contribution or group participation rules, pursuant to applicable State law.

(4) TERMINATION OF COVERAGE.—The issuer is ceasing to offer coverage in such market in accordance with subsection (c) and applicable State law.

(5) MOVEMENT OUTSIDE SERVICE AREA.—In the case of a health insurance issuer that offers health insurance coverage in the market through a network plan, there is no longer any enrollee in connection with such plan who lives, resides, or works in the service area of the issuer (or in the area for which the issuer is authorized to do business) and, in the case of the small group market, the issuer would deny enrollment with respect to such plan under section 2711(c)(1)(A).

(6) ASSOCIATION MEMBERSHIP CEASES.—In the case of health insurance coverage that is made available in the small or large group market (as the case may be) only through one or more bona fide associations, the membership of an employer in the association (on the basis of which the coverage is provided) ceases but only if such coverage is terminated under this paragraph uniformly without regard to any health status-related factor relating to any covered individual.

(c) REQUIREMENTS FOR UNIFORM TERMINATION OF COVERAGE.—

(1) PARTICULAR TYPE OF COVERAGE NOT OFFERED.—In any case in which an issuer decides to discontinue offering a particular type of group or individual health insurance coverage, coverage of such type may be discontinued by the issuer in accordance with applicable State law in such market only if—

(A) the issuer provides notice to each plan sponsor or individual, as applicable, provided coverage of this type in such market (and participants and beneficiaries covered under such coverage) of such discontinuation at least 90 days prior to the date of the discontinuation of such coverage;

(B) the issuer offers to each plan sponsor or individual, as applicable, provided coverage of this type in such market, the option to purchase all (or, in the case of the large group market, any) other health insurance coverage currently being offered by the issuer to a group health plan or individual health insurance coverage[5] *in such market; and*

(C) in exercising the option to discontinue coverage of this type and in offering the option of coverage under subparagraph (B), the issuer acts uniformly without regard to the claims experience of those sponsors or individuals, as applicable, or any health status-related factor relating to any participants or beneficiaries covered or new participants or beneficiaries who may become eligible for such coverage.

(2) DISCONTINUANCE OF ALL COVERAGE.—

(A) IN GENERAL.—In any case in which a health insurance issuer elects to discontinue offering all health insurance coverage in the individual or group market, or all markets, in a State, health insurance coverage may be dis-

[5] Section 1563(c)(9)(C)(i)(III)(bb) (relating to conforming amendments--originally designated as section 1562 and redesignated as section 1563 by section 10107(b)(1)) of Public Law 111–148 provides for an amendment to insert "or individual health insurance coverage". Such amendment did not specify where to insert this new language, however, it was carried out by inserting such language after "group health plan" to reflect the probable intent of Congress.

continued by the issuer only in accordance with applicable State law and if—

(i) the issuer provides notice to the applicable State authority and to each plan sponsor or individual, as applicable, (and participants and beneficiaries covered under such coverage) of such discontinuation at least 180 days prior to the date of the discontinuation of such coverage; and

(ii) all health insurance issued or delivered for issuance in the State in such market (or markets) are discontinued and coverage under such health insurance coverage in such market (or markets) is not renewed.

(B) PROHIBITION ON MARKET REENTRY.—In the case of a discontinuation under subparagraph (A) in a market, the issuer may not provide for the issuance of any health insurance coverage in the market and State involved during the 5-year period beginning on the date of the discontinuation of the last health insurance coverage not so renewed.

(d) EXCEPTION FOR UNIFORM MODIFICATION OF COVERAGE.—At the time of coverage renewal, a health insurance issuer may modify the health insurance coverage for a product offered to a group health plan—

(1) in the large group market; or

(2) in the small group market if, for coverage that is available in such market other than only through one or more bona fide associations, such modification is consistent with State law and effective on a uniform basis among group health plans with that product.

(e) APPLICATION TO COVERAGE OFFERED ONLY THROUGH ASSOCIATIONS.—In applying this section in the case of health insurance coverage that is made available by a health insurance issuer in the small or large group market to employers only through one or more associations, a reference to "plan sponsor" is deemed, with respect to coverage provided to an employer member of the association, to include a reference to such employer.

SEC. 2704.[300gg–3] PROHIBITION OF PREEXISTING CONDITION EXCLUSIONS OR OTHER DISCRIMINATION BASED ON HEALTH STATUS.

(a) IN GENERAL.—A group health plan and a health insurance issuer offering group or individual health insurance coverage may not impose any preexisting condition exclusion with respect to such plan or coverage.

(b) DEFINITIONS.—For purposes of this part—

(1) PREEXISTING CONDITION EXCLUSION.—

(A) IN GENERAL.—The term "preexisting condition exclusion" means, with respect to coverage, a limitation or exclusion of benefits relating to a condition based on the fact that the condition was present before the date of enrollment for such coverage, whether or not any medical advice, diagnosis, care, or treatment was recommended or received before such date.

(B) TREATMENT OF GENETIC INFORMATION.—Genetic information shall not be treated as a condition described in

subsection (a)(1) in the absence of a diagnosis of the condition related to such information.

(2) ENROLLMENT DATE.—The term "enrollment date" means, with respect to an individual covered under a group health plan or health insurance coverage, the date of enrollment of the individual in the plan or coverage or, if earlier, the first day of the waiting period for such enrollment.

(3) LATE ENROLLEE.—The term "late enrollee" means, with respect to coverage under a group health plan, a participant or beneficiary who enrolls under the plan other than during—

(A) the first period in which the individual is eligible to enroll under the plan, or

(B) a special enrollment period under subsection (f).

(4) WAITING PERIOD.—The term "waiting period" means, with respect to a group health plan and an individual who is a potential participant or beneficiary in the plan, the period that must pass with respect to the individual before the individual is eligible to be covered for benefits under the terms of the plan.

(c) RULES RELATING TO CREDITING PREVIOUS COVERAGE.—

(1) CREDITABLE COVERAGE DEFINED.—For purposes of this title, the term "creditable coverage" means, with respect to an individual, coverage of the individual under any of the following:

(A) A group health plan.

(B) Health insurance coverage.

(C) Part A or part B of title XVIII of the Social Security Act.

(D) Title XIX of the Social Security Act, other than coverage consisting solely of benefits under section 1928.

(E) Chapter 55 of title 10, United States Code.

(F) A medical care program of the Indian Health Service or of a tribal organization.

(G) A State health benefits risk pool.

(H) A health plan offered under chapter 89 of title 5, United States Code.

(I) A public health plan (as defined in regulations).

(J) A health benefit plan under section 5(e) of the Peace Corps Act (22 U.S.C. 2504(e)).

Such term does not include coverage consisting solely of coverage of excepted benefits (as defined in section 2791(c)).

(2) NOT COUNTING PERIODS BEFORE SIGNIFICANT BREAKS IN COVERAGE.—

(A) IN GENERAL.—A period of creditable coverage shall not be counted, with respect to enrollment of an individual under a group or individual health plan, if, after such period and before the enrollment date, there was a 63-day period during all of which the individual was not covered under any creditable coverage.

(B) WAITING PERIOD NOT TREATED AS A BREAK IN COVERAGE.—For purposes of subparagraph (A) and subsection (d)(4), any period that an individual is in a waiting period for any coverage under a group or individual health plan (or for group health insurance coverage) or is in an affili-

ation period (as defined in subsection (g)(2)) shall not be taken into account in determining the continuous period under subparagraph (A).

(C) TAA-ELIGIBLE INDIVIDUALS.—In the case of plan years beginning before January 1, 2014[6]—

(i) TAA PRE-CERTIFICATION PERIOD RULE.—In the case of a TAA-eligible individual, the period beginning on the date the individual has a TAA-related loss of coverage and ending on the date that is 7 days after the date of the issuance by the Secretary (or by any person or entity designated by the Secretary) of a qualified health insurance costs credit eligibility certificate for such individual for purposes of section 7527 of the Internal Revenue Code of 1986 shall not be taken into account in determining the continuous period under subparagraph (A).

(ii) DEFINITIONS.—The terms "TAA-eligible individual" and "TAA-related loss of coverage" have the meanings given such terms in section 2205(b)(4).

(3) METHOD OF CREDITING COVERAGE.—

(A) STANDARD METHOD.—Except as otherwise provided under subparagraph (B), for purposes of applying subsection (a)(3), a group health plan, and a health insurance issuer offering group or individual health insurance coverage, shall count a period of creditable coverage without regard to the specific benefits covered during the period.

(B) ELECTION OF ALTERNATIVE METHOD.—A group health plan, or a health insurance issuer offering group or individual health insurance, may elect to apply subsection (a)(3) based on coverage of benefits within each of several classes or categories of benefits specified in regulations rather than as provided under subparagraph (A). Such election shall be made on a uniform basis for all participants and beneficiaries. Under such election a group or individual health plan or issuer shall count a period of creditable coverage with respect to any class or category of benefits if any level of benefits is covered within such class or category.

(C) PLAN NOTICE.—In the case of an election with respect to a group health plan under subparagraph (B) (whether or not health insurance coverage is provided in connection with such plan), the plan shall—

(i) prominently state in any disclosure statements concerning the plan, and state to each enrollee at the time of enrollment under the plan, that the plan has made such election, and

(ii) include in such statements a description of the effect of this election.

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[6] The date specified in subparagraph (C) reflects the probable intent of Congress. Section 242(a)(4) of Public Law 112–40 provides for an amendment to section 2704(c)(2)(C) of the Public Health Service Act (as in effect for plan years beginning on or after January 1, 2014), by striking "February 13, 2011" and inserting "January 1, 2014".

The amendment made by Public Law 112–40 to section 2704(c)(2)(C), as transferred, redesignated, and amended by Public Law 111–148 (effective beginning on January 14, 2014), was carried after executing the amendment made by section 114(c) of Public Law 111–344.

(D) ISSUER NOTICE.—In the case of an election under subparagraph (B) with respect to health insurance coverage offered by an issuer in the individual or group group[7] *market, the issuer—*

(i) shall prominently state in any disclosure statements concerning the coverage, and to each employer at the time of the offer or sale of the coverage, that the issuer has made such election, and

(ii) shall include in such statements a description of the effect of such election.

(4) ESTABLISHMENT OF PERIOD.—Periods of creditable coverage with respect to an individual shall be established through presentation of certifications described in subsection (e) or in such other manner as may be specified in regulations.

(d) EXCEPTIONS.—

(1) EXCLUSION NOT APPLICABLE TO CERTAIN NEWBORNS.—Subject to paragraph (4), a group health plan, and a health insurance issuer offering group or individual health insurance coverage, may not impose any preexisting condition exclusion in the case of an individual who, as of the last day of the 30-day period beginning with the date of birth, is covered under creditable coverage.

(2) EXCLUSION NOT APPLICABLE TO CERTAIN ADOPTED CHILDREN.—Subject to paragraph (4), a group health plan, and a health insurance issuer offering group or individual health insurance coverage, may not impose any preexisting condition exclusion in the case of a child who is adopted or placed for adoption before attaining 18 years of age and who, as of the last day of the 30-day period beginning on the date of the adoption or placement for adoption, is covered under creditable coverage. The previous sentence shall not apply to coverage before the date of such adoption or placement for adoption.

(3) EXCLUSION NOT APPLICABLE TO PREGNANCY.—A group health plan, and health insurance issuer offering group or individual health insurance coverage, may not impose any preexisting condition exclusion relating to pregnancy as a preexisting condition.

(4) LOSS IF BREAK IN COVERAGE.—Paragraphs (1) and (2) shall no longer apply to an individual after the end of the first 63-day period during all of which the individual was not covered under any creditable coverage.

(e) CERTIFICATIONS AND DISCLOSURE OF COVERAGE.—

(1) REQUIREMENT FOR CERTIFICATION OF PERIOD OF CREDITABLE COVERAGE.—

(A) IN GENERAL.—A group health plan, and a health insurance issuer offering group or individual health insurance coverage, shall provide the certification described in subparagraph (B)—

(i) at the time an individual ceases to be covered under the plan or otherwise becomes covered under a COBRA continuation provision,

[7] So in law. See amendment made by section 1563(c)(1)(A)(ii)(II) (relating to conforming amendments--originally designated as section 1562 and redesignated as section 1563 by section 10107(b)(1)) of Public Law 111–148.

(ii) in the case of an individual becoming covered under such a provision, at the time the individual ceases to be covered under such provision, and

(iii) on the request on behalf of an individual made not later than 24 months after the date of cessation of the coverage described in clause (i) or (ii), whichever is later.

The certification under clause (i) may be provided, to the extent practicable, at a time consistent with notices required under any applicable COBRA continuation provision.

(B) CERTIFICATION.—The certification described in this subparagraph is a written certification of—

(i) the period of creditable coverage of the individual under such plan and the coverage (if any) under such COBRA continuation provision, and

(ii) the waiting period (if any) (and affiliation period, if applicable) imposed with respect to the individual for any coverage under such plan.

(C) ISSUER COMPLIANCE.—To the extent that medical care under a group health plan consists of group health insurance coverage, the plan is deemed to have satisfied the certification requirement under this paragraph if the health insurance issuer offering the coverage provides for such certification in accordance with this paragraph.

(2) DISCLOSURE OF INFORMATION ON PREVIOUS BENEFITS.—In the case of an election described in subsection (c)(3)(B) by a group health plan or health insurance issuer, if the plan or issuer enrolls an individual for coverage under the plan and the individual provides a certification of coverage of the individual under paragraph (1)—

(A) upon request of such plan or issuer, the entity which issued the certification provided by the individual shall promptly disclose to such requesting plan or issuer information on coverage of classes and categories of health benefits available under such entity's plan or coverage, and

(B) such entity may charge the requesting plan or issuer for the reasonable cost of disclosing such information.

(3) REGULATIONS.—The Secretary shall establish rules to prevent an entity's failure to provide information under paragraph (1) or (2) with respect to previous coverage of an individual from adversely affecting any subsequent coverage of the individual under another group health plan or health insurance coverage.

(f) SPECIAL ENROLLMENT PERIODS.—

(1) INDIVIDUALS LOSING OTHER COVERAGE.—A group health plan, and a health insurance issuer offering group health insurance coverage in connection with a group health plan, shall permit an employee who is eligible, but not enrolled, for coverage under the terms of the plan (or a dependent of such an employee if the dependent is eligible, but not enrolled, for coverage under such terms) to enroll for coverage under the terms of the plan if each of the following conditions is met:

(A) The employee or dependent was covered under a group health plan or had health insurance coverage at the time coverage was previously offered to the employee or dependent.

(B) The employee stated in writing at such time that coverage under a group health plan or health insurance coverage was the reason for declining enrollment, but only if the plan sponsor or issuer (if applicable) required such a statement at such time and provided the employee with notice of such requirement (and the consequences of such requirement) at such time.

(C) The employee's or dependent's coverage described in subparagraph (A)—

(i) was under a COBRA continuation provision and the coverage under such provision was exhausted; or

(ii) was not under such a provision and either the coverage was terminated as a result of loss of eligibility for the coverage (including as a result of legal separation, divorce, death, termination of employment, or reduction in the number of hours of employment) or employer contributions toward such coverage were terminated.

(D) Under the terms of the plan, the employee requests such enrollment not later than 30 days after the date of exhaustion of coverage described in subparagraph (C)(i) or termination of coverage or employer contribution described in subparagraph (C)(ii).

(2) FOR DEPENDENT BENEFICIARIES.—

(A) IN GENERAL.—If—

(i) a group health plan makes coverage available with respect to a dependent of an individual,

(ii) the individual is a participant under the plan (or has met any waiting period applicable to becoming a participant under the plan and is eligible to be enrolled under the plan but for a failure to enroll during a previous enrollment period), and

(iii) a person becomes such a dependent of the individual through marriage, birth, or adoption or placement for adoption,

the group health plan shall provide for a dependent special enrollment period described in subparagraph (B) during which the person (or, if not otherwise enrolled, the individual) may be enrolled under the plan as a dependent of the individual, and in the case of the birth or adoption of a child, the spouse of the individual may be enrolled as a dependent of the individual if such spouse is otherwise eligible for coverage.

(B) DEPENDENT SPECIAL ENROLLMENT PERIOD.—A dependent special enrollment period under this subparagraph shall be a period of not less than 30 days and shall begin on the later of—

(i) the date dependent coverage is made available, or

(ii) the date of the marriage, birth, or adoption or placement for adoption (as the case may be) described in subparagraph (A)(iii).

(C) NO WAITING PERIOD.—If an individual seeks to enroll a dependent during the first 30 days of such a dependent special enrollment period, the coverage of the dependent shall become effective—

(i) in the case of marriage, not later than the first day of the first month beginning after the date the completed request for enrollment is received;

(ii) in the case of a dependent's birth, as of the date of such birth; or

(iii) in the case of a dependent's adoption or placement for adoption, the date of such adoption or placement for adoption.

(3) SPECIAL RULES FOR APPLICATION IN CASE OF MEDICAID AND CHIP.—

(A) IN GENERAL.—A group health plan, and a health insurance issuer offering group health insurance coverage in connection with a group health plan, shall permit an employee who is eligible, but not enrolled, for coverage under the terms of the plan (or a dependent of such an employee if the dependent is eligible, but not enrolled, for coverage under such terms) to enroll for coverage under the terms of the plan if either of the following conditions is met:

(i) TERMINATION OF MEDICAID OR CHIP COVERAGE.—The employee or dependent is covered under a Medicaid plan under title XIX of the Social Security Act or under a State child health plan under title XXI of such Act and coverage of the employee or dependent under such a plan is terminated as a result of loss of eligibility for such coverage and the employee requests coverage under the group health plan (or health insurance coverage) not later than 60 days after the date of termination of such coverage.

(ii) ELIGIBILITY FOR EMPLOYMENT ASSISTANCE UNDER MEDICAID OR CHIP.—The employee or dependent becomes eligible for assistance, with respect to coverage under the group health plan or health insurance coverage, under such Medicaid plan or State child health plan (including under any waiver or demonstration project conducted under or in relation to such a plan), if the employee requests coverage under the group health plan or health insurance coverage not later than 60 days after the date the employee or dependent is determined to be eligible for such assistance.

(B) COORDINATION WITH MEDICAID AND CHIP.—

(i) OUTREACH TO EMPLOYEES REGARDING AVAILABILITY OF MEDICAID AND CHIP COVERAGE.—

(I) IN GENERAL.—Each employer that maintains a group health plan in a State that provides medical assistance under a State Medicaid plan under title XIX of the Social Security Act, or child health assistance under a State child health plan

under title XXI of such Act, in the form of premium assistance for the purchase of coverage under a group health plan, shall provide to each employee a written notice informing the employee of potential opportunities then currently available in the State in which the employee resides for premium assistance under such plans for health coverage of the employee or the employee's dependents. For purposes of compliance with this subclause, the employer may use any State-specific model notice developed in accordance with section 701(f)(3)(B)(i)(II) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1181(f)(3)(B)(i)(II)).

(II) OPTION TO PROVIDE CONCURRENT WITH PROVISION OF PLAN MATERIALS TO EMPLOYEE.—An employer may provide the model notice applicable to the State in which an employee resides concurrent with the furnishing of materials notifying the employee of health plan eligibility, concurrent with materials provided to the employee in connection with an open season or election process conducted under the plan, or concurrent with the furnishing of the summary plan description as provided in section 104(b) of the Employee Retirement Income Security Act of 1974.

(ii) DISCLOSURE ABOUT GROUP HEALTH PLAN BENEFITS TO STATES FOR MEDICAID AND CHIP ELIGIBLE INDIVIDUALS.—In the case of an enrollee in a group health plan who is covered under a Medicaid plan of a State under title XIX of the Social Security Act or under a State child health plan under title XXI of such Act, the plan administrator of the group health plan shall disclose to the State, upon request, information about the benefits available under the group health plan in sufficient specificity, as determined under regulations of the Secretary of Health and Human Services in consultation with the Secretary that require use of the model coverage coordination disclosure form developed under section 311(b)(1)(C) of the Children's Health Insurance Reauthorization Act of 2009, so as to permit the State to make a determination (under paragraph (2)(B), (3), or (10) of section 2105(c) of the Social Security Act or otherwise) concerning the cost-effectiveness of the State providing medical or child health assistance through premium assistance for the purchase of coverage under such group health plan and in order for the State to provide supplemental benefits required under paragraph (10)(E) of such section or other authority.

(g) USE OF AFFILIATION PERIOD BY HMOS AS ALTERNATIVE TO PREEXISTING CONDITION EXCLUSION.—

(1) IN GENERAL.—A health maintenance organization which offers health insurance coverage in connection with a group health plan and which does not impose any preexisting condi-

tion exclusion allowed under subsection (a) with respect to any particular coverage option may impose an affiliation period for such coverage option, but only if—

(A) such period is applied uniformly without regard to any health status-related factors; and

(B) such period does not exceed 2 months (or 3 months in the case of a late enrollee).

(2) AFFILIATION PERIOD.—

(A) DEFINED.—For purposes of this title, the term "affiliation period" means a period which, under the terms of the health insurance coverage offered by the health maintenance organization, must expire before the health insurance coverage becomes effective. The organization is not required to provide health care services or benefits during such period and no premium shall be charged to the participant or beneficiary for any coverage during the period.

(B) BEGINNING.—Such period shall begin on the enrollment date.

(C) RUNS CONCURRENTLY WITH WAITING PERIODS.—An affiliation period under a plan shall run concurrently with any waiting period under the plan.

(3) ALTERNATIVE METHODS.—A health maintenance organization described in paragraph (1) may use alternative methods, from those described in such paragraph, to address adverse selection as approved by the State insurance commissioner or official or officials designated by the State to enforce the requirements of this part for the State involved with respect to such issuer.

SEC. 2705.[300gg–4] PROHIBITING DISCRIMINATION AGAINST INDIVIDUAL PARTICIPANTS AND BENEFICIARIES BASED ON HEALTH STATUS.

(a) IN GENERAL.—A group health plan and a health insurance issuer offering group or individual health insurance coverage may not establish rules for eligibility (including continued eligibility) of any individual to enroll under the terms of the plan or coverage based on any of the following health status-related factors in relation to the individual or a dependent of the individual:

(1) Health status.

(2) Medical condition (including both physical and mental illnesses).

(3) Claims experience.

(4) Receipt of health care.

(5) Medical history.

(6) Genetic information.

(7) Evidence of insurability (including conditions arising out of acts of domestic violence).

(8) Disability.

(9) Any other health status-related factor determined appropriate by the Secretary.

(b) IN PREMIUM CONTRIBUTIONS.—

(1) IN GENERAL.—A group health plan, and a health insurance issuer offering group or individual health insurance coverage, may not require any individual (as a condition of enrollment or continued enrollment under the plan) to pay a pre-

mium or contribution which is greater than such premium or contribution for a similarly situated individual enrolled in the plan on the basis of any health status-related factor in relation to the individual or to an individual enrolled under the plan as a dependent of the individual.

(2) CONSTRUCTION.—Nothing in paragraph (1) shall be construed—

(A) to restrict the amount that an employer or individual may be charged for coverage under a group health plan except as provided in paragraph (3) or individual health coverage, as the case may be; or

(B) to prevent a group health plan, and a health insurance issuer offering group health insurance coverage, from establishing premium discounts or rebates or modifying otherwise applicable copayments or deductibles in return for adherence to programs of health promotion and disease prevention.

(3) NO GROUP-BASED DISCRIMINATION ON BASIS OF GENETIC INFORMATION.—

(A) IN GENERAL.—For purposes of this section, a group health plan, and health insurance issuer offering group or individual health insurance coverage, may not adjust premium or contribution amounts for the group covered under such plan on the basis of genetic information.

(B) RULE OF CONSTRUCTION.—Nothing in subparagraph (A) or in paragraphs (1) and (2) of subsection (d) shall be construed to limit the ability of a health insurance issuer offering group or individual health insurance coverage to increase the premium for an employer based on the manifestation of a disease or disorder of an individual who is enrolled in the plan. In such case, the manifestation of a disease or disorder in one individual cannot also be used as genetic information about other group members and to further increase the premium for the employer.

(c) GENETIC TESTING.—

(1) LIMITATION ON REQUESTING OR REQUIRING GENETIC TESTING.—A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, shall not request or require an individual or a family member of such individual to undergo a genetic test.

(2) RULE OF CONSTRUCTION.—Paragraph (1) shall not be construed to limit the authority of a health care professional who is providing health care services to an individual to request that such individual undergo a genetic test.

(3) RULE OF CONSTRUCTION REGARDING PAYMENT.—

(A) IN GENERAL.—Nothing in paragraph (1) shall be construed to preclude a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, from obtaining and using the results of a genetic test in making a determination regarding payment (as such term is defined for the purposes of applying the regulations promulgated by the Secretary under part C of title XI of the Social Security Act and section 264 of the Health Insurance Portability and Account-

ability Act of 1996, as may be revised from time to time) consistent with subsection (a).

(B) LIMITATION.—For purposes of subparagraph (A), a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, may request only the minimum amount of information necessary to accomplish the intended purpose.

(4) RESEARCH EXCEPTION.—Notwithstanding paragraph (1), a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, may request, but not require, that a participant or beneficiary undergo a genetic test if each of the following conditions is met:

(A) The request is made pursuant to research that complies with part 46 of title 45, Code of Federal Regulations, or equivalent Federal regulations, and any applicable State or local law or regulations for the protection of human subjects in research.

(B) The plan or issuer clearly indicates to each participant or beneficiary, or in the case of a minor child, to the legal guardian of such beneficiary, to whom the request is made that—

(i) compliance with the request is voluntary; and

(ii) non-compliance will have no effect on enrollment status or premium or contribution amounts.

(C) No genetic information collected or acquired under this paragraph shall be used for underwriting purposes.

(D) The plan or issuer notifies the Secretary in writing that the plan or issuer is conducting activities pursuant to the exception provided for under this paragraph, including a description of the activities conducted.

(E) The plan or issuer complies with such other conditions as the Secretary may by regulation require for activities conducted under this paragraph.

(d) PROHIBITION ON COLLECTION OF GENETIC INFORMATION.—

(1) IN GENERAL.—A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, shall not request, require, or purchase genetic information for underwriting purposes (as defined in section 2791).

(2) PROHIBITION ON COLLECTION OF GENETIC INFORMATION PRIOR TO ENROLLMENT.—A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, shall not request, require, or purchase genetic information with respect to any individual prior to such individual's enrollment under the plan or coverage in connection with such enrollment.

(3) INCIDENTAL COLLECTION.—If a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, obtains genetic information incidental to the requesting, requiring, or purchasing of other information concerning any individual, such request, requirement, or purchase shall not be considered a violation of

paragraph (2) if such request, requirement, or purchase is not in violation of paragraph (1).

(e) APPLICATION TO ALL PLANS.—The provisions of subsections (a)(6), (b)(3), (c), and (d) and subsection (b)(1) and section 2704 with respect to genetic information, shall apply to group health plans and health insurance issuers without regard to section 2735(a).

(f) GENETIC INFORMATION OF A FETUS OR EMBRYO.—Any reference in this part to genetic information concerning an individual or family member of an individual shall—

(1) with respect to such an individual or family member of an individual who is a pregnant woman, include genetic information of any fetus carried by such pregnant woman; and

(2) with respect to an individual or family member utilizing an assisted reproductive technology, include genetic information of any embryo legally held by the individual or family member.

(j)[8] *PROGRAMS OF HEALTH PROMOTION OR DISEASE PREVENTION.—*

(1) GENERAL PROVISIONS.—

(A) GENERAL RULE.—For purposes of subsection (b)(2)(B), a program of health promotion or disease prevention (referred to in this subsection as a "wellness program") shall be a program offered by an employer that is designed to promote health or prevent disease that meets the applicable requirements of this subsection.

(B) NO CONDITIONS BASED ON HEALTH STATUS FACTOR.—If none of the conditions for obtaining a premium discount or rebate or other reward for participation in a wellness program is based on an individual satisfying a standard that is related to a health status factor, such wellness program shall not violate this section if participation in the program is made available to all similarly situated individuals and the requirements of paragraph (2) are complied with.

(C) CONDITIONS BASED ON HEALTH STATUS FACTOR.—If any of the conditions for obtaining a premium discount or rebate or other reward for participation in a wellness program is based on an individual satisfying a standard that is related to a health status factor, such wellness program shall not violate this section if the requirements of paragraph (3) are complied with.

(2) WELLNESS PROGRAMS NOT SUBJECT TO REQUIREMENTS.—If none of the conditions for obtaining a premium discount or rebate or other reward under a wellness program as described in paragraph (1)(B) are based on an individual satisfying a standard that is related to a health status factor (or if such a wellness program does not provide such a reward), the wellness program shall not violate this section if participation in the program is made available to all similarly situated individuals. The following programs shall not have to comply with the requirements of paragraph (3) if participation in the program is made available to all similarly situated individuals:

[8] So in law. There are no subsections (g)–(i).

(A) A program that reimburses all or part of the cost for memberships in a fitness center.

(B) A diagnostic testing program that provides a reward for participation and does not base any part of the reward on outcomes.

(C) A program that encourages preventive care related to a health condition through the waiver of the copayment or deductible requirement under group health plan for the costs of certain items or services related to a health condition (such as prenatal care or well-baby visits).

(D) A program that reimburses individuals for the costs of smoking cessation programs without regard to whether the individual quits smoking.

(E) A program that provides a reward to individuals for attending a periodic health education seminar.

(3) WELLNESS PROGRAMS SUBJECT TO REQUIREMENTS.—If any of the conditions for obtaining a premium discount, rebate, or reward under a wellness program as described in paragraph (1)(C) is based on an individual satisfying a standard that is related to a health status factor, the wellness program shall not violate this section if the following requirements are complied with:

(A) The reward for the wellness program, together with the reward for other wellness programs with respect to the plan that requires satisfaction of a standard related to a health status factor, shall not exceed 30 percent of the cost of employee-only coverage under the plan. If, in addition to employees or individuals, any class of dependents (such as spouses or spouses and dependent children) may participate fully in the wellness program, such reward shall not exceed 30 percent of the cost of the coverage in which an employee or individual and any dependents are enrolled. For purposes of this paragraph, the cost of coverage shall be determined based on the total amount of employer and employee contributions for the benefit package under which the employee is (or the employee and any dependents are) receiving coverage. A reward may be in the form of a discount or rebate of a premium or contribution, a waiver of all or part of a cost-sharing mechanism (such as deductibles, copayments, or coinsurance), the absence of a surcharge, or the value of a benefit that would otherwise not be provided under the plan. The Secretaries of Labor, Health and Human Services, and the Treasury may increase the reward available under this subparagraph to up to 50 percent of the cost of coverage if the Secretaries determine that such an increase is appropriate.

(B) The wellness program shall be reasonably designed to promote health or prevent disease. A program complies with the preceding sentence if the program has a reasonable chance of improving the health of, or preventing disease in, participating individuals and it is not overly burdensome, is not a subterfuge for discriminating based on a health status factor, and is not highly suspect in the method chosen to promote health or prevent disease.

(C) The plan shall give individuals eligible for the program the opportunity to qualify for the reward under the program at least once each year.

(D) The full reward under the wellness program shall be made available to all similarly situated individuals. For such purpose, among other things:

(i) The reward is not available to all similarly situated individuals for a period unless the wellness program allows—

(I) for a reasonable alternative standard (or waiver of the otherwise applicable standard) for obtaining the reward for any individual for whom, for that period, it is unreasonably difficult due to a medical condition to satisfy the otherwise applicable standard; and

(II) for a reasonable alternative standard (or waiver of the otherwise applicable standard) for obtaining the reward for any individual for whom, for that period, it is medically inadvisable to attempt to satisfy the otherwise applicable standard.

(ii) If reasonable under the circumstances, the plan or issuer may seek verification, such as a statement from an individual's physician, that a health status factor makes it unreasonably difficult or medically inadvisable for the individual to satisfy or attempt to satisfy the otherwise applicable standard.

(E) The plan or issuer involved shall disclose in all plan materials describing the terms of the wellness program the availability of a reasonable alternative standard (or the possibility of waiver of the otherwise applicable standard) required under subparagraph (D). If plan materials disclose that such a program is available, without describing its terms, the disclosure under this subparagraph shall not be required.

(k) EXISTING PROGRAMS.—Nothing in this section shall prohibit a program of health promotion or disease prevention that was established prior to the date of enactment of this section and applied with all applicable regulations, and that is operating on such date, from continuing to be carried out for as long as such regulations remain in effect.

(l) WELLNESS PROGRAM DEMONSTRATION PROJECT.—

(1) IN GENERAL.—Not later than July 1, 2014, the Secretary, in consultation with the Secretary of the Treasury and the Secretary of Labor, shall establish a 10-State demonstration project under which participating States shall apply the provisions of subsection (j) to programs of health promotion offered by a health insurance issuer that offers health insurance coverage in the individual market in such State.

(2) EXPANSION OF DEMONSTRATION PROJECT.—If the Secretary, in consultation with the Secretary of the Treasury and the Secretary of Labor, determines that the demonstration project described in paragraph (1) is effective, such Secretaries may, beginning on July 1, 2017 expand such demonstration project to include additional participating States.

(3) REQUIREMENTS.—

(A) MAINTENANCE OF COVERAGE.—The Secretary, in consultation with the Secretary of the Treasury and the Secretary of Labor, shall not approve the participation of a State in the demonstration project under this section unless the Secretaries determine that the State's project is designed in a manner that—

(i) will not result in any decrease in coverage; and

(ii) will not increase the cost to the Federal Government in providing credits under section 36B of the Internal Revenue Code of 1986 or cost-sharing assistance under section 1402 of the Patient Protection and Affordable Care Act.

(B) OTHER REQUIREMENTS.—States that participate in the demonstration project under this subsection—

(i) may permit premium discounts or rebates or the modification of otherwise applicable copayments or deductibles for adherence to, or participation in, a reasonably designed program of health promotion and disease prevention;

(ii) shall ensure that requirements of consumer protection are met in programs of health promotion in the individual market;

(iii) shall require verification from health insurance issuers that offer health insurance coverage in the individual market of such State that premium discounts—

(I) do not create undue burdens for individuals insured in the individual market;

(II) do not lead to cost shifting; and

(III) are not a subterfuge for discrimination;

(iv) shall ensure that consumer data is protected in accordance with the requirements of section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note); and

(v) shall ensure and demonstrate to the satisfaction of the Secretary that the discounts or other rewards provided under the project reflect the expected level of participation in the wellness program involved and the anticipated effect the program will have on utilization or medical claim costs.

(m) REPORT.—

(1) IN GENERAL.—Not later than 3 years after the date of enactment of the Patient Protection and Affordable Care Act, the Secretary, in consultation with the Secretary of the Treasury and the Secretary of Labor, shall submit a report to the appropriate committees of Congress concerning—

(A) the effectiveness of wellness programs (as defined in subsection (j)) in promoting health and preventing disease;

(B) the impact of such wellness programs on the access to care and affordability of coverage for participants and non-participants of such programs;

(C) the impact of premium-based and cost-sharing incentives on participant behavior and the role of such programs in changing behavior; and

(D) the effectiveness of different types of rewards.

(2) DATA COLLECTION.—In preparing the report described in paragraph (1), the Secretaries shall gather relevant information from employers who provide employees with access to wellness programs, including State and Federal agencies.

(n) REGULATIONS.—Nothing in this section shall be construed as prohibiting the Secretaries of Labor, Health and Human Services, or the Treasury from promulgating regulations in connection with this section.

SEC. 2706.[300gg–5] NON-DISCRIMINATION IN HEALTH CARE.

(a) PROVIDERS.—A group health plan and a health insurance issuer offering group or individual health insurance coverage shall not discriminate with respect to participation under the plan or coverage against any health care provider who is acting within the scope of that provider's license or certification under applicable State law. This section shall not require that a group health plan or health insurance issuer contract with any health care provider willing to abide by the terms and conditions for participation established by the plan or issuer. Nothing in this section shall be construed as preventing a group health plan, a health insurance issuer, or the Secretary from establishing varying reimbursement rates based on quality or performance measures.

(b) INDIVIDUALS.—The provisions of section 1558 of the Patient Protection and Affordable Care Act (relating to non-discrimination) shall apply with respect to a group health plan or health insurance issuer offering group or individual health insurance coverage.

SEC. 2707.[300gg–6] COMPREHENSIVE HEALTH INSURANCE COVERAGE.

(a) COVERAGE FOR ESSENTIAL HEALTH BENEFITS PACKAGE.—A health insurance issuer that offers health insurance coverage in the individual or small group market shall ensure that such coverage includes the essential health benefits package required under section 1302(a) of the Patient Protection and Affordable Care Act.

(b) COST-SHARING UNDER GROUP HEALTH PLANS.—A group health plan shall ensure that any annual cost-sharing imposed under the plan does not exceed the limitations provided for under paragraphs (1) and (2) of section 1302(c).

(c) CHILD-ONLY PLANS.—If a health insurance issuer offers health insurance coverage in any level of coverage specified under section 1302(d) of the Patient Protection and Affordable Care Act, the issuer shall also offer such coverage in that level as a plan in which the only enrollees are individuals who, as of the beginning of a plan year, have not attained the age of 21.

(d) DENTAL ONLY.—This section shall not apply to a plan described in section 1302(d)(2)(B)(ii)(I).

SEC. 2708.[300gg–7] PROHIBITION ON EXCESSIVE WAITING PERIODS.

A group health plan and a health insurance issuer offering group health insurance coverage shall not apply any waiting period (as defined in section 2704(b)(4)) that exceeds 90 days.

SEC. 2709.[300gg–8] COVERAGE FOR INDIVIDUALS PARTICIPATING IN APPROVED CLINICAL TRIALS.[9].

(a) COVERAGE.—

(1) IN GENERAL.—If a group health plan or a health insurance issuer offering group or individual health insurance coverage provides coverage to a qualified individual, then such plan or issuer—

(A) may not deny the individual participation in the clinical trial referred to in subsection (b)(2);

(B) subject to subsection (c), may not deny (or limit or impose additional conditions on) the coverage of routine patient costs for items and services furnished in connection with participation in the trial; and

(C) may not discriminate against the individual on the basis of the individual's participation in such trial.

(2) ROUTINE PATIENT COSTS.—

(A) INCLUSION.—For purposes of paragraph (1)(B), subject to subparagraph (B), routine patient costs include all items and services consistent with the coverage provided in the plan (or coverage) that is typically covered for a qualified individual who is not enrolled in a clinical trial.

(B) EXCLUSION.—For purposes of paragraph (1)(B), routine patient costs does not include—

(i) the investigational item, device, or service, itself;

(ii) items and services that are provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient; or

(iii) a service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis.

(3) USE OF IN-NETWORK PROVIDERS.—If one or more participating providers is participating in a clinical trial, nothing in paragraph (1) shall be construed as preventing a plan or issuer from requiring that a qualified individual participate in the trial through such a participating provider if the provider will accept the individual as a participant in the trial.

(4) USE OF OUT-OF-NETWORK.—Notwithstanding paragraph (3), paragraph (1) shall apply to a qualified individual participating in an approved clinical trial that is conducted outside the State in which the qualified individual resides.

(b) QUALIFIED INDIVIDUAL DEFINED.—For purposes of subsection (a), the term "qualified individual" means an individual who is a participant or beneficiary in a health plan or with coverage described in subsection (a)(1) and who meets the following conditions:

(1) The individual is eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of cancer or other life-threatening disease or condition.

[9] So in law. There are two section 2709's. The first section 2709 (relating Disclosure of Information), was former section 2713, which was then redesignated as 2733 (by section 1001(3) of Public Law 111–148), then redesignated again to section 2709 and transfered to appear after section 2708 (by section 1563(c)(10)(C) (relating to conforming amendments--originally designated as section 1562 and redesignated as section 1563 by section 10107(b)(1)) of such Public Law).

(2) Either—

(A) the referring health care professional is a participating health care provider and has concluded that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1); or

(B) the participant or beneficiary provides medical and scientific information establishing that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1).

(c) LIMITATIONS ON COVERAGE.—This section shall not be construed to require a group health plan, or a health insurance issuer offering group or individual health insurance coverage, to provide benefits for routine patient care services provided outside of the plan's (or coverage's) health care provider network unless out-of-network benefits are otherwise provided under the plan (or coverage).

(d) APPROVED CLINICAL TRIAL DEFINED.—

(1) IN GENERAL.—In this section, the term "approved clinical trial" means a phase I, phase II, phase III, or phase IV clinical trial that is conducted in relation to the prevention, detection, or treatment of cancer or other life-threatening disease or condition and is described in any of the following subparagraphs:

(A) FEDERALLY FUNDED TRIALS.—The study or investigation is approved or funded (which may include funding through in-kind contributions) by one or more of the following:

(i) The National Institutes of Health.

(ii) The Centers for Disease Control and Prevention.

(iii) The Agency for Health Care Research and Quality.

(iv) The Centers for Medicare & Medicaid Services.

(v) cooperative group or center of any of the entities described in clauses (i) through (iv) or the Department of Defense or the Department of Veterans Affairs.

(vi) A qualified non-governmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants.

(vii) Any of the following if the conditions described in paragraph (2) are met:

(I) The Department of Veterans Affairs.

(II) The Department of Defense.

(III) The Department of Energy.

(B) The study or investigation is conducted under an investigational new drug application reviewed by the Food and Drug Administration.

(C) The study or investigation is a drug trial that is exempt from having such an investigational new drug application.

(2) CONDITIONS FOR DEPARTMENTS.—The conditions described in this paragraph, for a study or investigation conducted by a Department, are that the study or investigation has

been reviewed and approved through a system of peer review that the Secretary determines—

(A) to be comparable to the system of peer review of studies and investigations used by the National Institutes of Health, and

(B) assures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review.

(e) LIFE-THREATENING CONDITION DEFINED.—In this section, the term "life-threatening condition" means any disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted.

(f) CONSTRUCTION.—Nothing in this section shall be construed to limit a plan's or issuer's coverage with respect to clinical trials.

(g) APPLICATION TO FEHBP.—Notwithstanding any provision of chapter 89 of title 5, United States Code, this section shall apply to health plans offered under the program under such chapter.

(h) PREEMPTION.—Notwithstanding any other provision of this Act, nothing in this section shall preempt State laws that require a clinical trials policy for State regulated health insurance plans that is in addition to the policy required under this section.

SEC. 2709.[300gg–9] DISCLOSURE OF INFORMATION.

(a) DISCLOSURE OF INFORMATION BY HEALTH PLAN ISSUERS.—In connection with the offering of any health insurance coverage to a small employer or an individual, a health insurance issuer—

(1) shall make a reasonable disclosure to such employer,,[10] or individual, as applicable, as part of its solicitation and sales materials, of the availability of information described in subsection (b), and

(2) upon request of such a employer, or individual, as applicable,, or individual, as applicable, provide such information.

(b) INFORMATION DESCRIBED.—

(1) IN GENERAL.—Subject to paragraph (3), with respect to a health insurance issuer offering health insurance coverage to a employer, or individual, as applicable,, information described in this subsection is information concerning—

(A) the provisions of such coverage concerning issuer's right to change premium rates and the factors that may affect changes in premium rates; and

(B) the benefits and premiums available under all health insurance coverage for which the employer, or individual, as applicable, is qualified.

(2) FORM OF INFORMATION.—Information under this subsection shall be provided to employers, or individuals, as applicable, in a manner determined to be understandable by the average employer, or individual, as applicable,, and shall be sufficient to reasonably inform employers, or individuals, as applicable, of their rights and obligations under the health insurance coverage.

[10] So in law.

(3) EXCEPTION.—An issuer is not required under this section to disclose any information that is proprietary and trade secret information under applicable law.

Subpart II—Improving Coverage [11]

(C) in exercising the option to discontinue coverage of this type and in offering the option of coverage under subparagraph (B), the issuer acts uniformly without regard to the claims experience of those sponsors or individuals, as applicable, or any health status-related factor relating to any participants or beneficiaries covered or new participants or beneficiaries who may become eligible for such coverage.

(2) DISCONTINUANCE OF ALL COVERAGE.—

(A) IN GENERAL.—In any case in which a health insurance issuer elects to discontinue offering all health insurance coverage in the individual or group market, or all markets, in a State, health insurance coverage may be discontinued by the issuer only in accordance with applicable State law and if—

(i) the issuer provides notice to the applicable State authority and to each plan sponsor or individual, as applicable, (and participants and beneficiaries covered under such coverage) of such discontinuation at least 180 days prior to the date of the discontinuation of such coverage; and

(ii) all health insurance issued or delivered for issuance in the State in such market (or markets) are discontinued and coverage under such health insurance coverage in such market (or markets) is not renewed.

(B) PROHIBITION ON MARKET REENTRY.—In the case of a discontinuation under subparagraph (A) in a market, the issuer may not provide for the issuance of any health insurance coverage in the market and State involved during the 5-year period beginning on the date of the discontinuation of the last health insurance coverage not so renewed.

(d) EXCEPTION FOR UNIFORM MODIFICATION OF COVERAGE.—At the time of coverage renewal, a health insurance issuer may modify the health insurance coverage for a product offered to a group health plan—

(1) in the large group market; or

(2) in the small group market if, for coverage that is available in such market other than only through one or more bona fide associations, such modification is consistent with State law and effective on a uniform basis among group health plans with that product.

(e) APPLICATION TO COVERAGE OFFERED ONLY THROUGH ASSOCIATIONS.—In applying this section in the case of health insurance coverage that is made available by a health insurance issuer in the small or large group market to employers only through one or more associations, a reference to "plan sponsor" is deemed, with respect to coverage provided to an employer member of the association, to include a reference to such employer.

[11] There is a subpart 2 (arabic 2) beginning with section 2722.

SEC. 2704.[300gg–3] PROHIBITION OF PREEXISTING CONDITION EX-

(1) evidence-based items or services that have in effect a rating of "A" or "B" in the current recommendations of the United States Preventive Services Task Force;

(2) immunizations that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved; and

(3) with respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in the comprehensive guidelines supported by the Health Resources and Services Administration.

(4) with respect to women, such additional preventive care and screenings not described in paragraph (1) as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of this paragraph.

(5) for the purposes of this Act, and for the purposes of any other provision of law, the current recommendations of the United States Preventive Service Task Force regarding breast cancer screening, mammography, and prevention shall be considered the most current other than those issued in or around November 2009.

Nothing in this subsection shall be construed to prohibit a plan or issuer from providing coverage for services in addition to those recommended by United States Preventive Services Task Force or to deny coverage for services that are not recommended by such Task Force.

(b) INTERVAL.—

(1) IN GENERAL.—The Secretary shall establish a minimum interval between the date on which a recommendation described in subsection (a)(1) or (a)(2) or a guideline under subsection (a)(3) is issued and the plan year with respect to which the requirement described in subsection (a) is effective with respect to the service described in such recommendation or guideline.

(2) MINIMUM.—The interval described in paragraph (1) shall not be less than 1 year.

(c) VALUE-BASED INSURANCE DESIGN.—The Secretary may develop guidelines to permit a group health plan and a health insurance issuer offering group or individual health insurance coverage to utilize value-based insurance designs.

SEC. 2714.[300gg–14] EXTENSION OF DEPENDENT COVERAGE.

(a) IN GENERAL.—A group health plan and a health insurance issuer offering group or individual health insurance coverage that provides dependent coverage of children shall continue to make such coverage available for an adult child until the child turns 26 years of age. Nothing in this section shall require a health plan or a health insurance issuer described in the preceding sentence to make coverage available for a child of a child receiving dependent coverage.

(b) REGULATIONS.—The Secretary shall promulgate regulations to define the dependents to which coverage shall be made available under subsection (a).

(c) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to modify the definition of "dependent" as used in the In-

ternal Revenue Code of 1986 with respect to the tax treatment of the cost of coverage.

SEC. 2715.[300gg–15] DEVELOPMENT AND UTILIZATION OF UNIFORM EXPLANATION OF COVERAGE DOCUMENTS AND STANDARDIZED DEFINITIONS.

(a) IN GENERAL.—Not later than 12 months after the date of enactment of the Patient Protection and Affordable Care Act, the Secretary shall develop standards for use by a group health plan and a health insurance issuer offering group or individual health insurance coverage, in compiling and providing to applicants, enrollees, and policyholders or certificate holders a summary of benefits and coverage explanation that accurately describes the benefits and coverage under the applicable plan or coverage. In developing such standards, the Secretary shall consult with the National Association of Insurance Commissioners (referred to in this section as the "NAIC"), a working group composed of representatives of health insurance-related consumer advocacy organizations, health insurance issuers, health care professionals, patient advocates including those representing individuals with limited English proficiency, and other qualified individuals.

(b) REQUIREMENTS.—The standards for the summary of benefits and coverage developed under subsection (a) shall provide for the following:

(1) APPEARANCE.—The standards shall ensure that the summary of benefits and coverage is presented in a uniform format that does not exceed 4 pages in length and does not include print smaller than 12-point font.

(2) LANGUAGE.—The standards shall ensure that the summary is presented in a culturally and linguistically appropriate manner and utilizes terminology understandable by the average plan enrollee.

(3) CONTENTS.—The standards shall ensure that the summary of benefits and coverage includes—

(A) uniform definitions of standard insurance terms and medical terms (consistent with subsection (g)) so that consumers may compare health insurance coverage and understand the terms of coverage (or exception to such coverage);

(B) a description of the coverage, including cost sharing for—

(i) each of the categories of the essential health benefits described in subparagraphs (A) through (J) of section 1302(b)(1) of the Patient Protection and Affordable Care Act; and

(ii) other benefits, as identified by the Secretary;

(C) the exceptions, reductions, and limitations on coverage;

(D) the cost-sharing provisions, including deductible, coinsurance, and co-payment obligations;

(E) the renewability and continuation of coverage provisions;

(F) a coverage facts label that includes examples to illustrate common benefits scenarios, including pregnancy and serious or chronic medical conditions and related cost

sharing, such scenarios to be based on recognized clinical practice guidelines;

(G) a statement of whether the plan or coverage—

(i) provides minimum essential coverage (as defined under section 5000A(f) of the Internal Revenue Code 1986); and

(ii) ensures that the plan or coverage share of the total allowed costs of benefits provided under the plan or coverage is not less than 60 percent of such costs;

(H) a statement that the outline is a summary of the policy or certificate and that the coverage document itself should be consulted to determine the governing contractual provisions; and

(I) a contact number for the consumer to call with additional questions and an Internet web address where a copy of the actual individual coverage policy or group certificate of coverage can be reviewed and obtained.

(c) PERIODIC REVIEW AND UPDATING.—The Secretary shall periodically review and update, as appropriate, the standards developed under this section.

(d) REQUIREMENT TO PROVIDE.—

(1) IN GENERAL.—Not later than 24 months after the date of enactment of the Patient Protection and Affordable Care Act, each entity described in paragraph (3) shall provide, prior to any enrollment restriction, a summary of benefits and coverage explanation pursuant to the standards developed by the Secretary under subsection (a) to—

(A) an applicant at the time of application;

(B) an enrollee prior to the time of enrollment or reenrollment, as applicable; and

(C) a policyholder or certificate holder at the time of issuance of the policy or delivery of the certificate.

(2) COMPLIANCE.—An entity described in paragraph (3) is deemed to be in compliance with this section if the summary of benefits and coverage described in subsection (a) is provided in paper or electronic form.

(3) ENTITIES IN GENERAL.—An entity described in this paragraph is—

(A) a health insurance issuer (including a group health plan that is not a self-insured plan) offering health insurance coverage within the United States; or

(B) in the case of a self-insured group health plan, the plan sponsor or designated administrator of the plan (as such terms are defined in section 3(16) of the Employee Retirement Income Security Act of 1974).

(4) NOTICE OF MODIFICATIONS.—If a group health plan or health insurance issuer makes any material modification in any of the terms of the plan or coverage involved (as defined for purposes of section 102 of the Employee Retirement Income Security Act of 1974) that is not reflected in the most recently provided summary of benefits and coverage, the plan or issuer shall provide notice of such modification to enrollees not later than 60 days prior to the date on which such modification will become effective.

(e) PREEMPTION.—The standards developed under subsection (a) shall preempt any related State standards that require a summary of benefits and coverage that provides less information to consumers than that required to be provided under this section, as determined by the Secretary.

(f) FAILURE TO PROVIDE.—An entity described in subsection (d)(3) that willfully fails to provide the information required under this section shall be subject to a fine of not more than $1,000 for each such failure. Such failure with respect to each enrollee shall constitute a separate offense for purposes of this subsection.

(g) DEVELOPMENT OF STANDARD DEFINITIONS.—

(1) IN GENERAL.—The Secretary shall, by regulation, provide for the development of standards for the definitions of terms used in health insurance coverage, including the insurance-related terms described in paragraph (2) and the medical terms described in paragraph (3).

(2) INSURANCE-RELATED TERMS.—The insurance-related terms described in this paragraph are premium, deductible, coinsurance, co-payment, out-of-pocket limit, preferred provider, non-preferred provider, out-of-network co-payments, UCR (usual, customary and reasonable) fees, excluded services, grievance and appeals, and such other terms as the Secretary determines are important to define so that consumers may compare health insurance coverage and understand the terms of their coverage.

(3) MEDICAL TERMS.—The medical terms described in this paragraph are hospitalization, hospital outpatient care, emergency room care, physician services, prescription drug coverage, durable medical equipment, home health care, skilled nursing care, rehabilitation services, hospice services, emergency medical transportation, and such other terms as the Secretary determines are important to define so that consumers may compare the medical benefits offered by health insurance and understand the extent of those medical benefits (or exceptions to those benefits).

SEC. 2715A.[300gg–15a] PROVISION OF ADDITIONAL INFORMATION.

A group health plan and a health insurance issuer offering group or individual health insurance coverage shall comply with the provisions of section 1311(e)(3) of the Patient Protection and Affordable Care Act, except that a plan or coverage that is not offered through an Exchange shall only be required to submit the information required to the Secretary and the State insurance commissioner, and make such information available to the public.

SEC. 2716.[300gg–16] PROHIBITION ON DISCRIMINATION IN FAVOR OF HIGHLY COMPENSATED INDIVIDUALS.

(a) IN GENERAL.—A group health plan (other than a self-insured plan) shall satisfy the requirements of section 105(h)(2) of the Internal Revenue Code of 1986 (relating to prohibition on discrimination in favor of highly compensated individuals).

(b) RULES AND DEFINITIONS.—For purposes of this section—

(1) CERTAIN RULES TO APPLY.—Rules similar to the rules contained in paragraphs (3), (4), and (8) of section 105(h) of such Code shall apply.

(2) HIGHLY COMPENSATED INDIVIDUAL.—The term "highly compensated individual" has the meaning given such term by section 105(h)(5) of such Code.

SEC. 2717.[300gg–17] ENSURING THE QUALITY OF CARE.

(a) QUALITY REPORTING.—

(1) IN GENERAL.—Not later than 2 years after the date of enactment of the Patient Protection and Affordable Care Act, the Secretary, in consultation with experts in health care quality and stakeholders, shall develop reporting requirements for use by a group health plan, and a health insurance issuer offering group or individual health insurance coverage, with respect to plan or coverage benefits and health care provider reimbursement structures that—

(A) improve health outcomes through the implementation of activities such as quality reporting, effective case management, care coordination, chronic disease management, and medication and care compliance initiatives, including through the use of the medical homes model as defined for purposes of section 3602 of the Patient Protection and Affordable Care Act, for treatment or services under the plan or coverage;

(B) implement activities to prevent hospital readmissions through a comprehensive program for hospital discharge that includes patient-centered education and counseling, comprehensive discharge planning, and post discharge reinforcement by an appropriate health care professional;

(C) implement activities to improve patient safety and reduce medical errors through the appropriate use of best clinical practices, evidence based medicine, and health information technology under the plan or coverage; and

(D) implement wellness and health promotion activities.

(2) REPORTING REQUIREMENTS.—

(A) IN GENERAL.—A group health plan and a health insurance issuer offering group or individual health insurance coverage shall annually submit to the Secretary, and to enrollees under the plan or coverage, a report on whether the benefits under the plan or coverage satisfy the elements described in subparagraphs (A) through (D) of paragraph (1).

(B) TIMING OF REPORTS.—A report under subparagraph (A) shall be made available to an enrollee under the plan or coverage during each open enrollment period.

(C) AVAILABILITY OF REPORTS.—The Secretary shall make reports submitted under subparagraph (A) available to the public through an Internet website.

(D) PENALTIES.—In developing the reporting requirements under paragraph (1), the Secretary may develop and impose appropriate penalties for non-compliance with such requirements.

(E) EXCEPTIONS.—In developing the reporting requirements under paragraph (1), the Secretary may provide for

exceptions to such requirements for group health plans and health insurance issuers that substantially meet the goals of this section.

(b) WELLNESS AND PREVENTION PROGRAMS.—For purposes of subsection (a)(1)(D), wellness and health promotion activities may include personalized wellness and prevention services, which are coordinated, maintained or delivered by a health care provider, a wellness and prevention plan manager, or a health, wellness or prevention services organization that conducts health risk assessments or offers ongoing face-to-face, telephonic or web-based intervention efforts for each of the program's participants, and which may include the following wellness and prevention efforts:

(1) Smoking cessation.

(2) Weight management.

(3) Stress management.

(4) Physical fitness.

(5) Nutrition.

(6) Heart disease prevention.

(7) Healthy lifestyle support.

(8) Diabetes prevention.

(c) PROTECTION OF SECOND AMENDMENT GUN RIGHTS.—

(1) WELLNESS AND PREVENTION PROGRAMS.—A wellness and health promotion activity implemented under subsection (a)(1)(D) may not require the disclosure or collection of any information relating to—

(A) the presence or storage of a lawfully-possessed firearm or ammunition in the residence or on the property of an individual; or

(B) the lawful use, possession, or storage of a firearm or ammunition by an individual.

(2) LIMITATION ON DATA COLLECTION.—None of the authorities provided to the Secretary under the Patient Protection and Affordable Care Act or an amendment made by that Act shall be construed to authorize or may be used for the collection of any information relating to—

(A) the lawful ownership or possession of a firearm or ammunition;

(B) the lawful use of a firearm or ammunition; or

(C) the lawful storage of a firearm or ammunition.

(3) LIMITATION ON DATABASES OR DATA BANKS.—None of the authorities provided to the Secretary under the Patient Protection and Affordable Care Act or an amendment made by that Act shall be construed to authorize or may be used to maintain records of individual ownership or possession of a firearm or ammunition.

(4) LIMITATION ON DETERMINATION OF PREMIUM RATES OR ELIGIBILITY FOR HEALTH INSURANCE.—A premium rate may not be increased, health insurance coverage may not be denied, and a discount, rebate, or reward offered for participation in a wellness program may not be reduced or withheld under any health benefit plan issued pursuant to or in accordance with the Patient Protection and Affordable Care Act or an amendment made by that Act on the basis of, or on reliance upon—

(A) the lawful ownership or possession of a firearm or ammunition; or

(B) the lawful use or storage of a firearm or ammunition.

(5) LIMITATION ON DATA COLLECTION REQUIREMENTS FOR INDIVIDUALS.—No individual shall be required to disclose any information under any data collection activity authorized under the Patient Protection and Affordable Care Act or an amendment made by that Act relating to—

(A) the lawful ownership or possession of a firearm or ammunition; or

(B) the lawful use, possession, or storage of a firearm or ammunition.

(d) REGULATIONS.—Not later than 2 years after the date of enactment of the Patient Protection and Affordable Care Act, the Secretary shall promulgate regulations that provide criteria for determining whether a reimbursement structure is described in subsection (a).

(e) STUDY AND REPORT.—Not later than 180 days after the date on which regulations are promulgated under subsection (c), the Government Accountability Office shall review such regulations and conduct a study and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report regarding the impact the activities under this section have had on the quality and cost of health care.

SEC. 2718.[300gg–18] BRINGING DOWN THE COST OF HEALTH CARE COVERAGE.

(a) CLEAR ACCOUNTING FOR COSTS.—A health insurance issuer offering group or individual health insurance coverage (including a grandfathered health plan) shall, with respect to each plan year, submit to the Secretary a report concerning the ratio of the incurred loss (or incurred claims) plus the loss adjustment expense (or change in contract reserves) to earned premiums. Such report shall include the percentage of total premium revenue, after accounting for collections or receipts for risk adjustment and risk corridors and payments of reinsurance, that such coverage expends—

(1) on reimbursement for clinical services provided to enrollees under such coverage;

(2) for activities that improve health care quality; and

(3) on all other non-claims costs, including an explanation of the nature of such costs, and excluding Federal and State taxes and licensing or regulatory fees.

The Secretary shall make reports received under this section available to the public on the Internet website of the Department of Health and Human Services.

(b) ENSURING THAT CONSUMERS RECEIVE VALUE FOR THEIR PREMIUM PAYMENTS.—

(1) REQUIREMENT TO PROVIDE VALUE FOR PREMIUM PAYMENTS.—

(A) REQUIREMENT.—Beginning not later than January 1, 2011, a health insurance issuer offering group or individual health insurance coverage (including a grandfathered health plan) shall, with respect to each plan year,

provide an annual rebate to each enrollee under such coverage, on a pro rata basis, if the ratio of the amount of premium revenue expended by the issuer on costs described in paragraphs (1) and (2) of subsection (a) to the total amount of premium revenue (excluding Federal and State taxes and licensing or regulatory fees and after accounting for payments or receipts for risk adjustment, risk corridors, and reinsurance under sections 1341, 1342, and 1343 of the Patient Protection and Affordable Care Act) for the plan year (except as provided in subparagraph (B)(ii)), is less than—

(i) with respect to a health insurance issuer offering coverage in the large group market, 85 percent, or such higher percentage as a State may by regulation determine; or

(ii) with respect to a health insurance issuer offering coverage in the small group market or in the individual market, 80 percent, or such higher percentage as a State may by regulation determine, except that the Secretary may adjust such percentage with respect to a State if the Secretary determines that the application of such 80 percent may destabilize the individual market in such State.

(B) REBATE AMOUNT.—

(i) CALCULATION OF AMOUNT.—The total amount of an annual rebate required under this paragraph shall be in an amount equal to the product of—

(I) the amount by which the percentage described in clause (i) or (ii) of subparagraph (A) exceeds the ratio described in such subparagraph; and

(II) the total amount of premium revenue (excluding Federal and State taxes and licensing or regulatory fees and after accounting for payments or receipts for risk adjustment, risk corridors, and reinsurance under sections 1341, 1342, and 1343 of the Patient Protection and Affordable Care Act) for such plan year.

(ii) CALCULATION BASED ON AVERAGE RATIO.—Beginning on January 1, 2014, the determination made under subparagraph (A) for the year involved shall be based on the averages of the premiums expended on the costs described in such subparagraph and total premium revenue for each of the previous 3 years for the plan.

(2) CONSIDERATION IN SETTING PERCENTAGES.—In determining the percentages under paragraph (1), a State shall seek to ensure adequate participation by health insurance issuers, competition in the health insurance market in the State, and value for consumers so that premiums are used for clinical services and quality improvements.

(3) ENFORCEMENT.—The Secretary shall promulgate regulations for enforcing the provisions of this section and may provide for appropriate penalties.

(c) DEFINITIONS.—Not later than December 31, 2010, and subject to the certification of the Secretary, the National Association of Insurance Commissioners shall establish uniform definitions of the activities reported under subsection (a) and standardized methodologies for calculating measures of such activities, including definitions of which activities, and in what regard such activities, constitute activities described in subsection (a)(2). Such methodologies shall be designed to take into account the special circumstances of smaller plans, different types of plans, and newer plans.

(d) ADJUSTMENTS.—The Secretary may adjust the rates described in subsection (b) if the Secretary determines appropriate on account of the volatility of the individual market due to the establishment of State Exchanges.

(e) STANDARD HOSPITAL CHARGES.—Each hospital operating within the United States shall for each year establish (and update) and make public (in accordance with guidelines developed by the Secretary) a list of the hospital's standard charges for items and services provided by the hospital, including for diagnosis-related groups established under section 1886(d)(4) of the Social Security Act.

SEC. 2719.[300gg–19] APPEALS PROCESS.

(a) INTERNAL CLAIMS APPEALS.—

(1) IN GENERAL.—A group health plan and a health insurance issuer offering group or individual health insurance coverage shall implement an effective appeals process for appeals of coverage determinations and claims, under which the plan or issuer shall, at a minimum—

(A) have in effect an internal claims appeal process;

(B) provide notice to enrollees, in a culturally and linguistically appropriate manner, of available internal and external appeals processes, and the availability of any applicable office of health insurance consumer assistance or ombudsman established under section 2793 to assist such enrollees with the appeals processes; and

(C) allow an enrollee to review their file, to present evidence and testimony as part of the appeals process, and to receive continued coverage pending the outcome of the appeals process.

(2) ESTABLISHED PROCESSES.—To comply with paragraph (1)—

(A) a group health plan and a health insurance issuer offering group health coverage shall provide an internal claims and appeals process that initially incorporates the claims and appeals procedures (including urgent claims) set forth at section 2560.503–1 of title 29, Code of Federal Regulations, as published on November 21, 2000 (65 Fed. Reg. 70256), and shall update such process in accordance with any standards established by the Secretary of Labor for such plans and issuers; and

(B) a health insurance issuer offering individual health coverage, and any other issuer not subject to subparagraph (A), shall provide an internal claims and appeals process that initially incorporates the claims and appeals proce-

dures set forth under applicable law (as in existence on the date of enactment of this section), and shall update such process in accordance with any standards established by the Secretary of Health and Human Services for such issuers.

(b) EXTERNAL REVIEW.—A group health plan and a health insurance issuer offering group or individual health insurance coverage—

(1) shall comply with the applicable State external review process for such plans and issuers that, at a minimum, includes the consumer protections set forth in the Uniform External Review Model Act promulgated by the National Association of Insurance Commissioners and is binding on such plans; or

(2) shall implement an effective external review process that meets minimum standards established by the Secretary through guidance and that is similar to the process described under paragraph (1)—

(A) if the applicable State has not established an external review process that meets the requirements of paragraph (1); or

(B) if the plan is a self-insured plan that is not subject to State insurance regulation (including a State law that establishes an external review process described in paragraph (1)).

(c) SECRETARY AUTHORITY.—The Secretary may deem the external review process of a group health plan or health insurance issuer, in operation as of the date of enactment of this section, to be in compliance with the applicable process established under subsection (b), as determined appropriate by the Secretary.

SEC. 2719A.[300gg–19a] PATIENT PROTECTIONS.

(a) CHOICE OF HEALTH CARE PROFESSIONAL.—If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, requires or provides for designation by a participant, beneficiary, or enrollee of a participating primary care provider, then the plan or issuer shall permit each participant, beneficiary, and enrollee to designate any participating primary care provider who is available to accept such individual.

(b) COVERAGE OF EMERGENCY SERVICES.—

(1) IN GENERAL.—If a group health plan, or a health insurance issuer offering group or individual health insurance issuer, provides or covers any benefits with respect to services in an emergency department of a hospital, the plan or issuer shall cover emergency services (as defined in paragraph (2)(B))—

(A) without the need for any prior authorization determination;

(B) whether the health care provider furnishing such services is a participating provider with respect to such services;

(C) in a manner so that, if such services are provided to a participant, beneficiary, or enrollee—

(i) by a nonparticipating health care provider with or without prior authorization; or

(ii)(I) such services will be provided without imposing any requirement under the plan for prior authorization of services or any limitation on coverage where the provider of services does not have a contractual relationship with the plan for the providing of services that is more restrictive than the requirements or limitations that apply to emergency department services received from providers who do have such a contractual relationship with the plan; and

(II) if such services are provided out-of-network, the cost-sharing requirement (expressed as a copayment amount or coinsurance rate) is the same requirement that would apply if such services were provided in-network;[12]

(D) without regard to any other term or condition of such coverage (other than exclusion or coordination of benefits, or an affiliation or waiting period, permitted under section 2701 of this Act, section 701 of the Employee Retirement Income Security Act of 1974, or section 9801 of the Internal Revenue Code of 1986, and other than applicable cost-sharing).

(2) DEFINITIONS.—In this subsection:

(A) EMERGENCY MEDICAL CONDITION.—The term "emergency medical condition" means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act.

(B) EMERGENCY SERVICES.—The term "emergency services" means, with respect to an emergency medical condition—

(i) a medical screening examination (as required under section 1867 of the Social Security Act) that is within the capability of the emergency department of a hospital, including ancillary services routinely available to the emergency department to evaluate such emergency medical condition, and

(ii) within the capabilities of the staff and facilities available at the hospital, such further medical examination and treatment as are required under section 1867 of such Act to stabilize the patient.

(C) STABILIZE.—The term "to stabilize", with respect to an emergency medical condition (as defined in subparagraph (A)), has the meaning give in section 1867(e)(3) of the Social Security Act (42 U.S.C. 1395dd(e)(3)).

(c) ACCESS TO PEDIATRIC CARE.—

(1) PEDIATRIC CARE.—In the case of a person who has a child who is a participant, beneficiary, or enrollee under a group health plan, or health insurance coverage offered by a health insurance issuer in the group or individual market, if

[12] Probably should read "; and".

the plan or issuer requires or provides for the designation of a participating primary care provider for the child, the plan or issuer shall permit such person to designate a physician (allopathic or osteopathic) who specializes in pediatrics as the child's primary care provider if such provider participates in the network of the plan or issuer.

(2) CONSTRUCTION.—Nothing in paragraph (1) shall be construed to waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of pediatric care.

(d) PATIENT ACCESS TO OBSTETRICAL AND GYNECOLOGICAL CARE.—

(1) GENERAL RIGHTS.—

(A) DIRECT ACCESS.—A group health plan, or health insurance issuer offering group or individual health insurance coverage, described in paragraph (2) may not require authorization or referral by the plan, issuer, or any person (including a primary care provider described in paragraph (2)(B)) in the case of a female participant, beneficiary, or enrollee who seeks coverage for obstetrical or gynecological care provided by a participating health care professional who specializes in obstetrics or gynecology. Such professional shall agree to otherwise adhere to such plan's or issuer's policies and procedures, including procedures regarding referrals and obtaining prior authorization and providing services pursuant to a treatment plan (if any) approved by the plan or issuer.

(B) OBSTETRICAL AND GYNECOLOGICAL CARE.—A group health plan or health insurance issuer described in paragraph (2) shall treat the provision of obstetrical and gynecological care, and the ordering of related obstetrical and gynecological items and services, pursuant to the direct access described under subparagraph (A), by a participating health care professional who specializes in obstetrics or gynecology as the authorization of the primary care provider.

(2) APPLICATION OF PARAGRAPH.—A group health plan, or health insurance issuer offering group or individual health insurance coverage, described in this paragraph is a group health plan or coverage that—

(A) provides coverage for obstetric or gynecologic care; and

(B) requires the designation by a participant, beneficiary, or enrollee of a participating primary care provider.

(3) CONSTRUCTION.—Nothing in paragraph (1) shall be construed to—

(A) waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of obstetrical or gynecological care; or

(B) preclude the group health plan or health insurance issuer involved from requiring that the obstetrical or gynecological provider notify the primary care health care professional or the plan or issuer of treatment decisions.

SEC. 2725. [13]***[300gg–25] STANDARDS RELATING TO BENEFITS FOR MOTHERS AND NEWBORNS.***

(a) REQUIREMENTS FOR MINIMUM HOSPITAL STAY FOLLOWING BIRTH.—

(1) IN GENERAL.—A group health plan, and a health insurance issuer offering group or individual health insurance coverage, may not—

(A) except as provided in paragraph (2)—

(i) restrict benefits for any hospital length of stay in connection with childbirth for the mother or newborn child, following a normal vaginal delivery, to less than 48 hours, or

(ii) restrict benefits for any hospital length of stay in connection with childbirth for the mother or newborn child, following a cesarean section, to less than 96 hours, or

(B) require that a provider obtain authorization from the plan or the issuer for prescribing any length of stay required under subparagraph (A) (without regard to paragraph (2)).

(2) EXCEPTION.—Paragraph (1)(A) shall not apply in connection with any group health plan or health insurance issuer in any case in which the decision to discharge the mother or her newborn child prior to the expiration of the minimum length of stay otherwise required under paragraph (1)(A) is made by an attending provider in consultation with the mother.

(b) PROHIBITIONS.—A group health plan, and a health insurance issuer offering group or individual health insurance coverage, may not—

(1) deny to the mother or her newborn child eligibility, or continued eligibility, to enroll or to renew coverage under the terms of the plan or coverage, solely for the purpose of avoiding the requirements of this section;

(2) provide monetary payments or rebates to mothers to encourage such mothers to accept less than the minimum protections available under this section;

(3) penalize or otherwise reduce or limit the reimbursement of an attending provider because such provider provided care to an individual participant or beneficiary in accordance with this section;

(4) provide incentives (monetary or otherwise) to an attending provider to induce such provider to provide care to an individual participant or beneficiary in a manner inconsistent with this section; or

(5) subject to subsection (c)(3), restrict benefits for any portion of a period within a hospital length of stay required under subsection (a) in a manner which is less favorable than the benefits provided for any preceding portion of such stay.

(c) RULES OF CONSTRUCTION.—

[13] The placement of this section and succeeding sections 2726, 2727, and 2728 here, versus after section 2724, is ambiguous insofar as these sections at the time of their redesignation from sections 2704–2708 were not explicitly moved to follow section 2724, yet the failure to place them after section 2724 results in these sections not following ordinary sequential numbering.

(1) Nothing in this section shall be construed to require a mother who is a participant or beneficiary—

(A) to give birth in a hospital; or

(B) to stay in the hospital for a fixed period of time following the birth of her child.

(2) This section shall not apply with respect to any group health plan, or any health insurance issuer offering group or individual health insurance coverage, which does not provide benefits for hospital lengths of stay in connection with childbirth for a mother or her newborn child.

(3) Nothing in this section shall be construed as preventing a group health plan or health insurance issuer from imposing deductibles, coinsurance, or other cost-sharing in relation to benefits for hospital lengths of stay in connection with childbirth for a mother or newborn child under the plan (or under health insurance coverage offered in connection with a group health plan), except that such coinsurance or other cost-sharing for any portion of a period within a hospital length of stay required under subsection (a) may not be greater than such coinsurance or cost-sharing for any preceding portion of such stay.

(d) NOTICE.—A group health plan under this part shall comply with the notice requirement under section 711(d) of the Employee Retirement Income Security Act of 1974 with respect to the requirements of this section as if such section applied to such plan.

(e) LEVEL AND TYPE OF REIMBURSEMENTS.—Nothing in this section shall be construed to prevent a group health plan or a health insurance issuer offering group or individual health insurance coverage from negotiating the level and type of reimbursement with a provider for care provided in accordance with this section.

(f) PREEMPTION; EXCEPTION FOR HEALTH INSURANCE COVERAGE IN CERTAIN STATES.—

(1) IN GENERAL.—The requirements of this section shall not apply with respect to health insurance coverage if there is a State law (as defined in section 2723(d)(1)) for a State that regulates such coverage that is described in any of the following subparagraphs:

(A) Such State law requires such coverage to provide for at least a 48-hour hospital length of stay following a normal vaginal delivery and at least a 96-hour hospital length of stay following a cesarean section.

(B) Such State law requires such coverage to provide for maternity and pediatric care in accordance with guidelines established by the American College of Obstetricians and Gynecologists, the American Academy of Pediatrics, or other established professional medical associations.

(C) Such State law requires, in connection with such coverage for maternity care, that the hospital length of stay for such care is left to the decision of (or required to be made by) the attending provider in consultation with the mother.

(2) CONSTRUCTION.—Section 2723(a)(1) shall not be construed as superseding a State law described in paragraph (1).

SEC. 2726.[300gg–26] PARITY IN MENTAL HEALTH AND SUBSTANCE USE DISORDER BENEFITS.

(a) IN GENERAL.—

(1) AGGREGATE LIFETIME LIMITS.—In the case of a group health plan or a health insurance issuer offering group or individual health insurance coverage that provides both medical and surgical benefits and mental health or substance use disorder benefits—

(A) NO LIFETIME LIMIT.—If the plan or coverage does not include an aggregate lifetime limit on substantially all medical and surgical benefits, the plan or coverage may not impose any aggregate lifetime limit on mental health or substance use disorder benefits.

(B) LIFETIME LIMIT.—If the plan or coverage includes an aggregate lifetime limit on substantially all medical and surgical benefits (in this paragraph referred to as the "applicable lifetime limit"), the plan or coverage shall either—

(i) apply the applicable lifetime limit both to the medical and surgical benefits to which it otherwise would apply and to mental health and substance use disorder benefits and not distinguish in the application of such limit between such medical and surgical benefits and mental health and substance use disorder benefits; or

(ii) not include any aggregate lifetime limit on mental health or substance use disorder benefits that is less than the applicable lifetime limit.

(C) RULE IN CASE OF DIFFERENT LIMITS.—In the case of a plan or coverage that is not described in subparagraph (A) or (B) and that includes no or different aggregate lifetime limits on different categories of medical and surgical benefits, the Secretary shall establish rules under which subparagraph (B) is applied to such plan or coverage with respect to mental health and substance use disorder benefits by substituting for the applicable lifetime limit an average aggregate lifetime limit that is computed taking into account the weighted average of the aggregate lifetime limits applicable to such categories.

(2) ANNUAL LIMITS.—In the case of a group health plan or a health insurance issuer offering group or individual health insurance coverage that provides both medical and surgical benefits and mental health or substance use disorder benefits—

(A) NO ANNUAL LIMIT.—If the plan or coverage does not include an annual limit on substantially all medical and surgical benefits, the plan or coverage may not impose any annual limit on mental health or substance use disorder benefits.

(B) ANNUAL LIMIT.—If the plan or coverage includes an annual limit on substantially all medical and surgical benefits (in this paragraph referred to as the "applicable annual limit"), the plan or coverage shall either—

(i) apply the applicable annual limit both to medical and surgical benefits to which it otherwise would

apply and to mental health and substance use disorder benefits and not distinguish in the application of such limit between such medical and surgical benefits and mental health and substance use disorder benefits; or

(ii) not include any annual limit on mental health or substance use disorder benefits that is less than the applicable annual limit.

(C) RULE IN CASE OF DIFFERENT LIMITS.—In the case of a plan or coverage that is not described in subparagraph (A) or (B) and that includes no or different annual limits on different categories of medical and surgical benefits, the Secretary shall establish rules under which subparagraph (B) is applied to such plan or coverage with respect to mental health and substance use disorder benefits by substituting for the applicable annual limit an average annual limit that is computed taking into account the weighted average of the annual limits applicable to such categories.

(3) FINANCIAL REQUIREMENTS AND TREATMENT LIMITATIONS.—

(A) IN GENERAL.—In the case of a group health plan or a health insurance issuer offering group or individual health insurance coverage that provides both medical and surgical benefits and mental health or substance use disorder benefits, such plan or coverage shall ensure that—

(i) the financial requirements applicable to such mental health or substance use disorder benefits are no more restrictive than the predominant financial requirements applied to substantially all medical and surgical benefits covered by the plan (or coverage), and there are no separate cost sharing requirements that are applicable only with respect to mental health or substance use disorder benefits; and

(ii) the treatment limitations applicable to such mental health or substance use disorder benefits are no more restrictive than the predominant treatment limitations applied to substantially all medical and surgical benefits covered by the plan (or coverage) and there are no separate treatment limitations that are applicable only with respect to mental health or substance use disorder benefits.

(B) DEFINITIONS.—In this paragraph:

(i) FINANCIAL REQUIREMENT.—The term "financial requirement" includes deductibles, copayments, coinsurance, and out-of-pocket expenses, but excludes an aggregate lifetime limit and an annual limit subject to paragraphs (1) and (2).

(ii) PREDOMINANT.—A financial requirement or treatment limit is considered to be predominant if it is the most common or frequent of such type of limit or requirement.

(iii) TREATMENT LIMITATION.—The term "treatment limitation" includes limits on the frequency of treatment, number of visits, days of coverage, or other similar limits on the scope or duration of treatment.

(4) AVAILABILITY OF PLAN INFORMATION.—The criteria for medical necessity determinations made under the plan with respect to mental health or substance use disorder benefits (or the health insurance coverage offered in connection with the plan with respect to such benefits) shall be made available by the plan administrator (or the health insurance issuer offering such coverage) in accordance with regulations to any current or potential participant, beneficiary, or contracting provider upon request. The reason for any denial under the plan (or coverage) of reimbursement or payment for services with respect to mental health or substance use disorder benefits in the case of any participant or beneficiary shall, on request or as otherwise required, be made available by the plan administrator (or the health insurance issuer offering such coverage) to the participant or beneficiary in accordance with regulations.

(5) OUT-OF-NETWORK PROVIDERS.—In the case of a plan or coverage that provides both medical and surgical benefits and mental health or substance use disorder benefits, if the plan or coverage provides coverage for medical or surgical benefits provided by out-of-network providers, the plan or coverage shall provide coverage for mental health or substance use disorder benefits provided by out-of-network providers in a manner that is consistent with the requirements of this section.

(b) CONSTRUCTION.—Nothing in this section shall be construed—

(1) as requiring a group health plan or a health insurance issuer offering group or individual health insurance coverage to provide any mental health or substance use disorder benefits; or

(2) in the case of a group health plan or a health insurance issuer offering group or individual health insurance coverage that provides mental health or substance use disorder benefits, as affecting the terms and conditions of the plan or coverage relating to such benefits under the plan or coverage, except as provided in subsection (a).

(c) EXEMPTIONS.—

(1) SMALL EMPLOYER EXEMPTION.—This section shall not apply to any group health plan and a health insurance issuer offering group or individual health insurance coverage for any plan year of a small employer (as defined in section 2791(e)(4), except that for purposes of this paragraph such term shall include employers with 1 employee in the case of an employer residing in a State that permits small groups to include a single individual).

(2) COST EXEMPTION.—

(A) IN GENERAL.—With respect to a group health plan or a health insurance issuer offering group or individual health insurance coverage, if the application of this section to such plan (or coverage) results in an increase for the plan year involved of the actual total costs of coverage with respect to medical and surgical benefits and mental health and substance use disorder benefits under the plan (as determined and certified under subparagraph (C)) by an amount that exceeds the applicable percentage described in subparagraph (B) of the actual total plan costs, the provi-

sions of this section shall not apply to such plan (or coverage) during the following plan year, and such exemption shall apply to the plan (or coverage) for 1 plan year. An employer may elect to continue to apply mental health and substance use disorder parity pursuant to this section with respect to the group health plan (or coverage) involved regardless of any increase in total costs.

(B) APPLICABLE PERCENTAGE.—With respect to a plan (or coverage), the applicable percentage described in this subparagraph shall be—

(i) 2 percent in the case of the first plan year in which this section is applied; and

(ii) 1 percent in the case of each subsequent plan year.

(C) DETERMINATIONS BY ACTUARIES.—Determinations as to increases in actual costs under a plan (or coverage) for purposes of this section shall be made and certified by a qualified and licensed actuary who is a member in good standing of the American Academy of Actuaries. All such determinations shall be in a written report prepared by the actuary. The report, and all underlying documentation relied upon by the actuary, shall be maintained by the group health plan or health insurance issuer for a period of 6 years following the notification made under subparagraph (E).

(D) 6-MONTH DETERMINATIONS.—If a group health plan (or a health insurance issuer offering coverage in connection with a group health plan)[14] *seeks an exemption under this paragraph, determinations under subparagraph (A) shall be made after such plan (or coverage) has complied with this section for the first 6 months of the plan year involved.*

(E) NOTIFICATION.—

(i) IN GENERAL.—A group health plan (or a health insurance issuer offering coverage in connection with a group health plan) that, based upon a certification described under subparagraph (C), qualifies for an exemption under this paragraph, and elects to implement the exemption, shall promptly notify the Secretary, the appropriate State agencies, and participants and beneficiaries in the plan of such election.

(ii) REQUIREMENT.—A notification to the Secretary under clause (i) shall include—

(I) a description of the number of covered lives under the plan (or coverage) involved at the time of the notification, and as applicable, at the time of any prior election of the cost-exemption under this paragraph by such plan (or coverage);

(II) for both the plan year upon which a cost exemption is sought and the year prior, a descrip-

[14] In section 1563 (relating to conforming amendments--originally designated as section 1562 and redesignated as section 1563 by section 10107(b)(1)) of Public Law 111–148, Congress may have intended to replace the parenthetical with a reference to both group and individual health insurance. The Congression intent is unclear.

tion of the actual total costs of coverage with respect to medical and surgical benefits and mental health and substance use disorder benefits under the plan; and

(III) for both the plan year upon which a cost exemption is sought and the year prior, the actual total costs of coverage with respect to mental health and substance use disorder benefits under the plan.

(iii) CONFIDENTIALITY.—A notification to the Secretary under clause (i) shall be confidential. The Secretary shall make available, upon request and on not more than an annual basis, an anonymous itemization of such notifications, that includes—

(I) a breakdown of States by the size and type of employers submitting such notification; and

(II) a summary of the data received under clause (ii).

(F) AUDITS BY APPROPRIATE AGENCIES.—To determine compliance with this paragraph, the Secretary may audit the books and records of a group health plan or health insurance issuer relating to an exemption, including any actuarial reports prepared pursuant to subparagraph (C), during the 6 year period following the notification of such exemption under subparagraph (E). A State agency receiving a notification under subparagraph (E) may also conduct such an audit with respect to an exemption covered by such notification.

(d) SEPARATE APPLICATION TO EACH OPTION OFFERED.—In the case of a group health plan that offers a participant or beneficiary two or more benefit package options under the plan, the requirements of this section shall be applied separately with respect to each such option.

(e) DEFINITIONS.—For purposes of this section—

(1) AGGREGATE LIFETIME LIMIT.—The term "aggregate lifetime limit" means, with respect to benefits under a group health plan or health insurance coverage, a dollar limitation on the total amount that may be paid with respect to such benefits under the plan or health insurance coverage with respect to an individual or other coverage unit.

(2) ANNUAL LIMIT.—The term "annual limit" means, with respect to benefits under a group health plan or health insurance coverage, a dollar limitation on the total amount of benefits that may be paid with respect to such benefits in a 12-month period under the plan or health insurance coverage with respect to an individual or other coverage unit.

(3) MEDICAL OR SURGICAL BENEFITS.—The term "medical or surgical benefits" means benefits with respect to medical or surgical services, as defined under the terms of the plan or coverage (as the case may be), but does not include mental health or substance use disorder benefits.

(4) MENTAL HEALTH BENEFITS.—The term "mental health benefits" means benefits with respect to services for mental

health conditions, as defined under the terms of the plan and in accordance with applicable Federal and State law.

(5) SUBSTANCE USE DISORDER BENEFITS.—The term "substance use disorder benefits" means benefits with respect to services for substance use disorders, as defined under the terms of the plan and in accordance with applicable Federal and State law.

SEC. 2727.[300gg–27] REQUIRED COVERAGE FOR RECONSTRUCTIVE SURGERY FOLLOWING MASTECTOMIES.[15].

The provisions of section 713 of the Employee Retirement Income Security Act of 1974 shall apply to group health plans, and and[16] health insurance issuers offering group or individual health insurance coverage, as if included in this subpart.

SEC. 2728.[300gg–28] COVERAGE OF DEPENDENT STUDENTS ON MEDICALLY NECESSARY LEAVE OF ABSENCE.

(a) MEDICALLY NECESSARY LEAVE OF ABSENCE.—In this section, the term "medically necessary leave of absence" means, with respect to a dependent child described in subsection (b)(2) in connection with a group health plan or individual health insurance coverage, a leave of absence of such child from a postsecondary educational institution (including an institution of higher education as defined in section 102 of the Higher Education Act of 1965), or any other change in enrollment of such child at such an institution, that—

(1) commences while such child is suffering from a serious illness or injury;

(2) is medically necessary; and

(3) causes such child to lose student status for purposes of coverage under the terms of the plan or coverage.

(b) REQUIREMENT TO CONTINUE COVERAGE.—

(1) IN GENERAL.—In the case of a dependent child described in paragraph (2), a group health plan, or a health insurance issuer that offers group or individual health insurance coverage, shall not terminate coverage of such child under such plan or health insurance coverage due to a medically necessary leave of absence before the date that is the earlier of—

(A) the date that is 1 year after the first day of the medically necessary leave of absence; or

(B) the date on which such coverage would otherwise terminate under the terms of the plan or health insurance coverage.

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[15] Section 2706 (prior to its redesignation as 2727 by Public Law 111–148) was added by subsection (a) of section 903 of the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 1999 (as contained in section 101(f) of division A of Public Law 105–277; 112 Stat. 2681–438). Subsection (c) of such section 903 concerns effective dates, and paragraph (1) of the subsection provides as follows:

"(1) GROUP PLANS.—

"(A) IN GENERAL.—The amendment made by subsection (a) shall apply to group health plans for plan years beginning on or after the date of enactment of this Act.

"(B) SPECIAL RULE FOR COLLECTIVE BARGAINING AGREEMENTS.—In the case of a group health plan maintained pursuant to 1 or more collective bargaining agreements between employee representatives and 1 or more employers, any plan amendment made pursuant to a collective bargaining agreement relating to the plan which amends the plan solely to conform to any requirement added by the amendment made by subsection (a) shall not be treated as a termination of such collective bargaining agreement.".

The Public Law was enacted October 21, 1998.

[16] *So in law.*

(2) DEPENDENT CHILD DESCRIBED.—A dependent child described in this paragraph is, with respect to a group health plan or individual health insurance coverage, a beneficiary under the plan who—

(A) is a dependent child, under the terms of the plan or coverage, of a participant or beneficiary under the plan or coverage; and

(B) was enrolled in the plan or coverage, on the basis of being a student at a postsecondary educational institution (as described in subsection (a)), immediately before the first day of the medically necessary leave of absence involved.

(3) CERTIFICATION BY PHYSICIAN.—Paragraph (1) shall apply to a group health plan or individual health insurance coverage only if the plan or issuer of the coverage has received written certification by a treating physician of the dependent child which states that the child is suffering from a serious illness or injury and that the leave of absence (or other change of enrollment) described in subsection (a) is medically necessary.

(c) NOTICE.—A group health plan, and a health insurance issuer that offers group or individual health insurance coverage, shall include, with any notice regarding a requirement for certification of student status for coverage under the plan or coverage, a description of the terms of this section for continued coverage during medically necessary leaves of absence. Such description shall be in language which is understandable to the typical plan participant.

(d) NO CHANGE IN BENEFITS.—A dependent child whose benefits are continued under this section shall be entitled to the same benefits as if (during the medically necessary leave of absence) the child continued to be a covered student at the institution of higher education and was not on a medically necessary leave of absence.

(e) CONTINUED APPLICATION IN CASE OF CHANGED COVERAGE.—If—

(1) a dependent child of a participant or beneficiary is in a period of coverage under a group health plan or individual health insurance coverage, pursuant to a medically necessary leave of absence of the child described in subsection (b);

(2) the manner in which the participant or beneficiary is covered under the plan changes, whether through a change in health insurance coverage or health insurance issuer, a change between health insurance coverage and self-insured coverage, or otherwise; and

(3) the coverage as so changed continues to provide coverage of beneficiaries as dependent children,

this section shall apply to coverage of the child under the changed coverage for the remainder of the period of the medically necessary leave of absence of the dependent child under the plan in the same manner as it would have applied if the changed coverage had been the previous coverage.

Subpart 2—Exclusion of Plans; Enforcement; Preemption [17]

[18] *The numerical sequence of section enumerators beginning in subpart 2 so in law. See section enumerators at the end of subpart 1 of this part and amendments redesignating section enumerators in subpart 2 by section 1001(4) and section 1563(c)(12) of Public Law 111–148. See footnote accompanying section 2725 regarding ambiguity in placement of sections 2725–2728.*

There are conflicting amendments made to provisions of this section by section 1563(a) and section 1563(c)(12)(B) (relating to conforming amendments—originally designated as section 1562 and redesignated as section 1563 by section 10107(b)(1)) of Public Law 111–148). The amendments reflected here are from section 1563(a) of such Public Law and thereby renders the global amendment made by subsection (c)(12)(B) unexecutable.

[19] The references to "subparts 1 and 2" probably should read "subparts I and II".

[20] The references to "subparts 1 and 2" probably should read "subparts I and II".

[21] Section 1563 (relating to conforming amendments--originally designated as section 1562 and redesignated as section 1563 by section 10107(b)(1)) of Public Law 111–148 provides for an amendment to insert "or, with respect to individual coverage, under any health insurance coverage maintained by the same health insurance issuer". Such amendment did not specify where to insert this new language, however, it was carried out by inserting this new language before the period at the end in order to reflect the probable intent of Congress.

[22] Clauses (i) through (vii) probably should be redesignated as subparagraphs (A) through (G). See section 102(a) of Public Law 104–191 (110 Stat. 1971).

[23] See footnote accompanying section 2725 regarding ambiguity in placement of sections 2725–2728.

[24] Section 111(b) of Public Law 104–191 (110 Stat. 1987) provides as follows:

"(b) EFFECTIVE DATE.—

"(1) IN GENERAL.—Except as provided in this subsection, part B of title XXVII of the Public Health Service Act (as inserted by subsection (a)) shall apply with respect to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market after June 30, 1997, regardless of when a period of creditable coverage occurs.

"(2) APPLICATION OF CERTIFICATION RULES.—The provisions of section 102(d)(2) of this Act shall apply to section 2743 of the the Public Health Service Act in the same manner as it applies to section 2701(e) of such Act.".

With respect to paragraph (2) of such section 111(b), subsection (d) of section 102 of Public Law 104–191 is not divided into paragraphs (1) a

THE PROVISIONS OF SECTION 1311(E)(3) OF THE PATIENT PROTECTION AND AFFORDABLE CARE ACT, EXCEPT THAT A PLAN OR COVERAGE THAT IS NOT OFFERED THROUGH AN EXCHANGE SHALL ONLY BE REQUIRED TO SUBMIT THE INFORMATION REQUIRED TO THE SECRETARY AND THE STATE INSURANCE COMMISSIONER, AND MAKE SUCH INFORMATION AVAILABLE TO THE PUBLIC.

[17] There is a subpart II (roman II) beginning with section 2711.

SEC. 2722. [18] ***[300gg–21] EXCLUSION OF CERTAIN PLANS.***

(a) LIMITATION ON APPLICATION OF PROVISIONS RELATING TO GROUP HEALTH PLANS.—

(1) IN GENERAL.—The requirements of subparts 1 and 2 [19] *shall apply with respect to group health plans only—*

(A) subject to paragraph (2), in the case of a plan that is a nonfederal governmental plan, and

(B) with respect to health insurance coverage offered in connection with a group health plan (including such a plan that is a church plan or a governmental plan).

TION 2702 AND THE PROVISIONS OF SECTIONS 2701 AND 2702(B).

(E) ELECTION NOT APPLICABLE.—The election described in subparagraph (A) shall not be available with respect to the provisions of subparts I and II.

(b) EXCEPTION FOR CERTAIN BENEFITS.—The requirements of subparts 1 and 2[20] shall not apply to any individual coverage or any group health plan (or group health insurance coverage) in relation to its provision of excepted benefits described in section 2791(c)(1).

(c) EXCEPTION FOR CERTAIN BENEFITS IF CERTAIN CONDITIONS MET.—

(1) LIMITED, EXCEPTED BENEFITS.—The requirements of subparts 1 and 2 shall not apply to any individual coverage or any group health plan (and group health insurance coverage offered in connection with a group health plan) in relation to its provision of excepted benefits described in section 2791(c)(2) if the benefits—

(A) are provided under a separate policy, certificate, or contract of insurance; or

(B) are otherwise not an integral part of the plan.

(2) NONCOORDINATED, EXCEPTED BENEFITS.—The requirements of subparts 1 and 2 shall not apply to any individual coverage or any group health plan (and group health insurance coverage offered in connection with a group health plan) in relation to its provision of excepted benefits described in section 2791(c)(3) if all of the following conditions are met:

(A) The benefits are provided under a separate policy, certificate, or contract of insurance.

(B) There is no coordination between the provision of such benefits and any exclusion of benefits under any group health plan maintained by the same plan sponsor.

(C) Such benefits are paid with respect to an event without regard to whether benefits are provided with respect to such an event under any group health plan maintained by the same plan sponsor or, with respect to individual coverage, under any health insurance coverage maintained by the same health insurance issuer[21]*.*

(3) SUPPLEMENTAL EXCEPTED BENEFITS.—The requirements of this part shall not apply to any individual coverage or any group health plan (and group health insurance coverage) in relation to its provision of excepted benefits described in section 27971(c)(4) if the benefits are provided under a separate policy, certificate, or contract of insurance.

(d) TREATMENT OF PARTNERSHIPS.—For purposes of this part—

(1) TREATMENT AS A GROUP HEALTH PLAN.—Any plan, fund, or program which would not be (but for this subsection) an em-

[20] The references to "subparts 1 and 2" probably should read "subparts I and II".

[21] Section 1563 (relating to conforming amendments--originally designated as section 1562 and redesignated as section 1563 by section 10107(b)(1)) of Public Law 111–148 provides for an amendment to insert "or, with respect to individual coverage, under any health insurance coverage maintained by the same health insurance issuer". Such amendment did not specify where to insert this new language, however, it was carried out by inserting this new language before the period at the end in order to reflect the probable intent of Congress.

ployee welfare benefit plan and which is established or maintained by a partnership, to the extent that such plan, fund, or program provides medical care (including items and services paid for as medical care) to present or former partners in the partnership or to their dependents (as defined under the terms of the plan, fund, or program), directly or through insurance, reimbursement, or otherwise, shall be treated (subject to paragraph (2)) as an employee welfare benefit plan which is a group health plan.

(2) EMPLOYER.—In the case of a group health plan, the term "employer" also includes the partnership in relation to any partner.

(3) PARTICIPANTS OF GROUP HEALTH PLANS.—In the case of a group health plan, the term "participant" also includes—

(A) in connection with a group health plan maintained by a partnership, an individual who is a partner in relation to the partnership, or

(B) in connection with a group health plan maintained by a self-employed individual (under which one or more employees are participants), the self-employed individual,

if such individual is, or may become, eligible to receive a benefit under the plan or such individual's beneficiaries may be eligible to receive any such benefit.

SEC. 2723.[300gg–22] ENFORCEMENT.

(a) STATE ENFORCEMENT.—

(1) STATE AUTHORITY.—Subject to section 2723, each State may require that health insurance issuers that issue, sell, renew, or offer health insurance coverage in the State in the individual or group market meet the requirements of this part with respect to such issuers.

(2) FAILURE TO IMPLEMENT PROVISIONS.—In the case of a determination by the Secretary that a State has failed to substantially enforce a provision (or provisions) in this part with respect to health insurance issuers in the State, the Secretary shall enforce such provision (or provisions) under subsection (b) insofar as they relate to the issuance, sale, renewal, and offering of health insurance coverage in connection with group health plans or individual health insurance coverage in such State.

(b) SECRETARIAL ENFORCEMENT AUTHORITY.—

(1) LIMITATION.—The provisions of this subsection shall apply to enforcement of a provision (or provisions) of this part only—

(A) as provided under subsection (a)(2); and

(B) with respect to individual health insurance coverage or group health plans that are non-Federal governmental plans.

(2) IMPOSITION OF PENALTIES.—In the cases described in paragraph (1)—

(A) IN GENERAL.—Subject to the succeeding provisions of this subsection, any non-Federal governmental plan that is a group health plan and any health insurance issuer that fails to meet a provision of this part applicable to such

plan or issuer is subject to a civil money penalty under this subsection.

(B) LIABILITY FOR PENALTY.—In the case of a failure by—

(i) a health insurance issuer, the issuer is liable for such penalty, or

(ii) a group health plan that is a non-Federal governmental plan which is—

(I) sponsored by 2 or more employers, the plan is liable for such penalty, or

(II) not so sponsored, the employer is liable for such penalty.

(C) AMOUNT OF PENALTY.—

(i) IN GENERAL.—The maximum amount of penalty imposed under this paragraph is $100 for each day for each individual with respect to which such a failure occurs.

(ii) CONSIDERATIONS IN IMPOSITION.—In determining the amount of any penalty to be assessed under this paragraph, the Secretary shall take into account the previous record of compliance of the entity being assessed with the applicable provisions of this part and the gravity of the violation.

(iii) LIMITATIONS.—

(I) PENALTY NOT TO APPLY WHERE FAILURE NOT DISCOVERED EXERCISING REASONABLE DILIGENCE.—No civil money penalty shall be imposed under this paragraph on any failure during any period for which it is established to the satisfaction of the Secretary that none of the entities against whom the penalty would be imposed knew, or exercising reasonable diligence would have known, that such failure existed.

(II) PENALTY NOT TO APPLY TO FAILURES CORRECTED WITHIN 30 DAYS.—No civil money penalty shall be imposed under this paragraph on any failure if such failure was due to reasonable cause and not to willful neglect, and such failure is corrected during the 30-day period beginning on the first day any of the entities against whom the penalty would be imposed knew, or exercising reasonable diligence would have known, that such failure existed.

(D) ADMINISTRATIVE REVIEW.—

(i) OPPORTUNITY FOR HEARING.—The entity assessed shall be afforded an opportunity for hearing by the Secretary upon request made within 30 days after the date of the issuance of a notice of assessment. In such hearing the decision shall be made on the record pursuant to section 554 of title 5, United States Code. If no hearing is requested, the assessment shall constitute a final and unappealable order.

(ii) HEARING PROCEDURE.—If a hearing is requested, the initial agency decision shall be made by

an administrative law judge, and such decision shall become the final order unless the Secretary modifies or vacates the decision. Notice of intent to modify or vacate the decision of the administrative law judge shall be issued to the parties within 30 days after the date of the decision of the judge. A final order which takes effect under this paragraph shall be subject to review only as provided under subparagraph (E).

(E) JUDICIAL REVIEW.—

(i) FILING OF ACTION FOR REVIEW.—Any entity against whom an order imposing a civil money penalty has been entered after an agency hearing under this paragraph may obtain review by the United States district court for any district in which such entity is located or the United States District Court for the District of Columbia by filing a notice of appeal in such court within 30 days from the date of such order, and simultaneously sending a copy of such notice by registered mail to the Secretary.

(ii) CERTIFICATION OF ADMINISTRATIVE RECORD.—The Secretary shall promptly certify and file in such court the record upon which the penalty was imposed.

(iii) STANDARD FOR REVIEW.—The findings of the Secretary shall be set aside only if found to be unsupported by substantial evidence as provided by section 706(2)(E) of title 5, United States Code.

(iv) APPEAL.—Any final decision, order, or judgment of the district court concerning such review shall be subject to appeal as provided in chapter 83 of title 28 of such Code.

(F) FAILURE TO PAY ASSESSMENT; MAINTENANCE OF ACTION.—

(i) FAILURE TO PAY ASSESSMENT.—If any entity fails to pay an assessment after it has become a final and unappealable order, or after the court has entered final judgment in favor of the Secretary, the Secretary shall refer the matter to the Attorney General who shall recover the amount assessed by action in the appropriate United States district court.

(ii) NONREVIEWABILITY.—In such action the validity and appropriateness of the final order imposing the penalty shall not be subject to review.

(G) PAYMENT OF PENALTIES.—Except as otherwise provided, penalties collected under this paragraph shall be paid to the Secretary (or other officer) imposing the penalty and shall be available without appropriation and until expended for the purpose of enforcing the provisions with respect to which the penalty was imposed.

(3) ENFORCEMENT AUTHORITY RELATING TO GENETIC DISCRIMINATION.—

(A) GENERAL RULE.—In the cases described in paragraph (1), notwithstanding the provisions of paragraph (2)(C), the succeeding subparagraphs of this paragraph

shall apply with respect to an action under this subsection by the Secretary with respect to any failure of a health insurance issuer in connection with a group health plan, to meet the requirements of subsection (a)(1)(F), (b)(3), (c), or (d) of section 2702 or section 2701 or 2702(b)(1) with respect to genetic information in connection with the plan.

(B) AMOUNT.—

(i) IN GENERAL.—The amount of the penalty imposed under this paragraph shall be $100 for each day in the noncompliance period with respect to each participant or beneficiary to whom such failure relates.

(ii) NONCOMPLIANCE PERIOD.—For purposes of this paragraph, the term "noncompliance period" means, with respect to any failure, the period—

(I) beginning on the date such failure first occurs; and

(II) ending on the date the failure is corrected.

(C) MINIMUM PENALTIES WHERE FAILURE DISCOVERED.—Notwithstanding clauses (i) and (ii) of subparagraph (D):

(i) IN GENERAL.—In the case of 1 or more failures with respect to an individual—

(I) which are not corrected before the date on which the plan receives a notice from the Secretary of such violation; and

(II) which occurred or continued during the period involved;

the amount of penalty imposed by subparagraph (A) by reason of such failures with respect to such individual shall not be less than $2,500.

(ii) HIGHER MINIMUM PENALTY WHERE VIOLATIONS ARE MORE THAN DE MINIMIS.—To the extent violations for which any person is liable under this paragraph for any year are more than de minimis, clause (i) shall be applied by substituting "$15,000" for "$2,500" with respect to such person.

(D) LIMITATIONS.—

(i) PENALTY NOT TO APPLY WHERE FAILURE NOT DISCOVERED EXERCISING REASONABLE DILIGENCE.—No penalty shall be imposed by subparagraph (A) on any failure during any period for which it is established to the satisfaction of the Secretary that the person otherwise liable for such penalty did not know, and exercising reasonable diligence would not have known, that such failure existed.

(ii) PENALTY NOT TO APPLY TO FAILURES CORRECTED WITHIN CERTAIN PERIODS.—No penalty shall be imposed by subparagraph (A) on any failure if—

(I) such failure was due to reasonable cause and not to willful neglect; and

(II) such failure is corrected during the 30-day period beginning on the first date the person otherwise liable for such penalty knew, or exercising

reasonable diligence would have known, that such failure existed.

(iii) OVERALL LIMITATION FOR UNINTENTIONAL FAILURES.—In the case of failures which are due to reasonable cause and not to willful neglect, the penalty imposed by subparagraph (A) for failures shall not exceed the amount equal to the lesser of—

(I) 10 percent of the aggregate amount paid or incurred by the employer (or predecessor employer) during the preceding taxable year for group health plans; or

(II) $500,000.

(E) WAIVER BY SECRETARY.—In the case of a failure which is due to reasonable cause and not to willful neglect, the Secretary may waive part or all of the penalty imposed by subparagraph (A) to the extent that the payment of such penalty would be excessive relative to the failure involved.

SEC. 2724.[300gg–23] PREEMPTION; STATE FLEXIBILITY; CONSTRUCTION.

(a) CONTINUED APPLICABILITY OF STATE LAW WITH RESPECT TO HEALTH INSURANCE ISSUERS.—

(1) IN GENERAL.—Subject to paragraph (2) and except as provided in subsection (b), this part and part C insofar as it relates to this part shall not be construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with individual or group health insurance coverage except to the extent that such standard or requirement prevents the application of a requirement of this part.

(2) CONTINUED PREEMPTION WITH RESPECT TO GROUP HEALTH PLANS.—Nothing in this part shall be construed to affect or modify the provisions of section 514 of the Employee Retirement Income Security Act of 1974 with respect to group health plans.

(b) SPECIAL RULES IN CASE OF PORTABILITY REQUIREMENTS.—

(1) IN GENERAL.—Subject to paragraph (2), the provisions of this part relating to health insurance coverage offered by a health insurance issuer supersede any provision of State law which establishes, implements, or continues in effect a standard or requirement applicable to imposition of a preexisting condition exclusion specifically governed by section 701 which differs from the standards or requirements specified in such section.

(2) EXCEPTIONS.—Only in relation to health insurance coverage offered by a health insurance issuer, the provisions of this part do not supersede any provision of State law to the extent that such provision—

(i)[22] *substitutes for the reference to "6-month period" in section 2701(a)(1) a reference to any shorter period of time;*

[22] Clauses (i) through (vii) probably should be redesignated as subparagraphs (A) through (G). See section 102(a) of Public Law 104–191 (110 Stat. 1971).

(ii) substitutes for the reference to "12 months" and "18 months" in section 2701(a)(2) a reference to any shorter period of time;

(iii) substitutes for the references to "63" days in sections 2701(c)(2)(A) and 2701(d)(4)(A) a reference to any greater number of days;

(iv) substitutes for the reference to "30-day period" in sections 2701(b)(2) and 2701(d)(1) a reference to any greater period;

(v) prohibits the imposition of any preexisting condition exclusion in cases not described in section 2701(d) or expands the exceptions described in such section;

(vi) requires special enrollment periods in addition to those required under section 2701(f); or

(vii) reduces the maximum period permitted in an affiliation period under section 2701(g)(1)(B).

(c) RULES OF CONSTRUCTION.—Nothing in this part (other than section 2704) shall be construed as requiring a group health plan or health insurance coverage to provide specific benefits under the terms of such plan or coverage.

(d) DEFINITIONS.—For purposes of this section—

(1) STATE LAW.—The term "State law" includes all laws, decisions, rules, regulations, or other State action having the effect of law, of any State. A law of the United States applicable only to the District of Columbia shall be treated as a State law rather than a law of the United States.

(2) STATE.—The term "State" includes a State (including the Northern Mariana Islands), any political subdivisions of a State or such Islands, or any agency or instrumentality of either.[23]

PART B—INDIVIDUAL MARKET RULES[24]

Subpart 1—Portability, Access, and Renewability Requirements

SEC. 2741.[300gg–41] GUARANTEED AVAILABILITY OF INDIVIDUAL HEALTH INSURANCE COVERAGE TO CERTAIN INDIVIDUALS WITH PRIOR GROUP COVERAGE.

(a) GUARANTEED AVAILABILITY.—

(1) IN GENERAL.—Subject to the succeeding subsections of this section and section 2744, each health insurance issuer that offers health insurance coverage (as defined in section

[23] See footnote accompanying section 2725 regarding ambiguity in placement of sections 2725–2728.

[24] Section 111(b) of Public Law 104–191 (110 Stat. 1987) provides as follows:

"(b) EFFECTIVE DATE.—

"(1) IN GENERAL.—Except as provided in this subsection, part B of title XXVII of the Public Health Service Act (as inserted by subsection (a)) shall apply with respect to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market after June 30, 1997, regardless of when a period of creditable coverage occurs.

"(2) APPLICATION OF CERTIFICATION RULES.—The provisions of section 102(d)(2) of this Act shall apply to section 2743 of the the Public Health Service Act in the same manner as it applies to section 2701(e) of such Act.".

With respect to paragraph (2) of such section 111(b), subsection (d) of section 102 of Public Law 104–191 is not divided into paragraphs (1) and (2) (and the subsection relates to a technical correction). Subsection (c)(2) of such section 102 does relate to certifications.

2791(b)(1)) in the individual market in a State may not, with respect to an eligible individual (as defined in subsection (b)) desiring to enroll in individual health insurance coverage—

(A) decline to offer such coverage to, or deny enrollment of, such individual; or

(B) impose any preexisting condition exclusion (as defined in section 2701(b)(1)(A)) with respect to such coverage.

(2) SUBSTITUTION BY STATE OF ACCEPTABLE ALTERNATIVE MECHANISM.—The requirement of paragraph (1) shall not apply to health insurance coverage offered in the individual market in a State in which the State is implementing an acceptable alternative mechanism under section 2744.

(b) ELIGIBLE INDIVIDUAL DEFINED.—In this part, the term "eligible individual" means an individual—

(1)(A) for whom, as of the date on which the individual seeks coverage under this section, the aggregate of the periods of creditable coverage (as defined in section 2701(c)) is 18 or more months and (B) whose most recent prior creditable coverage was under a group health plan, governmental plan, or church plan (or health insurance coverage offered in connection with any such plan);

(2) who is not eligible for coverage under (A) a group health plan, (B) part A or part B of title XVIII of the Social Security Act, or (C) a State plan under title XIX of such Act (or any successor program), and does not have other health insurance coverage;

(3) with respect to whom the most recent coverage within the coverage period described in paragraph (1)(A) was not terminated based on a factor described in paragraph (1) or (2) of section 2712(b) (relating to nonpayment of premiums or fraud);

(4) if the individual had been offered the option of continuation coverage under a COBRA continuation provision or under a similar State program, who elected such coverage; and

(5) who, if the individual elected such continuation coverage, has exhausted such continuation coverage under such provision or program.

(c) ALTERNATIVE COVERAGE PERMITTED WHERE NO STATE MECHANISM.—

(1) IN GENERAL.—In the case of health insurance coverage offered in the individual market in a State in which the State is not implementing an acceptable alternative mechanism under section 2744, the health insurance issuer may elect to limit the coverage offered under subsection (a) so long as it offers at least two different policy forms of health insurance coverage both of which—

(A) are designed for, made generally available to, and actively marketed to, and enroll both eligible and other individuals by the issuer; and

(B) meet the requirement of paragraph (2) or (3), as elected by the issuer.

For purposes of this subsection, policy forms which have different cost-sharing arrangements or different riders shall be considered to be different policy forms.

(2) CHOICE OF MOST POPULAR POLICY FORMS.—The requirement of this paragraph is met, for health insurance coverage policy forms offered by an issuer in the individual market, if the issuer offers the policy forms for individual health insurance coverage with the largest, and next to largest, premium volume of all such policy forms offered by the issuer in the State or applicable marketing or service area (as may be prescribed in regulation) by the issuer in the individual market in the period involved.

(3) CHOICE OF 2 POLICY FORMS WITH REPRESENTATIVE COVERAGE.—

(A) IN GENERAL.—The requirement of this paragraph is met, for health insurance coverage policy forms offered by an issuer in the individual market, if the issuer offers a lower-level coverage policy form (as defined in subparagraph (B)) and a higher-level coverage policy form (as defined in subparagraph (C)) each of which includes benefits substantially similar to other individual health insurance coverage offered by the issuer in that State and each of which is covered under a method described in section 2744(c)(3)(A) (relating to risk adjustment, risk spreading, or financial subsidization).

(B) LOWER-LEVEL OF COVERAGE DESCRIBED.—A policy form is described in this subparagraph if the actuarial value of the benefits under the coverage is at least 85 percent but not greater than 100 percent of a weighted average (described in subparagraph (D)).

(C) HIGHER-LEVEL OF COVERAGE DESCRIBED.—A policy form is described in this subparagraph if—

(i) the actuarial value of the benefits under the coverage is at least 15 percent greater than the actuarial value of the coverage described in subparagraph (B) offered by the issuer in the area involved; and

(ii) the actuarial value of the benefits under the coverage is at least 100 percent but not greater than 120 percent of a weighted average (described in subparagraph (D)).

(D) WEIGHTED AVERAGE.—For purposes of this paragraph, the weighted average described in this subparagraph is the average actuarial value of the benefits provided by all the health insurance coverage issued (as elected by the issuer) either by that issuer or by all issuers in the State in the individual market during the previous year (not including coverage issued under this section), weighted by enrollment for the different coverage.

(4) ELECTION.—The issuer elections under this subsection shall apply uniformly to all eligible individuals in the State for that issuer. Such an election shall be effective for policies offered during a period of not shorter than 2 years.

(5) ASSUMPTIONS.—For purposes of paragraph (3), the actuarial value of benefits provided under individual health insurance coverage shall be calculated based on a standardized population and a set of standardized utilization and cost factors.

(d) SPECIAL RULES FOR NETWORK PLANS.—

(1) IN GENERAL.—In the case of a health insurance issuer that offers health insurance coverage in the individual market through a network plan, the issuer may—

(A) limit the individuals who may be enrolled under such coverage to those who live, reside, or work within the service area for such network plan; and

(B) within the service area of such plan, deny such coverage to such individuals if the issuer has demonstrated, if required, to the applicable State authority that—

(i) it will not have the capacity to deliver services adequately to additional individual enrollees because of its obligations to existing group contract holders and enrollees and individual enrollees, and

(ii) it is applying this paragraph uniformly to individuals without regard to any health status-related factor of such individuals and without regard to whether the individuals are eligible individuals.

(2) 180-DAY SUSPENSION UPON DENIAL OF COVERAGE.—An issuer, upon denying health insurance coverage in any service area in accordance with paragraph (1)(B), may not offer coverage in the individual market within such service area for a period of 180 days after such coverage is denied.

(e) APPLICATION OF FINANCIAL CAPACITY LIMITS.—

(1) IN GENERAL.—A health insurance issuer may deny health insurance coverage in the individual market to an eligible individual if the issuer has demonstrated, if required, to the applicable State authority that—

(A) it does not have the financial reserves necessary to underwrite additional coverage; and

(B) it is applying this paragraph uniformly to all individuals in the individual market in the State consistent with applicable State law and without regard to any health status-related factor of such individuals and without regard to whether the individuals are eligible individuals.

(2) 180-DAY SUSPENSION UPON DENIAL OF COVERAGE.—An issuer upon denying individual health insurance coverage in any service area in accordance with paragraph (1) may not offer such coverage in the individual market within such service area for a period of 180 days after the date such coverage is denied or until the issuer has demonstrated, if required under applicable State law, to the applicable State authority that the issuer has sufficient financial reserves to underwrite additional coverage, whichever is later. A State may provide for the application of this paragraph on a service-area-specific basis.

(e)[25] MARKET REQUIREMENTS.—

(1) IN GENERAL.—The provisions of subsection (a) shall not be construed to require that a health insurance issuer offering

[25] So in law. Probably should redesignate the second subsection (e) and subsection (f) as subsections (f) and (g), respectively. See section 111(a) of Pub. L. 104–191 (110 Stat. 1978).

health insurance coverage only in connection with group health plans or through one or more bona fide associations, or both, offer such health insurance coverage in the individual market.

(2) CONVERSION POLICIES.—A health insurance issuer offering health insurance coverage in connection with group health plans under this title shall not be deemed to be a health insurance issuer offering individual health insurance coverage solely because such issuer offers a conversion policy.

(f) CONSTRUCTION.—Nothing in this section shall be construed—

(1) to restrict the amount of the premium rates that an issuer may charge an individual for health insurance coverage provided in the individual market under applicable State law; or

(2) to prevent a health insurance issuer offering health insurance coverage in the individual market from establishing premium discounts or rebates or modifying otherwise applicable copayments or deductibles in return for adherence to programs of health promotion and disease prevention.

SEC. 2742.[300gg–42] GUARANTEED RENEWABILITY OF INDIVIDUAL HEALTH INSURANCE COVERAGE.

(a) IN GENERAL.—Except as provided in this section, a health insurance issuer that provides individual health insurance coverage to an individual shall renew or continue in force such coverage at the option of the individual.

(b) GENERAL EXCEPTIONS.—A health insurance issuer may nonrenew or discontinue health insurance coverage of an individual in the individual market based only on one or more of the following:

(1) NONPAYMENT OF PREMIUMS.—The individual has failed to pay premiums or contributions in accordance with the terms of the health insurance coverage or the issuer has not received timely premium payments.

(2) FRAUD.—The individual has performed an act or practice that constitutes fraud or made an intentional misrepresentation of material fact under the terms of the coverage.

(3) TERMINATION OF PLAN.—The issuer is ceasing to offer coverage in the individual market in accordance with subsection (c) and applicable State law.

(4) MOVEMENT OUTSIDE SERVICE AREA.—In the case of a health insurance issuer that offers health insurance coverage in the market through a network plan, the individual no longer resides, lives, or works in the service area (or in an area for which the issuer is authorized to do business) but only if such coverage is terminated under this paragraph uniformly without regard to any health status-related factor of covered individuals.

(5) ASSOCIATION MEMBERSHIP CEASES.—In the case of health insurance coverage that is made available in the individual market only through one or more bona fide associations, the membership of the individual in the association (on the basis of which the coverage is provided) ceases but only if such coverage is terminated under this paragraph uniformly without

regard to any health status-related factor of covered individuals.

(c) REQUIREMENTS FOR UNIFORM TERMINATION OF COVERAGE.—

(1) PARTICULAR TYPE OF COVERAGE NOT OFFERED.—In any case in which an issuer decides to discontinue offering a particular type of health insurance coverage offered in the individual market, coverage of such type may be discontinued by the issuer only if—

(A) the issuer provides notice to each covered individual provided coverage of this type in such market of such discontinuation at least 90 days prior to the date of the discontinuation of such coverage;

(B) the issuer offers to each individual in the individual market provided coverage of this type, the option to purchase any other individual health insurance coverage currently being offered by the issuer for individuals in such market; and

(C) in exercising the option to discontinue coverage of this type and in offering the option of coverage under subparagraph (B), the issuer acts uniformly without regard to any health status-related factor of enrolled individuals or individuals who may become eligible for such coverage.

(2) DISCONTINUANCE OF ALL COVERAGE.—

(A) IN GENERAL.—Subject to subparagraph (C), in any case in which a health insurance issuer elects to discontinue offering all health insurance coverage in the individual market in a State, health insurance coverage may be discontinued by the issuer only if—

(i) the issuer provides notice to the applicable State authority and to each individual of such discontinuation at least 180 days prior to the date of the expiration of such coverage, and

(ii) all health insurance issued or delivered for issuance in the State in such market are discontinued and coverage under such health insurance coverage in such market is not renewed.

(B) PROHIBITION ON MARKET REENTRY.—In the case of a discontinuation under subparagraph (A) in the individual market, the issuer may not provide for the issuance of any health insurance coverage in the market and State involved during the 5-year period beginning on the date of the discontinuation of the last health insurance coverage not so renewed.

(d) EXCEPTION FOR UNIFORM MODIFICATION OF COVERAGE.—At the time of coverage renewal, a health insurance issuer may modify the health insurance coverage for a policy form offered to individuals in the individual market so long as such modification is consistent with State law and effective on a uniform basis among all individuals with that policy form.

(e) APPLICATION TO COVERAGE OFFERED ONLY THROUGH ASSOCIATIONS.—In applying this section in the case of health insurance coverage that is made available by a health insurance issuer in the individual market to individuals only through one or more associa-

tions, a reference to an "individual" is deemed to include a reference to such an association (of which the individual is a member).

SEC. 2743.[300gg–43] CERTIFICATION OF COVERAGE.

The provisions of section 2701(e) shall apply to health insurance coverage offered by a health insurance issuer in the individual market in the same manner as it applies to health insurance coverage offered by a health insurance issuer in connection with a group health plan in the small or large group market.

SEC. 2744.[300gg–44] STATE FLEXIBILITY IN INDIVIDUAL MARKET REFORMS.

(a) WAIVER OF REQUIREMENTS WHERE IMPLEMENTATION OF ACCEPTABLE ALTERNATIVE MECHANISM.—

(1) IN GENERAL.—The requirements of section 2741 shall not apply with respect to health insurance coverage offered in the individual market in the State so long as a State is found to be implementing, in accordance with this section and consistent with section 2762(b), an alternative mechanism (in this section referred to as an "acceptable alternative mechanism")—

(A) under which all eligible individuals are provided a choice of health insurance coverage;

(B) under which such coverage does not impose any preexisting condition exclusion with respect to such coverage;

(C) under which such choice of coverage includes at least one policy form of coverage that is comparable to comprehensive health insurance coverage offered in the individual market in such State or that is comparable to a standard option of coverage available under the group or individual health insurance laws of such State; and

(D) in a State which is implementing—

(i) a model act described in subsection (c)(1),

(ii) a qualified high risk pool described in subsection (c)(2), or

(iii) a mechanism described in subsection (c)(3).

(2) PERMISSIBLE FORMS OF MECHANISMS.—A private or public individual health insurance mechanism (such as a health insurance coverage pool or programs, mandatory group conversion policies, guaranteed issue of one or more plans of individual health insurance coverage, or open enrollment by one or more health insurance issuers), or combination of such mechanisms, that is designed to provide access to health benefits for individuals in the individual market in the State in accordance with this section may constitute an acceptable alternative mechanism.

(b) APPLICATION OF ACCEPTABLE ALTERNATIVE MECHANISMS.—

(1) PRESUMPTION.—

(A) IN GENERAL.—Subject to the succeeding provisions of this subsection, a State is presumed to be implementing an acceptable alternative mechanism in accordance with this section as of July 1, 1997, if, by not later than April 1, 1997, the chief executive officer of a State—

(i) notifies the Secretary that the State has enacted or intends to enact (by not later than January

1, 1998, or July 1, 1998, in the case of a State described in subparagraph (B)(ii)) any necessary legislation to provide for the implementation of a mechanism reasonably designed to be an acceptable alternative mechanism as of January 1, 1998, (or, in the case of a State described in subparagraph (B)(ii), July 1, 1998); and

(ii) provides the Secretary with such information as the Secretary may require to review the mechanism and its implementation (or proposed implementation) under this subsection.

(B) DELAY PERMITTED FOR CERTAIN STATES.—

(i) EFFECT OF DELAY.—In the case of a State described in clause (ii) that provides notice under subparagraph (A)(i), for the presumption to continue on and after July 1, 1998, the chief executive officer of the State by April 1, 1998—

(I) must notify the Secretary that the State has enacted any necessary legislation to provide for the implementation of a mechanism reasonably designed to be an acceptable alternative mechanism as of July 1, 1998; and

(II) must provide the Secretary with such information as the Secretary may require to review the mechanism and its implementation (or proposed implementation) under this subsection.

(ii) STATES DESCRIBED.—A State described in this clause is a State that has a legislature that does not meet within the 12-month period beginning on the date of enactment of this Act.

(C) CONTINUED APPLICATION.—In order for a mechanism to continue to be presumed to be an acceptable alternative mechanism, the State shall provide the Secretary every 3 years with information described in subparagraph (A)(ii) or (B)(i)(II) (as the case may be).

(2) NOTICE.—If the Secretary finds, after review of information provided under paragraph (1) and in consultation with the chief executive officer of the State and the insurance commissioner or chief insurance regulatory official of the State, that such a mechanism is not an acceptable alternative mechanism or is not (or no longer) being implemented, the Secretary—

(A) shall notify the State of—

(i) such preliminary determination, and

(ii) the consequences under paragraph (3) of a failure to implement such a mechanism; and

(B) shall permit the State a reasonable opportunity in which to modify the mechanism (or to adopt another mechanism) in a manner so that may be an acceptable alternative mechanism or to provide for implementation of such a mechanism.

(3) FINAL DETERMINATION.—If, after providing notice and opportunity under paragraph (2), the Secretary finds that the mechanism is not an acceptable alternative mechanism or the

State is not implementing such a mechanism, the Secretary shall notify the State that the State is no longer considered to be implementing an acceptable alternative mechanism and that the requirements of section 2741 shall apply to health insurance coverage offered in the individual market in the State, effective as of a date specified in the notice.

(4) LIMITATION ON SECRETARIAL AUTHORITY.—The Secretary shall not make a determination under paragraph (2) or (3) on any basis other than the basis that a mechanism is not an acceptable alternative mechanism or is not being implemented.

(5) FUTURE ADOPTION OF MECHANISMS.—If a State, after January 1, 1997, submits the notice and information described in paragraph (1), unless the Secretary makes a finding described in paragraph (3) within the 90-day period beginning on the date of submission of the notice and information, the mechanism shall be considered to be an acceptable alternative mechanism for purposes of this section, effective 90 days after the end of such period, subject to the second sentence of paragraph (1).

(c) PROVISION RELATED TO RISK.—

(1) ADOPTION OF NAIC MODELS.—The model act referred to in subsection (a)(1)(D)(i) is the Small Employer and Individual Health Insurance Availability Model Act (adopted by the National Association of Insurance Commissioners on June 3, 1996) insofar as it applies to individual health insurance coverage or the Individual Health Insurance Portability Model Act (also adopted by such Association on such date).

(2) QUALIFIED HIGH RISK POOL.—For purposes of subsection (a)(1)(D)(ii), a "qualified high risk pool" described in this paragraph is a high risk pool that—

(A) provides to all eligible individuals health insurance coverage (or comparable coverage) that does not impose any preexisting condition exclusion with respect to such coverage for all eligible individuals, and

(B) provides for premium rates and covered benefits for such coverage consistent with standards included in the NAIC Model Health Plan for Uninsurable Individuals Act (as in effect as of the date of the enactment of this title).

(3) OTHER MECHANISMS.—For purposes of subsection (a)(1)(D)(iii), a mechanism described in this paragraph—

(A) provides for risk adjustment, risk spreading, or a risk spreading mechanism (among issuers or policies of an issuer) or otherwise provides for some financial subsidization for eligible individuals, including through assistance to participating issuers; or

(B) is a mechanism under which each eligible individual is provided a choice of all individual health insurance coverage otherwise available.

SEC. 2745.[300gg–45] RELIEF FOR HIGH RISK POOLS.

(a) SEED GRANTS TO STATES.—The Secretary shall provide from the funds appropriated under subsection (d)(1)(A) a grant of up to

$1,000,000 to each State that has not created a qualified high risk pool as of the date of enactment of the State High Risk Pool Funding Extension Act of 2006 for the State's costs of creation and initial operation of such a pool.

(b) GRANTS FOR OPERATIONAL LOSSES.—

(1) IN GENERAL.—In the case of a State that has established a qualified high risk pool that—

(A) restricts premiums charged under the pool to no more than 200 percent of the premium for applicable standard risk rates;

(B) offers a choice of two or more coverage options through the pool; and

(C) has in effect a mechanism reasonably designed to ensure continued funding of losses incurred by the State in connection with operation of the pool after the end of the last fiscal year for which a grant is provided under this paragraph;

the Secretary shall provide, from the funds appropriated under paragraphs (1)(B)(i) and (2)(A) of subsection (d) and allotted to the State under paragraph (2), a grant for the losses incurred by the State in connection with the operation of the pool.

(2) ALLOTMENT.—Subject to paragraph (4), the amounts appropriated under paragraphs (1)(B)(i) and (2)(A) of subsection (d) for a fiscal year shall be allotted and made available to the States (or the entities that operate the high risk pool under applicable State law) that qualify for a grant under paragraph (1) as follows:

(A) An amount equal to 40 percent of such appropriated amount for the fiscal year shall be allotted in equal amounts to each qualifying State that is one of the 50 States or the District of Columbia and that applies for a grant under this subsection.

(B) An amount equal to 30 percent of such appropriated amount for the fiscal year shall be allotted among qualifying States that apply for such a grant so that the amount allotted to such a State bears the same ratio to such appropriated amount as the number of uninsured individuals in the State bears to the total number of uninsured individuals (as determined by the Secretary) in all qualifying States that so apply.

(C) An amount equal to 30 percent of such appropriated amount for the fiscal year shall be allotted among qualifying States that apply for such a grant so that the amount allotted to a State bears the same ratio to such appropriated amount as the number of individuals enrolled in health care coverage through the qualified high risk pool of the State bears to the total number of individuals so enrolled through qualified high risk pools (as determined by the Secretary) in all qualifying States that so apply.

(3) SPECIAL RULE FOR POOLS CHARGING HIGHER PREMIUMS.—In the case of a qualified high risk pool of a State which charges premiums that exceed 150 percent of the premium for applicable standard risks, the State shall use at least

50 percent of the amount of the grant provided to the State to carry out this subsection to reduce premiums for enrollees.

(4) LIMITATION FOR TERRITORIES.—In no case shall the aggregate amount allotted and made available under paragraph (2) for a fiscal year to States that are not the 50 States or the District of Columbia exceed $1,000,000.

(c) BONUS GRANTS FOR SUPPLEMENTAL CONSUMER BENEFITS.—

(1) IN GENERAL.—In the case of a State that is one of the 50 States or the District of Columbia, that has established a qualified high risk pool, and that is receiving a grant under subsection (b)(1), the Secretary shall provide, from the funds appropriated under paragraphs (1)(B)(ii) and (2)(B) of subsection (d) and allotted to the State under paragraph (3), a grant to be used to provide supplemental consumer benefits to enrollees or potential enrollees (or defined subsets of such enrollees or potential enrollees) in qualified high risk pools.

(2) BENEFITS.—A State shall use amounts received under a grant under this subsection to provide one or more of the following benefits:

(A) Low-income premium subsidies.

(B) A reduction in premium trends, actual premiums, or other cost-sharing requirements.

(C) An expansion or broadening of the pool of individuals eligible for coverage, such as through eliminating waiting lists, increasing enrollment caps, or providing flexibility in enrollment rules.

(D) Less stringent rules, or additional waiver authority, with respect to coverage of pre-existing conditions.

(E) Increased benefits.

(F) The establishment of disease management programs.

(3) ALLOTMENT; LIMITATION.—The Secretary shall allot funds appropriated under paragraphs (1)(B)(ii) and (2)(B) of subsection (d) among States qualifying for a grant under paragraph (1) in a manner specified by the Secretary, but in no case shall the amount so allotted to a State for a fiscal year exceed 10 percent of the funds so appropriated for the fiscal year.

(4) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to prohibit a State that, on the date of the enactment of the State High Risk Pool Funding Extension Act of 2006, is in the process of implementing a program to provide benefits of the type described in paragraph (2), from being eligible for a grant under this subsection.

(d) FUNDING.—

(1) APPROPRIATION FOR FISCAL YEAR 2006.—There are authorized to be appropriated for fiscal year 2006—

(A) $15,000,000 to carry out subsection (a); and

(B) $75,000,000, of which, subject to paragraph (4)—

(i) two-thirds of the amount appropriated shall be made available for allotments under subsection (b)(2); and

(ii) one-third of the amount appropriated shall be made available for allotments under subsection (c)(3).

(2) AUTHORIZATION OF APPROPRIATIONS FOR FISCAL YEARS 2007 THROUGH 2010.—There are authorized to be appropriated $75,000,000 for each of fiscal years 2007 through 2010, of which, subject to paragraph (4)—

(A) two-thirds of the amount appropriated for a fiscal year shall be made available for allotments under subsection (b)(2); and

(B) one-third of the amount appropriated for a fiscal year shall be made available for allotments under subsection (c)(3).

(3) AVAILABILITY.—Funds appropriated for purposes of carrying out this section for a fiscal year shall remain available for obligation through the end of the following fiscal year.

(4) REALLOTMENT.—If, on June 30 of each fiscal year for which funds are appropriated under paragraph (1)(B) or (2), the Secretary determines that all the amounts so appropriated are not allotted or otherwise made available to States, such remaining amounts shall be allotted and made available under subsection (b) among States receiving grants under subsection (b) for the fiscal year based upon the allotment formula specified in such subsection.

(5) NO ENTITLEMENT.—Nothing in this section shall be construed as providing a State with an entitlement to a grant under this section.

(e) APPLICATIONS.—To be eligible for a grant under this section, a State shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

(f) ANNUAL REPORT.—The Secretary shall submit to Congress an annual report on grants provided under this section. Each such report shall include information on the distribution of such grants among States and the use of grant funds by States.

(g) DEFINITIONS.—In this section:

(1) QUALIFIED HIGH RISK POOL.—

(A) IN GENERAL.—The term "qualified high risk pool" has the meaning given such term in section 2744(c)(2), except that a State may elect to meet the requirement of subparagraph (A) of such section (insofar as it requires the provision of coverage to all eligible individuals) through providing for the enrollment of eligible individuals through an acceptable alternative mechanism (as defined for purposes of section 2744) that includes a high risk pool as a component.

(2) STANDARD RISK RATE.—The term "standard risk rate" means a rate—

(A) determined under the State high risk pool by considering the premium rates charged by other health insurers offering health insurance coverage to individuals in the insurance market served;

(B) that is established using reasonable actuarial techniques; and

(C) that reflects anticipated claims experience and expenses for the coverage involved.

(3) STATE.—The term "State" means any of the 50 States and the District of Columbia and includes Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

Subpart 2—Other Requirements

SEC. 2751.[300gg–51] STANDARDS RELATING TO BENEFITS FOR MOTHERS AND NEWBORNS.

(a) IN GENERAL.—The provisions of section 2704 (other than subsections (d) and (f)) shall apply to health insurance coverage offered by a health insurance issuer in the individual market in the same manner as it applies to health insurance coverage offered by a health insurance issuer in connection with a group health plan in the small or large group market.

(b) NOTICE REQUIREMENT.—A health insurance issuer under this part shall comply with the notice requirement under section 711(d) of the Employee Retirement Income Security Act of 1974 with respect to the requirements referred to in subsection (a) as if such section applied to such issuer and such issuer were a group health plan.

(c) PREEMPTION; EXCEPTION FOR HEALTH INSURANCE COVERAGE IN CERTAIN STATES.—

(1) IN GENERAL.—The requirements of this section shall not apply with respect to health insurance coverage if there is a State law (as defined in section 2723(d)(1)) for a State that regulates such coverage that is described in any of the following subparagraphs:

(A) Such State law requires such coverage to provide for at least a 48-hour hospital length of stay following a normal vaginal delivery and at least a 96-hour hospital length of stay following a cesarean section.

(B) Such State law requires such coverage to provide for maternity and pediatric care in accordance with guidelines established by the American College of Obstetricians and Gynecologists, the American Academy of Pediatrics, or other established professional medical associations.

(C) Such State law requires, in connection with such coverage for maternity care, that the hospital length of stay for such care is left to the decision of (or required to be made by) the attending provider in consultation with the mother.

(2) CONSTRUCTION.—Section 2762(a) shall not be construed as superseding a State law described in paragraph (1).

SEC. 2752.[300gg–52] REQUIRED COVERAGE FOR RECONSTRUCTIVE SURGERY FOLLOWING MASTECTOMIES.[26].

The provisions of section 2706 shall apply to health insurance coverage offered by a health insurance issuer in the individual

[26] Section 2752 was added by subsection (b) of section 903 of the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 1999 (as contained in section 101(f) of division A of Public Law 105–277 (112 Stat. 2681–438)). Subsection (c) of such section 903 concerns effective dates, and paragraph (2) of the subsection provides as follows:

Continued

market in the same manner as they apply to health insurance coverage offered by a health insurance issuer in connection with a group health plan in the small or large group market.

SEC. 2753.[27] [300gg–53] PROHIBITION OF HEALTH DISCRIMINATION ON THE BASIS OF GENETIC INFORMATION.

(a) PROHIBITION ON GENETIC INFORMATION AS A CONDITION OF ELIGIBILITY.—

(1) IN GENERAL.—A health insurance issuer offering health insurance coverage in the individual market may not establish rules for the eligibility (including continued eligibility) of any individual to enroll in individual health insurance coverage based on genetic information.

(2) RULE OF CONSTRUCTION.—Nothing in paragraph (1) or in paragraphs (1) and (2) of subsection (e) shall be construed to preclude a health insurance issuer from establishing rules for eligibility for an individual to enroll in individual health insurance coverage based on the manifestation of a disease or disorder in that individual, or in a family member of such individual where such family member is covered under the policy that covers such individual.

(b) PROHIBITION ON GENETIC INFORMATION IN SETTING PREMIUM RATES.—

(1) IN GENERAL.—A health insurance issuer offering health insurance coverage in the individual market shall not adjust premium or contribution amounts for an individual on the basis of genetic information concerning the individual or a family member of the individual.

(2) RULE OF CONSTRUCTION.—Nothing in paragraph (1) or in paragraphs (1) and (2) of subsection (e) shall be construed to preclude a health insurance issuer from adjusting premium or contribution amounts for an individual on the basis of a manifestation of a disease or disorder in that individual, or in a family member of such individual where such family member is covered under the policy that covers such individual. In such case, the manifestation of a disease or disorder in one individual cannot also be used as genetic information about other individuals covered under the policy issued to such individual and to further increase premiums or contribution amounts.

(c) PROHIBITION ON GENETIC INFORMATION AS PREEXISTING CONDITION.—

(1) IN GENERAL.—A health insurance issuer offering health insurance coverage in the individual market may not, on the basis of genetic information, impose any preexisting condition exclusion (as defined in section 2701(b)(1)(A)) with respect to such coverage.

(2) RULE OF CONSTRUCTION.—Nothing in paragraph (1) or in paragraphs (1) and (2) of subsection (e) shall be construed to preclude a health insurance issuer from imposing any pre-

"(2) INDIVIDUAL PLANS.—The amendment made by subsection (b) shall apply with respect to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market on or after the date of enactment of this Act.".

The Public Law was enacted October 21, 1998.

[27] Another section designated as section 2753 appears at the end of part B. There are details in a footnote regarding its placement at the end.

existing condition exclusion for an individual with respect to health insurance coverage on the basis of a manifestation of a disease or disorder in that individual.

(d) GENETIC TESTING.—

(1) LIMITATION ON REQUESTING OR REQUIRING GENETIC TESTING.—A health insurance issuer offering health insurance coverage in the individual market shall not request or require an individual or a family member of such individual to undergo a genetic test.

(2) RULE OF CONSTRUCTION.—Paragraph (1) shall not be construed to limit the authority of a health care professional who is providing health care services to an individual to request that such individual undergo a genetic test.

(3) RULE OF CONSTRUCTION REGARDING PAYMENT.—

(A) IN GENERAL.—Nothing in paragraph (1) shall be construed to preclude a health insurance issuer offering health insurance coverage in the individual market from obtaining and using the results of a genetic test in making a determination regarding payment (as such term is defined for the purposes of applying the regulations promulgated by the Secretary under part C of title XI of the Social Security Act and section 264 of the Health Insurance Portability and Accountability Act of 1996, as may be revised from time to time) consistent with subsection (a) and (c).

(B) LIMITATION.—For purposes of subparagraph (A), a health insurance issuer offering health insurance coverage in the individual market may request only the minimum amount of information necessary to accomplish the intended purpose.

(4) RESEARCH EXCEPTION.—Notwithstanding paragraph (1), a health insurance issuer offering health insurance coverage in the individual market may request, but not require, that an individual or a family member of such individual undergo a genetic test if each of the following conditions is met:

(A) The request is made pursuant to research that complies with part 46 of title 45, Code of Federal Regulations, or equivalent Federal regulations, and any applicable State or local law or regulations for the protection of human subjects in research.

(B) The issuer clearly indicates to each individual, or in the case of a minor child, to the legal guardian of such child, to whom the request is made that—

(i) compliance with the request is voluntary; and

(ii) non-compliance will have no effect on enrollment status or premium or contribution amounts.

(C) No genetic information collected or acquired under this paragraph shall be used for underwriting purposes.

(D) The issuer notifies the Secretary in writing that the issuer is conducting activities pursuant to the exception provided for under this paragraph, including a description of the activities conducted.

(E) The issuer complies with such other conditions as the Secretary may by regulation require for activities conducted under this paragraph.

(e) PROHIBITION ON COLLECTION OF GENETIC INFORMATION.—

(1) IN GENERAL.—A health insurance issuer offering health insurance coverage in the individual market shall not request, require, or purchase genetic information for underwriting purposes (as defined in section 2791).

(2) PROHIBITION ON COLLECTION OF GENETIC INFORMATION PRIOR TO ENROLLMENT.—A health insurance issuer offering health insurance coverage in the individual market shall not request, require, or purchase genetic information with respect to any individual prior to such individual's enrollment under the plan in connection with such enrollment.

(3) INCIDENTAL COLLECTION.—If a health insurance issuer offering health insurance coverage in the individual market obtains genetic information incidental to the requesting, requiring, or purchasing of other information concerning any individual, such request, requirement, or purchase shall not be considered a violation of paragraph (2) if such request, requirement, or purchase is not in violation of paragraph (1).

(f) GENETIC INFORMATION OF A FETUS OR EMBRYO.—Any reference in this part to genetic information concerning an individual or family member of an individual shall—

(1) with respect to such an individual or family member of an individual who is a pregnant woman, include genetic information of any fetus carried by such pregnant woman; and

(2) with respect to an individual or family member utilizing an assisted reproductive technology, include genetic information of any embryo legally held by the individual or family member.

Subpart 3—General Provisions [28]

SEC. 2761.[300gg–61] ENFORCEMENT.

(a) STATE ENFORCEMENT.—

(1) STATE AUTHORITY.—Subject to section 2762, each State may require that health insurance issuers that issue, sell, renew, or offer health insurance coverage in the State in the individual market meet the requirements established under this part with respect to such issuers.

(2) FAILURE TO IMPLEMENT REQUIREMENTS.—In the case of a State that fails to substantially enforce the requirements set forth in this part with respect to health insurance issuers in the State, the Secretary shall enforce the requirements of this part under subsection (b) insofar as they relate to the issuance, sale, renewal, and offering of health insurance coverage in the individual market in such State.

(b) SECRETARIAL ENFORCEMENT AUTHORITY.—The Secretary shall have the same authority in relation to enforcement of the provisions of this part with respect to issuers of health insurance coverage in the individual market in a State as the Secretary has

[28] Section 605(a)(3) of Public Law 104–204 (110 Stat. 2941) adds this subpart designation and heading to part B.

under section 2722(b)(2), and section 2722(b)(3) with respect to violations of genetic nondiscrimination provisions, in relation to the enforcement of the provisions of part A with respect to issuers of health insurance coverage in the small group market in the State.

SEC. 2762.[300gg–62] PREEMPTION.[29].

(a) IN GENERAL.—Subject to subsection (b), nothing in this part (or part C insofar as it applies to this part) shall be construed to prevent a State from establishing, implementing, or continuing in effect standards and requirements unless such standards and requirements prevent the application of a requirement of this part.

(b) RULES OF CONSTRUCTION.—(1) Nothing in this part (or part C insofar as it applies to this part) shall be construed to affect or modify the provisions of section 514 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1144).

(2) Nothing in this part (other than section 2751) shall be construed as requiring health insurance coverage offered in the individual market to provide specific benefits under the terms of such coverage.

[Note: Section 1563(c)(15)(B) (relating to conforming amendments--originally designated as section 1562 and redesignated as section 1563 by section 10107(b)(1)) of Public Law 111–148 provides for an amendment to add a new subsection (c) at the end of section 2762. Such amendment takes effect on date of enactment of Public Law 111–148 (March 23, 2010); however, they're being treated here as if they take effect on January 1, 2014 to reflect the probable intent of Congress and in order to be consistent with the execution of different amendments made by such section 1563 to part A of this title (see details regarding the effective date in a note to a second version of part A). Upon such date, the following new subsection (c) reads as follows:]

(c) APPLICATION OF PART A PROVISIONS.—

(1) IN GENERAL.—The provisions of part A shall apply to health insurance issuers providing health insurance coverage in the individual market in a State as provided for in such part.

(2) CLARIFICATION.—To the extent that any provision of this part conflicts with a provision of part A with respect to health insurance issuers providing health insurance coverage in the individual market in a State, the provisions of such part A shall apply.

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[29] Section 1563(c)(15)(A) (relating to conforming amendments--originally designated as section 1562 and redesignated as section 1563 by section 10107(b)(1)) of Public Law 111–148 provides for an amendment in the section heading by inserting "AND APPLICATION" before the period. Section 1563(c)(15)(B) (as so redesignated) of such Public Law provides for an amendment to add at the end a new subsection (c). See note set out in italic typeface that appears after subsection (b) below.

The amendments to section 2762 made by section 1563(c)(15), as so redesignated, takes effect on date of enactment of Public Law 111–148 (March 23, 2010); however, they're being treated here as if they take effect on January 1, 2014 to reflect the probable intent of Congress and in order to be consistent with the execution of different amendments made by such section 1563 to part A of this title (see details regarding the effective date in a note to a second version of part A).

SEC. 2763.[300gg–63] GENERAL EXCEPTIONS.

(a) EXCEPTION FOR CERTAIN BENEFITS.—The requirements of this part shall not apply to any health insurance coverage in relation to its provision of excepted benefits described in section 2791(c)(1).

(b) EXCEPTION FOR CERTAIN BENEFITS IF CERTAIN CONDITIONS MET.—The requirements of this part shall not apply to any health insurance coverage in relation to its provision of excepted benefits described in paragraph (2), (3), or (4) of section 2791(c) if the benefits are provided under a separate policy, certificate, or contract of insurance.

SEC. 2753.[300gg–54] COVERAGE OF DEPENDENT STUDENTS ON MEDICALLY NECESSARY LEAVE OF ABSENCE.[30].

The provisions of section 2707 shall apply to health insurance coverage offered by a health insurance issuer in the individual market in the same manner as they apply to health insurance coverage offered by a health insurance issuer in connection with a group health plan in the small or large group market.

PART C—DEFINITIONS; MISCELLANEOUS PROVISIONS

SEC. 2791.[300gg–91] DEFINITIONS.

(a) GROUP HEALTH PLAN.—

(1) DEFINITION.—The term "group health plan" means an employee welfare benefit plan (as defined in section 3(1) of the Employee Retirement Income Security Act of 1974) to the extent that the plan provides medical care (as defined in paragraph (2)) and including items and services paid for as medical care) to employees or their dependents (as defined under the terms of the plan) directly or through insurance, reimbursement, or otherwise.

(2) MEDICAL CARE.—The term "medical care" means amounts paid for—

(A) the diagnosis, cure, mitigation, treatment, or prevention of disease, or amounts paid for the purpose of affecting any structure or function of the body,

(B) amounts paid for transportation primarily for and essential to medical care referred to in subparagraph (A), and

(C) amounts paid for insurance covering medical care referred to in subparagraphs (A) and (B).

(3) TREATMENT OF CERTAIN PLANS AS GROUP HEALTH PLAN FOR NOTICE PROVISION.—A program under which creditable coverage described in subparagraph (C), (D), (E), or (F) of section 2701(c)(1) is provided shall be treated as a group health plan for purposes of applying section 2701(e).

(b) DEFINITIONS RELATING TO HEALTH INSURANCE.—

(1) HEALTH INSURANCE COVERAGE.—The term "health insurance coverage" means benefits consisting of medical care (provided directly, through insurance or reimbursement, or

[30] The placement of section 2753 at the end of subpart 3 is so in law. See amendment made by section 2(b)(2) of Public Law 110–381 122 Stat. 4084). Section 102(b)(1)(A) of Public Law 110–233 redesignated subpart 3 of part B as subpart 2. Also, another section designated as section 2753 was added by section 102(b)(1)(B) of such Public Law (122 Stat. 893).

otherwise and including items and services paid for as medical care) under any hospital or medical service policy or certificate, hospital or medical service plan contract, or health maintenance organization contract offered by a health insurance issuer.

(2) HEALTH INSURANCE ISSUER.—The term "health insurance issuer" means an insurance company, insurance service, or insurance organization (including a health maintenance organization, as defined in paragraph (3)) which is licensed to engage in the business of insurance in a State and which is subject to State law which regulates insurance (within the meaning of section 514(b)(2) of the Employee Retirement Income Security Act of 1974). Such term does not include a group health plan.

(3) HEALTH MAINTENANCE ORGANIZATION.—The term "health maintenance organization" means—

(A) a Federally qualified health maintenance organization (as defined in section 1301(a)),

(B) an organization recognized under State law as a health maintenance organization, or

(C) a similar organization regulated under State law for solvency in the same manner and to the same extent as such a health maintenance organization.

(4) GROUP HEALTH INSURANCE COVERAGE.—The term "group health insurance coverage" means, in connection with a group health plan, health insurance coverage offered in connection with such plan.

(5) INDIVIDUAL HEALTH INSURANCE COVERAGE.—The term "individual health insurance coverage" means health insurance coverage offered to individuals in the individual market, but does not include short-term limited duration insurance.

(c) EXCEPTED BENEFITS.—For purposes of this title, the term "excepted benefits" means benefits under one or more (or any combination thereof) of the following:

(1) BENEFITS NOT SUBJECT TO REQUIREMENTS.—

(A) Coverage only for accident, or disability income insurance, or any combination thereof.

(B) Coverage issued as a supplement to liability insurance.

(C) Liability insurance, including general liability insurance and automobile liability insurance.

(D) Workers' compensation or similar insurance.

(E) Automobile medical payment insurance.

(F) Credit-only insurance.

(G) Coverage for on-site medical clinics.

(H) Other similar insurance coverage, specified in regulations, under which benefits for medical care are secondary or incidental to other insurance benefits.

(2) BENEFITS NOT SUBJECT TO REQUIREMENTS IF OFFERED SEPARATELY.—

(A) Limited scope dental or vision benefits.

(B) Benefits for long-term care, nursing home care, home health care, community-based care, or any combination thereof.

(C) Such other similar, limited benefits as are specified in regulations.

(3) BENEFITS NOT SUBJECT TO REQUIREMENTS IF OFFERED AS INDEPENDENT, NONCOORDINATED BENEFITS.—

(A) Coverage only for a specified disease or illness.

(B) Hospital indemnity or other fixed indemnity insurance.

(4) BENEFITS NOT SUBJECT TO REQUIREMENTS IF OFFERED AS SEPARATE INSURANCE POLICY.—Medicare supplemental health insurance (as defined under section 1882(g)(1) of the Social Security Act), coverage supplemental to the coverage provided under chapter 55 of title 10, United States Code, and similar supplemental coverage provided to coverage under a group health plan.

(d)[31] OTHER DEFINITIONS.—

(1) APPLICABLE STATE AUTHORITY.—The term "applicable State authority" means, with respect to a health insurance issuer in a State, the State insurance commissioner or official or officials designated by the State to enforce the requirements of this title for the State involved with respect to such issuer.

(2) BENEFICIARY.—The term "beneficiary" has the meaning given such term under section 3(8) of the Employee Retirement Income Security Act of 1974.

(3) BONA FIDE ASSOCIATION.—The term "bona fide association" means, with respect to health insurance coverage offered in a State, an association which—

(A) has been actively in existence for at least 5 years;

(B) has been formed and maintained in good faith for purposes other than obtaining insurance;

(C) does not condition membership in the association on any health status-related factor relating to an individual (including an employee of an employer or a dependent of an employee);

(D) makes health insurance coverage offered through the association available to all members regardless of any health status-related factor relating to such members (or individuals eligible for coverage through a member);

(E) does not make health insurance coverage offered through the association available other than in connection with a member of the association; and

(F) meets such additional requirements as may be imposed under State law.

(4) COBRA CONTINUATION PROVISION.—The term "COBRA continuation provision" means any of the following:

(A) Section 4980B of the Internal Revenue Code of 1986, other than subsection (f)(1) of such section insofar as it relates to pediatric vaccines.

(B) Part 6 of subtitle B of title I of the Employee Retirement Income Security Act of 1974, other than section 609 of such Act.

[31] For version of law for section 2791(d)(20)–(21) (as amended by section 1563(b) (relating to conforming amendments--originally designated as section 1562 and redesignated as section 1563 by section 10107(b)(1)) of Public Law 111–148) see note set out in italic typeface that appears after paragraph (19).

(C) Title XXII of this Act.

(5) EMPLOYEE.—The term "employee" has the meaning given such term under section 3(6) of the Employee Retirement Income Security Act of 1974.

(6) EMPLOYER.—The term "employer" has the meaning given such term under section 3(5) of the Employee Retirement Income Security Act of 1974, except that such term shall include only employers of two or more employees.

(7) CHURCH PLAN.—The term "church plan" has the meaning given such term under section 3(33) of the Employee Retirement Income Security Act of 1974.

(8) GOVERNMENTAL PLAN.—(A) The term "governmental plan" has the meaning given such term under section 3(32) of the Employee Retirement Income Security Act of 1974 and any Federal governmental plan.

(B) FEDERAL GOVERNMENTAL PLAN.—The term "Federal governmental plan" means a governmental plan established or maintained for its employees by the Government of the United States or by any agency or instrumentality of such Government.

(C) NON-FEDERAL GOVERNMENTAL PLAN.—The term "non-Federal governmental plan" means a governmental plan that is not a Federal governmental plan.

(9) HEALTH STATUS-RELATED FACTOR.—The term "health status-related factor" means any of the factors described in section 2702(a)(1).

(10) NETWORK PLAN.—The term "network plan" means health insurance coverage of a health insurance issuer under which the financing and delivery of medical care (including items and services paid for as medical care) are provided, in whole or in part, through a defined set of providers under contract with the issuer.

(11) PARTICIPANT.—The term "participant" has the meaning given such term under section 3(7) of the Employee Retirement Income Security Act of 1974.

(12) PLACED FOR ADOPTION DEFINED.—The term "placement", or being "placed", for adoption, in connection with any placement for adoption of a child with any person, means the assumption and retention by such person of a legal obligation for total or partial support of such child in anticipation of adoption of such child. The child's placement with such person terminates upon the termination of such legal obligation.

(13) PLAN SPONSOR.—The term "plan sponsor" has the meaning given such term under section 3(16)(B) of the Employee Retirement Income Security Act of 1974.

(14) STATE.—The term "State" means each of the several States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

(15) FAMILY MEMBER.—The term "family member" means, with respect to any individual—

(A) a dependent (as such term is used for purposes of section 2701(f)(2)) of such individual; and

(B) any other individual who is a first-degree, second-degree, third-degree, or fourth-degree relative of such individual or of an individual described in subparagraph (A).

(16) GENETIC INFORMATION.—

(A) IN GENERAL.—The term "genetic information" means, with respect to any individual, information about—

(i) such individual's genetic tests,

(ii) the genetic tests of family members of such individual, and

(iii) the manifestation of a disease or disorder in family members of such individual.

(B) INCLUSION OF GENETIC SERVICES AND PARTICIPATION IN GENETIC RESEARCH.—Such term includes, with respect to any individual, any request for, or receipt of, genetic services, or participation in clinical research which includes genetic services, by such individual or any family member of such individual.

(C) EXCLUSIONS.—The term "genetic information" shall not include information about the sex or age of any individual.

(17) GENETIC TEST.—

(A) IN GENERAL.—The term "genetic test" means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, that detects genotypes, mutations, or chromosomal changes.

(B) EXCEPTIONS.—The term "genetic test" does not mean—

(i) an analysis of proteins or metabolites that does not detect genotypes, mutations, or chromosomal changes; or

(ii) an analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition that could reasonably be detected by a health care professional with appropriate training and expertise in the field of medicine involved.

(18) GENETIC SERVICES.—The term "genetic services" means—

(A) a genetic test;

(B) genetic counseling (including obtaining, interpreting, or assessing genetic information); or

(C) genetic education.

(19) UNDERWRITING PURPOSES.—The term "underwriting purposes" means, with respect to any group health plan, or health insurance coverage offered in connection with a group health plan—

(A) rules for, or determination of, eligibility (including enrollment and continued eligibility) for benefits under the plan or coverage;

(B) the computation of premium or contribution amounts under the plan or coverage;

(C) the application of any pre-existing condition exclusion under the plan or coverage; and

(D) other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits.

[Note: Section 1563(b) (relating to conforming amendments--originally designated as section 1562 and redesignated as section 1563 by section 10107(b)(1)) of Public Law 111–148 provides for an amendment to add new paragraphs (20)–(21) at the end of section 2791(d). Such amendment takes effect on date of enactment of Public Law 111–148 (March 23, 2010); however, they're being treated here as if they take effect on January 1, 2014 to reflect the probable intent of Congress and in order to be consistent with the execution of different amendments made by such section 1563 to part A of this title (see details regarding the effective date in a note to a second version of part A). Upon such date, paragraphs (20)–(21) read as follows:]

(20) QUALIFIED HEALTH PLAN.—The term "qualified health plan" has the meaning given such term in section 1301(a) of the Patient Protection and Affordable Care Act.

(21) EXCHANGE.—The term "Exchange" means an American Health Benefit Exchange established under section 1311 of the Patient Protection and Affordable Care Act.

(e) DEFINITIONS RELATING TO MARKETS AND SMALL EMPLOYERS.—For purposes of this title:

(1) INDIVIDUAL MARKET.—

(A) IN GENERAL.—The term "individual market" means the market for health insurance coverage offered to individuals other than in connection with a group health plan.

(B) TREATMENT OF VERY SMALL GROUPS.—

(i) IN GENERAL.—Subject to clause (ii), such terms includes coverage offered in connection with a group health plan that has fewer than two participants as current employees on the first day of the plan year.

(ii) STATE EXCEPTION.—Clause (i) shall not apply in the case of a State that elects to regulate the coverage described in such clause as coverage in the small group market.

(2) LARGE EMPLOYER.—The term "large employer" means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 51[32] employees on business days during the preceding calendar year and who employs at least 2 employees on the first day of the plan year.

[32] Section 1563(c)(16)(A) (relating to conforming amendments--originally designated as section 1562 and redesignated as section 1563 by section 10107(b)(1)) of Public Law 111–148 provides for an amendment to section 2791(e)(2) by striking "51" and inserting "101".

The amendment to section 2791(e) made by section 1563(c)(16)(A), as so redesignated, takes effect on date of enactment of Public Law 111–148 (March 23, 2010); however, they're being treated here as if they take effect on January 1, 2014 to reflect the probable intent of Congress and in order to be consistent with the execution of different amendments made by such section 1563 to part A of this title (see details regarding the effective date in a note to a second version of part A).

(3) LARGE GROUP MARKET.—The term "large group market" means the health insurance market under which individuals obtain health insurance coverage (directly or through any arrangement) on behalf of themselves (and their dependents) through a group health plan maintained by a large employer.

(4)[33] SMALL EMPLOYER.—The term "small employer" means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 2 but not more than 50 employees on business days during the preceding calendar year and who employs at least 2 employees on the first day of the plan year.

[Note: Section 1563(c)(16)(B) (relating to conforming amendments--originally designated as section 1562 and redesignated as section 1563 by section 10107(b)(1)) of Public Law 111–148 provides for amendments to paragraph (4) of section 2791(e). Such amendments take effect on date of enactment of Public Law 111–148 (March 23, 2010); however, they're being treated here as if they take effect on January 1, 2014 to reflect the probable intent of Congress and in order to be consistent with the execution of different amendments made by such section 1563 to part A of this title (see details regarding the effective date in a note to a second version of part A). Upon such date, paragraph (4) reads as follows:]

(4) SMALL EMPLOYER.—The term "small employer" means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 1 but not more than 100 employees on business days during the preceding calendar year and who employs at least 1 employees on the first day of the plan year.

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(5) SMALL GROUP MARKET.—The term "small group market" means the health insurance market under which individuals obtain health insurance coverage (directly or through any arrangement) on behalf of themselves (and their dependents) through a group health plan maintained by a small employer.

(6) APPLICATION OF CERTAIN RULES IN DETERMINATION OF EMPLOYER SIZE.—For purposes of this subsection—

(A) APPLICATION OF AGGREGATION RULE FOR EMPLOYERS.—all persons treated as a single employer under subsection (b), (c), (m), or (o) of section 414 of the Internal Revenue Code of 1986 shall be treated as 1 employer.

(B) EMPLOYERS NOT IN EXISTENCE IN PRECEDING YEAR.—In the case of an employer which was not in existence throughout the preceding calendar year, the determination of whether such employer is a small or large employer shall be based on the average number of employees that it is reasonably expected such employer will employ on business days in the current calendar year.

[33] For version of law of paragraph (4) (as amended by section 1563(c)(16)(B) (relating to conforming amendments--originally designated as section 1562 and redesignated as section 1563 by section 10107(b)(1)) of Public Law 111–148) see note set out in italic typeface that appears after this paragraph.

(C) PREDECESSORS.—Any reference in this subsection to an employer shall include a reference to any predecessor of such employer.

SEC. 2792.[300gg–92] REGULATIONS.

The Secretary, consistent with section 104 of the Health Care Portability and Accountability Act of 1996, may promulgate such regulations as may be necessary or appropriate to carry out the provisions of this title. The Secretary may promulgate any interim final rules as the Secretary determines are appropriate to carry out this title.

SEC. 2793.[300gg–93] HEALTH INSURANCE CONSUMER INFORMATION.

(a) IN GENERAL.—The Secretary shall award grants to States to enable such States (or the Exchanges operating in such States) to establish, expand, or provide support for—

(1) offices of health insurance consumer assistance; or

(2) health insurance ombudsman programs.

(b) ELIGIBILITY.—

(1) IN GENERAL.—To be eligible to receive a grant, a State shall designate an independent office of health insurance consumer assistance, or an ombudsman, that, directly or in coordination with State health insurance regulators and consumer assistance organizations, receives and responds to inquiries and complaints concerning health insurance coverage with respect to Federal health insurance requirements and under State law.

(2) CRITERIA.—A State that receives a grant under this section shall comply with criteria established by the Secretary for carrying out activities under such grant.

(c) DUTIES.—The office of health insurance consumer assistance or health insurance ombudsman shall—

(1) assist with the filing of complaints and appeals, including filing appeals with the internal appeal or grievance process of the group health plan or health insurance issuer involved and providing information about the external appeal process;

(2) collect, track, and quantify problems and inquiries encountered by consumers;

(3) educate consumers on their rights and responsibilities with respect to group health plans and health insurance coverage;

(4) assist consumers with enrollment in a group health plan or health insurance coverage by providing information, referral, and assistance; and

(5) resolve problems with obtaining premium tax credits under section 36B of the Internal Revenue Code of 1986.

(d) DATA COLLECTION.—As a condition of receiving a grant under subsection (a), an office of health insurance consumer assistance or ombudsman program shall be required to collect and report data to the Secretary on the types of problems and inquiries encountered by consumers. The Secretary shall utilize such data to identify areas where more enforcement action is necessary and shall share such information with State insurance regulators, the Secretary of Labor, and the Secretary of the Treasury for use in the enforcement activities of such agencies.

(e) FUNDING.—

(1) INITIAL FUNDING.—There is hereby appropriated to the Secretary, out of any funds in the Treasury not otherwise appropriated, $30,000,000 for the first fiscal year for which this section applies to carry out this section. Such amount shall remain available without fiscal year limitation.

(2) AUTHORIZATION FOR SUBSEQUENT YEARS.—There is authorized to be appropriated to the Secretary for each fiscal year following the fiscal year described in paragraph (1), such sums as may be necessary to carry out this section.

SEC. 2794.[300gg–94] ENSURING THAT CONSUMERS GET VALUE FOR THEIR DOLLARS.

(a) INITIAL PREMIUM REVIEW PROCESS.—

(1) IN GENERAL.—The Secretary, in conjunction with States, shall establish a process for the annual review, beginning with the 2010 plan year and subject to subsection (b)(2)(A), of unreasonable increases in premiums for health insurance coverage.

(2) JUSTIFICATION AND DISCLOSURE.—The process established under paragraph (1) shall require health insurance issuers to submit to the Secretary and the relevant State a justification for an unreasonable premium increase prior to the implementation of the increase. Such issuers shall prominently post such information on their Internet websites. The Secretary shall ensure the public disclosure of information on such increases and justifications for all health insurance issuers.

(b) CONTINUING PREMIUM REVIEW PROCESS.—

(1) INFORMING SECRETARY OF PREMIUM INCREASE PATTERNS.—As a condition of receiving a grant under subsection (c)(1), a State, through its Commissioner of Insurance, shall—

(A) provide the Secretary with information about trends in premium increases in health insurance coverage in premium rating areas in the State; and

(B) make recommendations, as appropriate, to the State Exchange about whether particular health insurance issuers should be excluded from participation in the Exchange based on a pattern or practice of excessive or unjustified premium increases.

(2) MONITORING BY SECRETARY OF PREMIUM INCREASES.—

(A) IN GENERAL.—Beginning with plan years beginning in 2014, the Secretary, in conjunction with the States and consistent with the provisions of subsection (a)(2), shall monitor premium increases of health insurance coverage offered through an Exchange and outside of an Exchange.

(B) CONSIDERATION IN OPENING EXCHANGE.—In determining under section 1312(f)(2)(B) of the Patient Protection and Affordable Care Act whether to offer qualified health plans in the large group market through an Exchange, the State shall take into account any excess of premium growth outside of the Exchange as compared to the rate of such growth inside the Exchange.

(c) GRANTS IN SUPPORT OF PROCESS.—

(1) PREMIUM REVIEW GRANTS DURING 2010 THROUGH 2014.—The Secretary shall carry out a program to award grants to States during the 5-year period beginning with fiscal year 2010 to assist such States in carrying out subsection (a), including—

(A) in reviewing and, if appropriate under State law, approving premium increases for health insurance coverage;

(B) in providing information and recommendations to the Secretary under subsection (b)(1); and

(C) in establishing centers (consistent with subsection (d)) at academic or other nonprofit institutions to collect medical reimbursement information from health insurance issuers, to analyze and organize such information, and to make such information available to such issuers, health care providers, health researchers, health care policy makers, and the general public.

(2) FUNDING.—

(A) IN GENERAL.—Out of all funds in the Treasury not otherwise appropriated, there are appropriated to the Secretary $250,000,000, to be available for expenditure for grants under paragraph (1) and subparagraph (B).

(B) FURTHER AVAILABILITY FOR INSURANCE REFORM AND CONSUMER PROTECTION.—If the amounts appropriated under subparagraph (A) are not fully obligated under grants under paragraph (1) by the end of fiscal year 2014, any remaining funds shall remain available to the Secretary for grants to States for planning and implementing the insurance reforms and consumer protections under part A.

(C) ALLOCATION.—The Secretary shall establish a formula for determining the amount of any grant to a State under this subsection. Under such formula—

(i) the Secretary shall consider the number of plans of health insurance coverage offered in each State and the population of the State; and

(ii) no State qualifying for a grant under paragraph (1) shall receive less than $1,000,000, or more than $5,000,000 for a grant year.

(d) MEDICAL REIMBURSEMENT DATA CENTERS.—

(1) FUNCTIONS.—A center established under subsection (c)(1)(C) shall—

(A) develop fee schedules and other database tools that fairly and accurately reflect market rates for medical services and the geographic differences in those rates;

(B) use the best available statistical methods and data processing technology to develop such fee schedules and other database tools;

(C) regularly update such fee schedules and other database tools to reflect changes in charges for medical services;

(D) make health care cost information readily available to the public through an Internet website that allows consumers to understand the amounts that health care

providers in their area charge for particular medical services; and

(E) regularly publish information concerning the statistical methodologies used by the center to analyze health charge data and make such data available to researchers and policy makers.

(2) CONFLICTS OF INTEREST.—A center established under subsection (c)(1)(C) shall adopt by-laws that ensures that the center (and all members of the governing board of the center) is independent and free from all conflicts of interest. Such by-laws shall ensure that the center is not controlled or influenced by, and does not have any corporate relation to, any individual or entity that may make or receive payments for health care services based on the center's analysis of health care costs.

(3) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to permit a center established under subsection (c)(1)(C) to compel health insurance issuers to provide data to the center.

SEC. 2794.[300gg–95] UNIFORM FRAUD AND ABUSE REFERRAL FORMAT.[34].

The Secretary shall request the National Association of Insurance Commissioners to develop a model uniform report form for private health insurance issuer seeking to refer suspected fraud and abuse to State insurance departments or other responsible State agencies for investigation. The Secretary shall request that the National Association of Insurance Commissioners develop recommendations for uniform reporting standards for such referrals.

[34] So in law. There are two sections 2794s'. Sections 1003 and 6603 of Public Law 111–148 add new section 2794s' to the end of part C of title XXVII.

TITLE XXVIII—NATIONAL ALL-HAZARDS PREPAREDNESS FOR PUBLIC HEALTH EMERGENCIES

Subtitle A—National All-Hazards Preparedness and Response Planning, Coordinating, and Reporting

SEC. 2801.PUBLIC HEALTH AND MEDICAL PREPAREDNESS AND RESPONSE FUNCTIONS.

(a) IN GENERAL.—The Secretary of Health and Human Services shall lead all Federal public health and medical response to public health emergencies and incidents covered by the National Response Plan developed pursuant to section 502(6) of the Homeland Security Act of 2002, or any successor plan.

(b) INTERAGENCY AGREEMENT.—The Secretary, in collaboration with the Secretary of Veterans Affairs, the Secretary of Transportation, the Secretary of Defense, the Secretary of Homeland Security, and the head of any other relevant Federal agency, shall establish an interagency agreement, consistent with the National Response Plan or any successor plan, under which agreement the Secretary of Health and Human Services shall assume operational control of emergency public health and medical response assets, as necessary, in the event of a public health emergency, except that members of the armed forces under the authority of the Secretary of Defense shall remain under the command and control of the Secretary of Defense, as shall any associated assets of the Department of Defense.

SEC. 2802.NATIONAL HEALTH SECURITY STRATEGY.

(a) IN GENERAL.—

(1) PREPAREDNESS AND RESPONSE REGARDING PUBLIC HEALTH EMERGENCIES.—Beginning in 2014 and every four years thereafter, the Secretary shall prepare and submit to the relevant committees of Congress a coordinated strategy (to be known as the National Health Security Strategy) and any revisions thereof, and an accompanying implementation plan for public health emergency preparedness and response. Such National Health Security Strategy shall identify the process for achieving the preparedness goals described in subsection (b) and shall be consistent with the National Preparedness Goal, the National Incident Management System, and the National

Response Plan developed pursuant to section 502(6) of the Homeland Security Act of 2002, or any successor plan.

(2) EVALUATION OF PROGRESS.—The National Health Security Strategy shall include an evaluation of the progress made by Federal, State, local, and tribal entities, based on the evidence-based benchmarks and objective standards that measure levels of preparedness established pursuant to section 319C–1(g). Such evaluation shall include aggregate and State-specific breakdowns of obligated funding spent by major category (as defined by the Secretary) for activities funded through awards pursuant to sections 319C–1 and 319C–2.

(3) PUBLIC HEALTH WORKFORCE.—In 2009, the National Health Security Strategy shall include a national strategy for establishing an effective and prepared public health workforce, including defining the functions, capabilities, and gaps in such workforce, and identifying strategies to recruit, retain, and protect such workforce from workplace exposures during public health emergencies.

(b) PREPAREDNESS GOALS.—The National Health Security Strategy shall include provisions in furtherance of the following:

(1) INTEGRATION.—Integrating public health and public and private medical capabilities with other first responder systems, including through—

(A) the periodic evaluation of Federal, State, local, and tribal preparedness and response capabilities through drills and exercises, including drills and exercises to ensure medical surge capacity for events without notice; and

(B) integrating public and private sector public health and medical donations and volunteers.

(2) PUBLIC HEALTH.—Developing and sustaining Federal, State, local, and tribal essential public health security capabilities, including the following:

(A) Disease situational awareness domestically and abroad, including detection, identification, and investigation.

(B) Disease containment including capabilities for isolation, quarantine, social distancing, and decontamination.

(C) Risk communication and public preparedness.

(D) Rapid distribution and administration of medical countermeasures.

(3) MEDICAL.—Increasing the preparedness, response capabilities, and surge capacity of hospitals, other health care facilities (including mental health and ambulatory care facilities and which may include dental health facilities), and trauma care, critical care, and emergency medical service systems, with respect to public health emergencies (including related availability, accessibility, and coordination), which shall include developing plans for the following:

(A) Strengthening public health emergency medical and trauma management and treatment capabilities.

(B) Fatality management.

(C) Coordinated medical triage and evacuation to appropriate medical institutions based on patient medical need, taking into account regionalized systems of care.

(D) Rapid distribution and administration of medical countermeasures.

(E) Effective utilization of any available public and private mobile medical assets (which may include such dental health assets) and integration of other Federal assets.

(F) Protecting health care workers and health care first responders from workplace exposures during a public health emergency.

(G) Optimizing a coordinated and flexible approach to the medical surge capacity of hospitals, other health care facilities, critical care, trauma care (which may include trauma centers), and emergency medical systems.

(4) AT-RISK INDIVIDUALS.—

(A) Taking into account the public health and medical needs of at-risk individuals, including the unique needs and considerations of individuals with disabilities, in the event of a public health emergency.

(B) For the purpose of this section and sections 319C–1, 319F, and 319L, the term "at-risk individuals" means children, pregnant women, senior citizens and other individuals who have special needs in the event of a public health emergency, as determined by the Secretary.

(5) COORDINATION.—Minimizing duplication of, and ensuring coordination between, Federal, State, local, and tribal planning, preparedness, and response activities (including the State Emergency Management Assistance Compact). Such planning shall be consistent with the National Response Plan, or any successor plan, and National Incident Management System and the National Preparedness Goal.

(6) CONTINUITY OF OPERATIONS.—Maintaining vital public health and medical services to allow for optimal Federal, State, local, and tribal operations in the event of a public health emergency.

(7) COUNTERMEASURES.—

(A) Promoting strategic initiatives to advance countermeasures to diagnose, mitigate, prevent, or treat harm from any biological agent or toxin, chemical, radiological, or nuclear agent or agents, whether naturally occurring, unintentional, or deliberate.

(B) For purposes of this paragraph, the term "countermeasures" has the same meaning as the terms "qualified countermeasures" under section 319F–1, "qualified pandemic and epidemic products" under section 319F–3, and "security countermeasures" under section 319F–2.

(8) MEDICAL AND PUBLIC HEALTH COMMUNITY RESILIENCY.—Strengthening the ability of States, local communities, and tribal communities to prepare for, respond to, and be resilient in the event of public health emergencies, whether naturally occurring, unintentional, or deliberate by—

(A) optimizing alignment and integration of medical and public health preparedness and response planning and capabilities with and into routine daily activities; and

(B) promoting familiarity with local medical and public health systems.

SEC. 2803.ENHANCING MEDICAL SURGE CAPACITY.

(a) STUDY OF ENHANCING MEDICAL SURGE CAPACITY.—As part of the joint review described in section 2812(b), the Secretary shall evaluate the benefits and feasibility of improving the capacity of the Department of Health and Human Services to provide additional medical surge capacity to local communities in the event of a public health emergency. Such study shall include an assessment of the need for and feasibility of improving surge capacity through—

(1) acquisition and operation of mobile medical assets by the Secretary to be deployed, on a contingency basis, to a community in the event of a public health emergency;

(2) integrating the practice of telemedicine within the National Disaster Medical System; and

(3) other strategies to improve such capacity as determined appropriate by the Secretary.

(b) AUTHORITY TO ACQUIRE AND OPERATE MOBILE MEDICAL ASSETS.—In addition to any other authority to acquire, deploy, and operate mobile medical assets, the Secretary may acquire, deploy, and operate mobile medical assets if, taking into consideration the evaluation conducted under subsection (a), such acquisition, deployment, and operation is determined to be beneficial and feasible in improving the capacity of the Department of Health and Human Services to provide additional medical surge capacity to local communities in the event of a public health emergency.

(c) USING FEDERAL FACILITIES TO ENHANCE MEDICAL SURGE CAPACITY.—

(1) ANALYSIS.—The Secretary shall conduct an analysis of whether there are Federal facilities which, in the event of a public health emergency, could practicably be used as facilities in which to provide health care.

(2) MEMORANDA OF UNDERSTANDING.—If, based on the analysis conducted under paragraph (1), the Secretary determines that there are Federal facilities which, in the event of a public health emergency, could be used as facilities in which to provide health care, the Secretary shall, with respect to each such facility, seek to conclude a memorandum of understanding with the head of the Department or agency that operates such facility that permits the use of such facility to provide health care in the event of a public health emergency.

Subtitle B—All-Hazards Emergency Preparedness and Response

SEC. 2811.COORDINATION OF PREPAREDNESS FOR AND RESPONSE TO ALL-HAZARDS PUBLIC HEALTH EMERGENCIES.

(a) IN GENERAL.—There is established within the Department of Health and Human Services the position of the Assistant Secretary for Preparedness and Response. The President, with the advice and consent of the Senate, shall appoint an individual to serve

in such position. Such Assistant Secretary shall report to the Secretary.

(b) DUTIES.—Subject to the authority of the Secretary, the Assistant Secretary for Preparedness and Response shall carry out the following functions:

(1) LEADERSHIP.—Serve as the principal advisor to the Secretary on all matters related to Federal public health and medical preparedness and response for public health emergencies.

(2) PERSONNEL.—Register, credential, organize, train, equip, and have the authority to deploy Federal public health and medical personnel under the authority of the Secretary, including the National Disaster Medical System, and coordinate such personnel with the Medical Reserve Corps and the Emergency System for Advance Registration of Volunteer Health Professionals.

(3) COUNTERMEASURES.—Oversee advanced research, development, and procurement of qualified countermeasures (as defined in section 319F–1), security countermeasures (as defined in section 319F–2), and qualified pandemic or epidemic products (as defined in section 319F–3).

(4) COORDINATION.—

(A) FEDERAL INTEGRATION.—Coordinate with relevant Federal officials to ensure integration of Federal preparedness and response activities for public health emergencies.

(B) STATE, LOCAL, AND TRIBAL INTEGRATION.—Coordinate with State, local, and tribal public health officials, the Emergency Management Assistance Compact, health care systems, and emergency medical service systems to ensure effective integration of Federal public health and medical assets during a public health emergency.

(C) EMERGENCY MEDICAL SERVICES.—Promote improved emergency medical services medical direction, system integration, research, and uniformity of data collection, treatment protocols, and policies with regard to public health emergencies.

(D) POLICY COORDINATION AND STRATEGIC DIRECTION.—Provide integrated policy coordination and strategic direction with respect to all matters related to Federal public health and medical preparedness and execution and deployment of the Federal response for public health emergencies and incidents covered by the National Response Plan developed pursuant to section 504(6) of the Homeland Security Act of 2002, or any successor plan, before, during, and following public health emergencies.

(E) IDENTIFICATION OF INEFFICIENCIES.—Identify and minimize gaps, duplication, and other inefficiencies in medical and public health preparedness and response activities and the actions necessary to overcome these obstacles.

(F) COORDINATION OF GRANTS AND AGREEMENTS.—Align and coordinate medical and public health grants and cooperative agreements as applicable to preparedness and response activities authorized under this Act, to the extent possible, including program requirements, timelines, and

measurable goals, and in consultation with the Secretary of Homeland Security, to—

(i) optimize and streamline medical and public health preparedness and response capabilities and the ability of local communities to respond to public health emergencies; and

(ii) gather and disseminate best practices among grant and cooperative agreement recipients, as appropriate.

(G) DRILL AND OPERATIONAL EXERCISES.—Carry out drills and operational exercises, in consultation with the Department of Homeland Security, the Department of Defense, the Department of Veterans Affairs, and other applicable Federal departments and agencies, as necessary and appropriate, to identify, inform, and address gaps in and policies related to all-hazards medical and public health preparedness and response, including exercises based on—

(i) identified threats for which countermeasures are available and for which no countermeasures are available; and

(ii) unknown threats for which no countermeasures are available.

(H) NATIONAL SECURITY PRIORITY.—On a periodic basis consult with, as applicable and appropriate, the Assistant to the President for National Security Affairs, to provide an update on, and discuss, medical and public health preparedness and response activities pursuant to this Act and the Federal Food, Drug, and Cosmetic Act, including progress on the development, approval, clearance, and licensure of medical countermeasures.

(5) LOGISTICS.—In coordination with the Secretary of Veterans Affairs, the Secretary of Homeland Security, the General Services Administration, and other public and private entities, provide logistical support for medical and public health aspects of Federal responses to public health emergencies.

(6) LEADERSHIP.—Provide leadership in international programs, initiatives, and policies that deal with public health and medical emergency preparedness and response.

(7) COUNTERMEASURES BUDGET PLAN.—Develop, and update on an annual basis, a coordinated 5-year budget plan based on the medical countermeasure priorities described in subsection (d). Each such plan shall—

(A) include consideration of the entire medical countermeasures enterprise, including—

(i) basic research and advanced research and development;

(ii) approval, clearance, licensure, and authorized uses of products; and

(iii) procurement, stockpiling, maintenance, and replenishment of all products in the Strategic National Stockpile;

(B) inform prioritization of resources and include measurable outputs and outcomes to allow for the tracking of the progress made toward identified priorities;

(C) identify medical countermeasure life-cycle costs to inform planning, budgeting, and anticipated needs within the continuum of the medical countermeasure enterprise consistent with section 319F–2; and

(D) be made available to the appropriate committees of Congress upon request.

(c) FUNCTIONS.—The Assistant Secretary for Preparedness and Response shall—

(1) have lead responsibility within the Department of Health and Human Services for emergency preparedness and response policy coordination and strategic direction;

(2) have authority over and responsibility for—

(A) the National Disaster Medical System pursuant to section 2812;

(B) the Hospital Preparedness Cooperative Agreement Program pursuant to section 319C–2;

(C) the Biomedical Advanced Research and Development Authority pursuant to section 319L;

(D) the Medical Reserve Corps pursuant to section 2813;

(E) the Emergency System for Advance Registration of Volunteer Health Professionals pursuant to section 319I; and

(F) administering grants and related authorities related to trauma care under parts A through C of title XII, such authority to be transferred by the Secretary from the Administrator of the Health Resources and Services Administration to such Assistant Secretary;

(3) exercise the responsibilities and authorities of the Secretary with respect to the coordination of—

(A) the Public Health Emergency Preparedness Cooperative Agreement Program pursuant to section 319C–1;

(B) the Strategic National Stockpile pursuant to section 319F–2; and

(C) the Cities Readiness Initiative; and

(4) assume other duties as determined appropriate by the Secretary.

(d) PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURES ENTERPRISE STRATEGY AND IMPLEMENTATION PLAN.—

(1) IN GENERAL.—Not later than 180 days after the date of enactment of this subsection, and every year thereafter, the Assistant Secretary for Preparedness and Response shall develop and submit to the appropriate committees of Congress a coordinated strategy and accompanying implementation plan for medical countermeasures to address chemical, biological, radiological, and nuclear threats. In developing such a plan, the Assistant Secretary for Preparedness and Response shall consult with the Director of the Biomedical Advanced Research and Development Authority, the Director of the National Institutes of Health, the Director of the Centers for Disease Control and Prevention, and the Commissioner of Food and Drugs. Such strategy and plan shall be known as the "Public Health Emergency Medical Countermeasures Enterprise Strategy and Implementation Plan".

(2) REQUIREMENTS.—The plan under paragraph (1) shall—

(A) describe the chemical, biological, radiological, and nuclear agent or agents that may present a threat to the Nation and the corresponding efforts to develop qualified countermeasures (as defined in section 319F–1), security countermeasures (as defined in section 319F–2), or qualified pandemic or epidemic products (as defined in section 319F–3) for each threat;

(B) evaluate the progress of all activities with respect to such countermeasures or products, including research, advanced research, development, procurement, stockpiling, deployment, distribution, and utilization;

(C) identify and prioritize near-, mid-, and long-term needs with respect to such countermeasures or products to address a chemical, biological, radiological, and nuclear threat or threats;

(D) identify, with respect to each category of threat, a summary of all awards and contracts, including advanced research and development and procurement, that includes—

(i) the time elapsed from the issuance of the initial solicitation or request for a proposal to the adjudication (such as the award, denial of award, or solicitation termination); and

(ii) an identification of projected timelines, anticipated funding allocations, benchmarks, and milestones for each medical countermeasure priority under subparagraph (C), including projected needs with regard to replenishment of the Strategic National Stockpile;

(E) be informed by the recommendations of the National Biodefense Science Board pursuant to section 319M;

(F) evaluate progress made in meeting timelines, allocations, benchmarks, and milestones identified under subparagraph (D)(ii);

(G) report on the amount of funds available for procurement in the special reserve fund as defined in section 319F–2(h) and the impact this funding will have on meeting the requirements under section 319F–2;

(H) incorporate input from Federal, State, local, and tribal stakeholders;

(I) identify the progress made in meeting the medical countermeasure priorities for at-risk individuals (as defined in 2802(b)(4)(B)), as applicable under subparagraph (C), including with regard to the projected needs for related stockpiling and replenishment of the Strategic National Stockpile, including by addressing the needs of pediatric populations with respect to such countermeasures and products in the Strategic National Stockpile, including—

(i) a list of such countermeasures and products necessary to address the needs of pediatric populations;

(ii) a description of measures taken to coordinate with the Office of Pediatric Therapeutics of the Food

and Drug Administration to maximize the labeling, dosages, and formulations of such countermeasures and products for pediatric populations;

(iii) a description of existing gaps in the Strategic National Stockpile and the development of such countermeasures and products to address the needs of pediatric populations; and

(iv) an evaluation of the progress made in addressing priorities identified pursuant to subparagraph (C);

(J) identify the use of authority and activities undertaken pursuant to sections 319F–1(b)(1), 319F–1(b)(2), 319F–1(b)(3), 319F–1(c), 319F–1(d), 319F–1(e), 319F–2(c)(7)(C)(iii), 319F–2(c)(7)(C)(iv), and 319F–2(c)(7)(C)(v) of this Act, and subsections (a)(1), (b)(1), and (e) of section 564 of the Federal Food, Drug, and Cosmetic Act, by summarizing—

(i) the particular actions that were taken under the authorities specified, including, as applicable, the identification of the threat agent, emergency, or the biomedical countermeasure with respect to which the authority was used;

(ii) the reasons underlying the decision to use such authorities, including, as applicable, the options that were considered and rejected with respect to the use of such authorities;

(iii) the number of, nature of, and other information concerning the persons and entities that received a grant, cooperative agreement, or contract pursuant to the use of such authorities, and the persons and entities that were considered and rejected for such a grant, cooperative agreement, or contract, except that the report need not disclose the identity of any such person or entity;

(iv) whether, with respect to each procurement that is approved by the President under section 319F–2(c)(6), a contract was entered into within one year after such approval by the President; and

(v) with respect to section 319F–1(d), for the one-year period for which the report is submitted, the number of persons who were paid amounts totaling $100,000 or greater and the number of persons who were paid amounts totaling at least $50,000 but less than $100,000; and

(K) be made publicly available.

(3) GAO REPORT.—

(A) IN GENERAL.—Not later than 1 year after the date of the submission to the Congress of the first Public Health Emergency Medical Countermeasures Enterprise Strategy and Implementation Plan, the Comptroller General of the United States shall conduct an independent evaluation, and submit to the appropriate committees of Congress a report, concerning such Strategy and Implementation Plan.

(B) CONTENT.—The report described in subparagraph (A) shall review and assess—

(i) the near-term, mid-term, and long-term medical countermeasure needs and identified priorities of the Federal Government pursuant to paragraph (2)(C);

(ii) the activities of the Department of Health and Human Services with respect to advanced research and development pursuant to section 319L; and

(iii) the progress made toward meeting the timelines, allocations, benchmarks, and milestones identified in the Public Health Emergency Medical Countermeasures Enterprise Strategy and Implementation Plan under this subsection.

(e) PROTECTION OF NATIONAL SECURITY.—In carrying out subsections (b)(7) and (d), the Secretary shall ensure that information and items that could compromise national security, contain confidential commercial information, or contain proprietary information are not disclosed.

SEC. 2811A.NATIONAL ADVISORY COMMITTEE ON CHILDREN AND DISASTERS.

(a) ESTABLISHMENT.—The Secretary, in consultation with the Secretary of Homeland Security, shall establish an advisory committee to be known as the "National Advisory Committee on Children and Disasters" (referred to in this section as the "Advisory Committee").

(b) DUTIES.—The Advisory Committee shall—

(1) provide advice and consultation with respect to the activities carried out pursuant to section 2814, as applicable and appropriate;

(2) evaluate and provide input with respect to the medical and public health needs of children as they relate to preparation for, response to, and recovery from all-hazards emergencies; and

(3) provide advice and consultation with respect to State emergency preparedness and response activities and children, including related drills and exercises pursuant to the preparedness goals under section 2802(b).

(c) ADDITIONAL DUTIES.—The Advisory Committee may provide advice and recommendations to the Secretary with respect to children and the medical and public health grants and cooperative agreements as applicable to preparedness and response activities authorized under this title and title III.

(d) MEMBERSHIP.—

(1) IN GENERAL.—The Secretary, in consultation with such other Secretaries as may be appropriate, shall appoint not to exceed 15 members to the Advisory Committee. In appointing such members, the Secretary shall ensure that the total membership of the Advisory Committee is an odd number.

(2) REQUIRED MEMBERS.—The Secretary, in consultation with such other Secretaries as may be appropriate, may appoint to the Advisory Committee under paragraph (1) such individuals as may be appropriate to perform the duties described in subsections (b) and (c), which may include—

(A) the Assistant Secretary for Preparedness and Response;

(B) the Director of the Biomedical Advanced Research and Development Authority;

(C) the Director of the Centers for Disease Control and Prevention;

(D) the Commissioner of Food and Drugs;

(E) the Director of the National Institutes of Health;

(F) the Assistant Secretary of the Administration for Children and Families;

(G) the Administrator of the Federal Emergency Management Agency;

(H) at least two non-Federal health care professionals with expertise in pediatric medical disaster planning, preparedness, response, or recovery;

(I) at least two representatives from State, local, territorial, or tribal agencies with expertise in pediatric disaster planning, preparedness, response, or recovery; and

(J) representatives from such Federal agencies (such as the Department of Education and the Department of Homeland Security) as determined necessary to fulfill the duties of the Advisory Committee, as established under subsections (b) and (c).

(e) MEETINGS.—The Advisory Committee shall meet not less than biannually.

(f) SUNSET.—The Advisory Committee shall terminate on September 30, 2018.

SEC. 2812.NATIONAL DISASTER MEDICAL SYSTEM.

(a) NATIONAL DISASTER MEDICAL SYSTEM.—

(1) IN GENERAL.—The Secretary shall provide for the operation in accordance with this section of a system to be known as the National Disaster Medical System. The Secretary shall designate the Assistant Secretary for Preparedness and Response as the head of the National Disaster Medical System, subject to the authority of the Secretary.

(2) FEDERAL AND STATE COLLABORATIVE SYSTEM.—

(A) IN GENERAL.—The National Disaster Medical System shall be a coordinated effort by the Federal agencies specified in subparagraph (B), working in collaboration with the States and other appropriate public or private entities, to carry out the purposes described in paragraph (3).

(B) PARTICIPATING FEDERAL AGENCIES.—The Federal agencies referred to in subparagraph (A) are the Department of Health and Human Services, the Department of Homeland Security, the Department of Defense, and the Department of Veterans Affairs.

(3) PURPOSE OF SYSTEM.—

(A) IN GENERAL.—The Secretary may activate the National Disaster Medical System to—

(i) provide health services, health-related social services, other appropriate human services, and appropriate auxiliary services to respond to the needs of victims of a public health emergency, including at-risk

individuals as applicable (whether or not determined to be a public health emergency under section 319); or

(ii) be present at locations, and for limited periods of time, specified by the Secretary on the basis that the Secretary has determined that a location is at risk of a public health emergency during the time specified.

(B) ONGOING ACTIVITIES.—The National Disaster Medical System shall carry out such ongoing activities as may be necessary to prepare for the provision of services described in subparagraph (A) in the event that the Secretary activates the National Disaster Medical System for such purposes.

(C) CONSIDERATIONS FOR AT-RISK POPULATIONS.—The Secretary shall take steps to ensure that an appropriate specialized and focused range of public health and medical capabilities are represented in the National Disaster Medical System, which take into account the needs of at-risk individuals, in the event of a public health emergency.

(D) ADMINISTRATION.—The Secretary may determine and pay claims for reimbursement for services under subparagraph (A) directly or through contracts that provide for payment in advance or by way of reimbursement.

(E) TEST FOR MOBILIZATION OF SYSTEM.—During the one-year period beginning on the date of the enactment of the Pandemic and All-Hazards Preparedness Act, the Secretary shall conduct an exercise to test the capability and timeliness of the National Disaster Medical System to mobilize and otherwise respond effectively to a bioterrorist attack or other public health emergency that affects two or more geographic locations concurrently. Thereafter, the Secretary may periodically conduct such exercises regarding the National Disaster Medical System as the Secretary determines to be appropriate.

(b) MODIFICATIONS.—

(1) IN GENERAL.—Taking into account the findings from the joint review described under paragraph (2), the Secretary shall modify the policies of the National Disaster Medical System as necessary.

(2) JOINT REVIEW AND MEDICAL SURGE CAPACITY STRATEGIC PLAN.—Not later than 180 days after the date of enactment of the Pandemic and All-Hazards Preparedness Act, the Secretary, in coordination with the Secretary of Homeland Security, the Secretary of Defense, and the Secretary of Veterans Affairs, shall conduct a joint review of the National Disaster Medical System. Such review shall include an evaluation of medical surge capacity, as described by section 2803(a). As part of the National Health Security Strategy under section 2802, the Secretary shall update the findings from such review and further modify the policies of the National Disaster Medical System as necessary.

(3) PARTICIPATION AGREEMENTS FOR NON-FEDERAL ENTITIES.—In carrying out paragraph (1), the Secretary shall establish criteria regarding the participation of States and private entities in the National Disaster Medical System, including cri-

teria regarding agreements for such participation. The criteria shall include the following:

(A) Provisions relating to the custody and use of Federal personal property by such entities, which may in the discretion of the Secretary include authorizing the custody and use of such property to respond to emergency situations for which the National Disaster Medical System has not been activated by the Secretary pursuant to subsection (a)(3)(A). Any such custody and use of Federal personal property shall be on a reimbursable basis.

(B) Provisions relating to circumstances in which an individual or entity has agreements with both the National Disaster Medical System and another entity regarding the provision of emergency services by the individual. Such provisions shall address the issue of priorities among the agreements involved.

(c) INTERMITTENT DISASTER-RESPONSE PERSONNEL.—

(1) IN GENERAL.—For the purpose of assisting the National Disaster Medical System in carrying out duties under this section, the Secretary may appoint individuals to serve as intermittent personnel of such System in accordance with applicable civil service laws and regulations.

(2) LIABILITY.—For purposes of section 224(a) and the remedies described in such section, an individual appointed under paragraph (1) shall, while acting within the scope of such appointment, be considered to be an employee of the Public Health Service performing medical, surgical, dental, or related functions. With respect to the participation of individuals appointed under paragraph (1) in training programs authorized by the Assistant Secretary for Preparedness and Response or a comparable official of any Federal agency specified in subsection (a)(2)(B), acts of individuals so appointed that are within the scope of such participation shall be considered within the scope of the appointment under paragraph (1) (regardless of whether the individuals receive compensation for such participation).

(d) CERTAIN EMPLOYMENT ISSUES REGARDING INTERMITTENT APPOINTMENTS.—

(1) INTERMITTENT DISASTER-RESPONSE APPOINTEE.—For purposes of this subsection, the term "intermittent disaster-response appointee" means an individual appointed by the Secretary under subsection (c).

(2) COMPENSATION FOR WORK INJURIES.—An intermittent disaster-response appointee shall, while acting in the scope of such appointment, be considered to be an employee of the Public Health Service performing medical, surgical, dental, or related functions, and an injury sustained by such an individual shall be deemed "in the performance of duty", for purposes of chapter 81 of title 5, United States Code, pertaining to compensation for work injuries. With respect to the participation of individuals appointed under subsection (c) in training programs authorized by the Assistant Secretary for Preparedness and Response or a comparable official of any Federal agency specified in subsection (a)(2)(B), injuries sustained by such an

individual, while acting within the scope of such participation, also shall be deemed "in the performance of duty" for purposes of chapter 81 of title 5, United States Code (regardless of whether the individuals receive compensation for such participation). In the event of an injury to such an intermittent disaster-response appointee, the Secretary of Labor shall be responsible for making determinations as to whether the claimant is entitled to compensation or other benefits in accordance with chapter 81 of title 5, United States Code.

(3) EMPLOYMENT AND REEMPLOYMENT RIGHTS.—

(A) IN GENERAL.—Service as an intermittent disaster-response appointee when the Secretary activates the National Disaster Medical System or when the individual participates in a training program authorized by the Assistant Secretary for Preparedness and Response or a comparable official of any Federal agency specified in subsection (a)(2)(B) shall be deemed "service in the uniformed services" for purposes of chapter 43 of title 38, United States Code, pertaining to employment and reemployment rights of individuals who have performed service in the uniformed services (regardless of whether the individual receives compensation for such participation). All rights and obligations of such persons and procedures for assistance, enforcement, and investigation shall be as provided for in chapter 43 of title 38, United States Code.

(B) NOTICE OF ABSENCE FROM POSITION OF EMPLOYMENT.—Preclusion of giving notice of service by necessity of Service as an intermittent disaster-response appointee when the Secretary activates the National Disaster Medical System shall be deemed preclusion by "military necessity" for purposes of section 4312(b) of title 38, United States Code, pertaining to giving notice of absence from a position of employment. A determination of such necessity shall be made by the Secretary, in consultation with the Secretary of Defense, and shall not be subject to judicial review.

(4) LIMITATION.—An intermittent disaster-response appointee shall not be deemed an employee of the Department of Health and Human Services for purposes other than those specifically set forth in this section.

(e) RULE OF CONSTRUCTION REGARDING USE OF COMMISSIONED CORPS.—If the Secretary assigns commissioned officers of the Regular or Reserve Corps to serve with the National Disaster Medical System, such assignments do not affect the terms and conditions of their appointments as commissioned officers of the Regular or Reserve Corps, respectively (including with respect to pay and allowances, retirement, benefits, rights, privileges, and immunities).

(f) DEFINITION.—For purposes of this section, the term "auxiliary services" includes mortuary services, veterinary services, and other services that are determined by the Secretary to be appropriate with respect to the needs referred to in subsection (a)(3)(A).

(g) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of providing for the Assistant Secretary for Preparedness and Response and the operations of the National Disaster Medical Sys-

tem, other than purposes for which amounts in the Public Health Emergency Fund under section 319 are available, there are authorized to be appropriated $52,700,000 for each of fiscal years 2014 through 2018.

SEC. 2813.VOLUNTEER MEDICAL RESERVE CORPS.

(a) IN GENERAL.—Not later than 180 days after the date of enactment of the Pandemic and All-Hazards Preparedness Act, the Secretary, in collaboration with State, local, and tribal officials, shall build on State, local, and tribal programs in existence on the date of enactment of such Act to establish and maintain a Medical Reserve Corps (referred to in this section as the "Corps") to provide for an adequate supply of volunteers in the case of a Federal, State, local, or tribal public health emergency. The Corps shall be headed by a Director who shall be appointed by the Secretary and shall oversee the activities of the Corps chapters that exist at the State, local, and tribal levels.

(b) STATE, LOCAL, AND TRIBAL COORDINATION.—The Corps shall be established using existing State, local, and tribal teams and shall not alter such teams.

(c) COMPOSITION.—The Corps shall be composed of individuals who—

(1)(A) are health professionals who have appropriate professional training and expertise as determined appropriate by the Director of the Corps; or

(B) are non-health professionals who have an interest in serving in an auxiliary or support capacity to facilitate access to health care services in a public health emergency;

(2) are certified in accordance with the certification program developed under subsection (d);

(3) are geographically diverse in residence;

(4) have registered and carry out training exercises with a local chapter of the Medical Reserve Corps; and

(5) indicate whether they are willing to be deployed outside the area in which they reside in the event of a public health emergency.

(d) CERTIFICATION; DRILLS.—

(1) CERTIFICATION.—The Director, in collaboration with State, local, and tribal officials, shall establish a process for the periodic certification of individuals who volunteer for the Corps, as determined by the Secretary, which shall include the completion by each individual of the core training programs developed under section 319F, as required by the Director. Such certification shall not supercede State licensing or credentialing requirements.

(2) DRILLS.—In conjunction with the core training programs referred to in paragraph (1), and in order to facilitate the integration of trained volunteers into the health care system at the local level, Corps members shall engage in periodic training exercises to be carried out at the local level. Such training exercises shall, as appropriate and applicable, incorporate the needs of at-risk individuals in the event of a public health emergency.

(e) DEPLOYMENT.—During a public health emergency, the Secretary shall have the authority to activate and deploy willing members of the Corps to areas of need, taking into consideration the public health and medical expertise required, with the concurrence of the State, local, or tribal officials from the area where the members reside.

(f) EXPENSES AND TRANSPORTATION.—While engaged in performing duties as a member of the Corps pursuant to an assignment by the Secretary (including periods of travel to facilitate such assignment), members of the Corps who are not otherwise employed by the Federal Government shall be allowed travel or transportation expenses, including per diem in lieu of subsistence.

(g) IDENTIFICATION.—The Secretary, in cooperation and consultation with the States, shall develop a Medical Reserve Corps Identification Card that describes the licensure and certification information of Corps members, as well as other identifying information determined necessary by the Secretary.

(h) INTERMITTENT DISASTER-RESPONSE PERSONNEL.—

(1) IN GENERAL.—For the purpose of assisting the Corps in carrying out duties under this section, during a public health emergency, the Secretary may appoint selected individuals to serve as intermittent personnel of such Corps in accordance with applicable civil service laws and regulations. In all other cases, members of the Corps are subject to the laws of the State in which the activities of the Corps are undertaken.

(2) APPLICABLE PROTECTIONS.—Subsections (c)(2), (d), and (e) of section 2812 shall apply to an individual appointed under paragraph (1) in the same manner as such subsections apply to an individual appointed under section 2812(c).

(3) LIMITATION.—State, local, and tribal officials shall have no authority to designate a member of the Corps as Federal intermittent disaster-response personnel, but may request the services of such members.

(i) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $11,200,000 for each of fiscal years 2014 through 2018.

SEC. 2814.AT-RISK INDIVIDUALS.

The Secretary, acting through such employee of the Department of Health and Human Services as determined by the Secretary and designated publicly (which may, at the discretion of the Secretary, involve the appointment or designation of an individual as the Director of At-Risk Individuals), shall—

(1) monitor emerging issues and concerns as they relate to medical and public health preparedness and response for at-risk individuals in the event of a public health emergency declared by the Secretary under section 319;

(2) oversee the implementation of the preparedness goals described in section 2802(b) with respect to the public health and medical needs of at-risk individuals in the event of a public health emergency, as described in section 2802(b)(4);

(3) assist other Federal agencies responsible for planning for, responding to, and recovering from public health emergencies in addressing the needs of at-risk individuals;

(4) provide guidance to and ensure that recipients of State and local public health grants include preparedness and response strategies and capabilities that take into account the medical and public health needs of at-risk individuals in the event of a public health emergency, as described in section 319C–1(b)(2)(A)(iii);

(5) ensure that the contents of the strategic national stockpile take into account at-risk populations as described in section 2802(b)(4)(B);

(6) oversee curriculum development for the public health and medical response training program on medical management of casualties, as it concerns at-risk individuals as described in subparagraphs (A) through (C) of section 319F(a)(2);

(7) disseminate and, as appropriate, update novel and best practices of outreach to and care of at-risk individuals before, during, and following public health emergencies in as timely a manner as is practicable, including from the time a public health threat is identified; and

(8) ensure that public health and medical information distributed by the Department of Health and Human Services during a public health emergency is delivered in a manner that takes into account the range of communication needs of the intended recipients, including at-risk individuals.

SEC. 2815.[42 U.S.C. 300hh–17] EMERGENCY RESPONSE COORDINATION OF PRIMARY CARE PROVIDERS.

The Secretary, acting through Administrator[1] of the Health Resources and Services Administration, and in coordination with the Assistant Secretary for Preparedness and Response, shall

(1) provide guidance and technical assistance to health centers funded under section 330 and to State and local health departments and emergency managers to integrate health centers into State and local emergency response plans and to better meet the primary care needs of populations served by health centers during public health emergencies; and

(2) encourage employees at health centers funded under section 330 to participate in emergency medical response programs including the National Disaster Medical System authorized in section 2812, the Volunteer Medical Reserve Corps authorized in section 2813, and the Emergency System for Advance Registration of Health Professions Volunteers authorized in section 319I.

Subtitle C—Strengthening Public Health Surveillance Systems

SEC. 2821.EPIDEMIOLOGY-LABORATORY CAPACITY GRANTS.

(a) IN GENERAL.—Subject to the availability of appropriations, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish an Epidemiology and Laboratory Capacity Grant Program to award grants to State health departments as well as local health departments and tribal

[1] So in law. Probably should read "the Administrator".

jurisdictions that meet such criteria as the Director determines appropriate. Academic centers that assist State and eligible local and tribal health departments may also be eligible for funding under this section as the Director determines appropriate. Grants shall be awarded under this section to assist public health agencies in improving surveillance for, and response to, infectious diseases and other conditions of public health importance by—

(1) strengthening epidemiologic capacity to identify and monitor the occurrence of infectious diseases and other conditions of public health importance;

(2) enhancing laboratory practice as well as systems to report test orders and results electronically;

(3) improving information systems including developing and maintaining an information exchange using national guidelines and complying with capacities and functions determined by an advisory council established and appointed by the Director; and

(4) developing and implementing prevention and control strategies.

(b) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $190,000,000 for each of fiscal years 2010 through 2013, of which—

(1) not less than $95,000,000 shall be made available each such fiscal year for activities under paragraphs (1) and (4) of subsection (a);

(2) not less than $60,000,000 shall be made available each such fiscal year for activities under subsection (a)(3); and

(3) not less than $32,000,000 shall be made available each such fiscal year for activities under subsection (a)(2).

PUBLIC HEALTH SERVICE ACT

As Amended Through P.L. 112–240, Enacted January 2, 2013

TITLE XXIX—LIFESPAN RESPITE CARE

SEC. 2901.[300ii] DEFINITIONS.

In this title:

(1) ADULT WITH A SPECIAL NEED.—The term "adult with a special need" means a person 18 years of age or older who requires care or supervision to—

(A) meet the person's basic needs;

(B) prevent physical self-injury or injury to others; or

(C) avoid placement in an institutional facility.

(2) AGING AND DISABILITY RESOURCE CENTER.—The term "aging and disability resource center" means an entity administering a program established by the State, as part of the State's system of long-term care, to provide a coordinated system for providing—

(A) comprehensive information on available public and private long-term care programs, options, and resources;

(B) personal counseling to assist individuals in assessing their existing or anticipated long-term care needs, and developing and implementing a plan for long-term care designed to meet their specific needs and circumstances; and

(C) consumer access to the range of publicly supported long-term care programs for which consumers may be eligible, by serving as a convenient point of entry for such programs.

(3) CHILD WITH A SPECIAL NEED.—The term "child with a special need" means an individual less than 18 years of age who requires care or supervision beyond that required of children generally to—

(A) meet the child's basic needs; or

(B) prevent physical injury, self-injury, or injury to others.

(4) ELIGIBLE STATE AGENCY.—The term "eligible State agency" means a State agency that—

(A) administers the State's program under the Older Americans Act of 1965, administers the State's program under title XIX of the Social Security Act, or is designated by the Governor of such State to administer the State's programs under this title;

(B) is an aging and disability resource center;

(C) works in collaboration with a public or private nonprofit statewide respite care coalition or organization; and

(D) demonstrates—

(i) an ability to work with other State and community-based agencies;

(ii) an understanding of respite care and family caregiver issues across all age groups, disabilities, and chronic conditions; and

(iii) the capacity to ensure meaningful involvement of family members, family caregivers, and care recipients.

(5) FAMILY CAREGIVER.—The term "family caregiver" means an unpaid family member, a foster parent, or another unpaid adult, who provides in-home monitoring, management, supervision, or treatment of a child or adult with a special need.

(6) LIFESPAN RESPITE CARE.—The term "lifespan respite care" means a coordinated system of accessible, community-based respite care services for family caregivers of children or adults with special needs.

(7) RESPITE CARE.—The term "respite care" means planned or emergency care provided to a child or adult with a special need in order to provide temporary relief to the family caregiver of that child or adult.

(8) STATE.—The term "State" means any of the several States, the District of Columbia, the Virgin Islands of the United States, the Commonwealth of Puerto Rico, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

SEC. 2902.[300ii–1] LIFESPAN RESPITE CARE GRANTS AND COOPERATIVE AGREEMENTS.

(a) PURPOSES.—The purposes of this section are—

(1) to expand and enhance respite care services to family caregivers;

(2) to improve the statewide dissemination and coordination of respite care; and

(3) to provide, supplement, or improve access and quality of respite care services to family caregivers, thereby reducing family caregiver strain.

(b) AUTHORIZATION.—Subject to subsection (e), the Secretary is authorized to award grants or cooperative agreements for the purposes described in subsection (a) to eligible State agencies for which an application is submitted pursuant to subsection (d).

(c) FEDERAL LIFESPAN APPROACH.—In carrying out this section, the Secretary shall work in cooperation with the National Family Caregiver Support Program of the Administration on Aging and other respite care programs within the Department of Health and Human Services to ensure coordination of respite care services for family caregivers of children and adults with special needs.

(d) APPLICATION.—

(1) SUBMISSION.—Each Governor desiring the eligible State agency of his or her State to receive a grant or cooperative agreement under this section shall submit an application on behalf of such agency to the Secretary at such time, in such manner, and containing such information as the Secretary shall require.

(2) CONTENTS.—Each application submitted under this section shall include—

(A) a description of the eligible State agency's—

(i) ability to work with other State and community-based agencies;

(ii) understanding of respite care and family caregiver issues across all age groups, disabilities, and chronic conditions; and

(iii) capacity to ensure meaningful involvement of family members, family caregivers, and care recipients;

(B) with respect to the population of family caregivers to whom respite care information or services will be provided or for whom respite care workers and volunteers will be recruited and trained, a description of—

(i) the population of family caregivers;

(ii) the extent and nature of the respite care needs of that population;

(iii) existing respite care services for that population, including numbers of family caregivers being served and extent of unmet need;

(iv) existing methods or systems to coordinate respite care information and services to the population at the State and local level and extent of unmet need;

(v) how respite care information dissemination and coordination, respite care services, respite care worker and volunteer recruitment and training programs, or training programs for family caregivers that assist such family caregivers in making informed decisions about respite care services will be provided using grant or cooperative agreement funds;

(vi) a plan for administration, collaboration, and coordination of the proposed respite care activities with other related services or programs offered by public or private, nonprofit entities, including area agencies on aging;

(vii) how the population, including family caregivers, care recipients, and relevant public or private agencies, will participate in the planning and implementation of the proposed respite care activities;

(viii) how the proposed respite care activities will make use, to the maximum extent feasible, of other Federal, State, and local funds, programs, contributions, other forms of reimbursements, personnel, and facilities;

(ix) respite care services available to family caregivers in the eligible State agency's State or locality, including unmet needs and how the eligible State agency's plan for use of funds will improve the coordination and distribution of respite care services for family caregivers of children and adults with special needs;

(x) the criteria used to identify family caregivers eligible for respite care services;

(xi) how the quality and safety of any respite care services provided will be monitored, including methods to ensure that respite care workers and volunteers are appropriately screened and possess the necessary skills to care for the needs of the care recipient in the absence of the family caregiver; and

(xii) the results expected from proposed respite care activities and the procedures to be used for evaluating those results;

(C) assurances that, where appropriate, the eligible State agency will have a system for maintaining the confidentiality of care recipient and family caregiver records; and

(D) a memorandum of agreement regarding the joint responsibility for the eligible State agency's lifespan respite program between—

(i) the eligible State agency; and

(ii) a public or private nonprofit statewide respite coalition or organization.

(e) PRIORITY; CONSIDERATIONS.—When awarding grants or cooperative agreements under this section, the Secretary shall—

(1) give priority to eligible State agencies that the Secretary determines show the greatest likelihood of implementing or enhancing lifespan respite care statewide; and

(2) give consideration to eligible State agencies that are building or enhancing the capacity of their long-term care systems to respond to the comprehensive needs, including respite care needs, of their residents.

(f) USE OF GRANT OR COOPERATIVE AGREEMENT FUNDS.—

(1) IN GENERAL.—

(A) REQUIRED USES OF FUNDS.—Each eligible State agency awarded a grant or cooperative agreement under this section shall use all or part of the funds—

(i) to develop or enhance lifespan respite care at the State and local levels;

(ii) to provide respite care services for family caregivers caring for children or adults;

(iii) to train and recruit respite care workers and volunteers;

(iv) to provide information to caregivers about available respite and support services; and

(v) to assist caregivers in gaining access to such services.

(B) OPTIONAL USES OF FUNDS.—Each eligible State agency awarded a grant or cooperative agreement under this section may use part of the funds for—

(i) training programs for family caregivers to assist such family caregivers in making informed decisions about respite care services;

(ii) other services essential to the provision of respite care as the Secretary may specify; or

(iii) training and education for new caregivers.

(2) SUBCONTRACTS.—Each eligible State agency awarded a grant or cooperative agreement under this section may carry

out the activities described in paragraph (1) directly or by grant to, or contract with, public or private entities.

(3) MATCHING FUNDS.—

(A) IN GENERAL.—With respect to the costs of the activities to be carried out under paragraph (1), a condition for the receipt of a grant or cooperative agreement under this section is that the eligible State agency agrees to make available (directly or through donations from public or private entities) non-Federal contributions toward such costs in an amount that is not less than 25 percent of such costs.

(B) DETERMINATION OF AMOUNT CONTRIBUTED.—Non-Federal contributions required by subparagraph (A) may be in cash or in kind, fairly evaluated, including plant, equipment, or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

(g) TERM OF GRANTS OR COOPERATIVE AGREEMENTS.—

(1) IN GENERAL.—The Secretary shall award grants or cooperative agreements under this section for terms that do not exceed 5 years.

(2) RENEWAL.—The Secretary may renew a grant or cooperative agreement under this section at the end of the term of the grant or cooperative agreement determined under paragraph (1).

(h) MAINTENANCE OF EFFORT.—Funds made available under this section shall be used to supplement and not supplant other Federal, State, and local funds available for respite care services.

SEC. 2903.[300ii–2] NATIONAL LIFESPAN RESPITE RESOURCE CENTER.

(a) ESTABLISHMENT.—The Secretary may award a grant or cooperative agreement to a public or private nonprofit entity to establish a National Resource Center on Lifespan Respite Care (referred to in this section as the "center").

(b) PURPOSES OF THE CENTER.—The center shall—

(1) maintain a national database on lifespan respite care;

(2) provide training and technical assistance to State, community, and nonprofit respite care programs; and

(3) provide information, referral, and educational programs to the public on lifespan respite care.

SEC. 2904.[300ii–3] REPORT.

Not later than January 1, 2009, the Secretary shall report to the Congress on the activities undertaken under this title. Such report shall evaluate—

(1) the number of States that have lifespan respite care programs;

(2) the demographics of the caregivers receiving respite care services through grants or cooperative agreements under this title; and

(3) the effectiveness of entities receiving grants or cooperative agreements under this title.

SEC. 2905.[300ii–4] AUTHORIZATION OF APPROPRIATIONS.

There are authorized to be appropriated to carry out this title—

(1) $30,000,000 for fiscal year 2007;
(2) $40,000,000 for fiscal year 2008;
(3) $53,330,000 for fiscal year 2009;
(4) $71,110,000 for fiscal year 2010; and
(5) $94,810,000 for fiscal year 2011.

PUBLIC HEALTH SERVICE ACT

As Amended Through P.L. 112–240, Enacted January 2, 2013

TITLE XXX—HEALTH INFORMATION TECHNOLOGY AND QUALITY

SEC. 3000.[300jj] DEFINITIONS.

In this title:

(1) CERTIFIED EHR TECHNOLOGY.—The term "certified EHR technology" means a qualified electronic health record that is certified pursuant to section 3001(c)(5) as meeting standards adopted under section 3004 that are applicable to the type of record involved (as determined by the Secretary, such as an ambulatory electronic health record for office-based physicians or an inpatient hospital electronic health record for hospitals).

(2) ENTERPRISE INTEGRATION.—The term "enterprise integration" means the electronic linkage of health care providers, health plans, the government, and other interested parties, to enable the electronic exchange and use of health information among all the components in the health care infrastructure in accordance with applicable law, and such term includes related application protocols and other related standards.

(3) HEALTH CARE PROVIDER.—The term "health care provider" includes a hospital, skilled nursing facility, nursing facility, home health entity or other long term care facility, health care clinic, community mental health center (as defined in section 1913(b)(1)), renal dialysis facility, blood center, ambulatory surgical center described in section 1833(i) of the Social Security Act, emergency medical services provider, Federally qualified health center, group practice, a pharmacist, a pharmacy, a laboratory, a physician (as defined in section 1861(r) of the Social Security Act), a practitioner (as described in section 1842(b)(18)(C) of the Social Security Act), a provider operated by, or under contract with, the Indian Health Service or by an Indian tribe (as defined in the Indian Self-Determination and Education Assistance Act), tribal organization, or urban Indian organization (as defined in section 4 of the Indian Health Care Improvement Act), a rural health clinic, a covered entity under section 340B, an ambulatory surgical center described in section 1833(i) of the Social Security Act, a therapist (as defined in section 1848(k)(3)(B)(iii) of the Social Security Act), and any other category of health care facility, entity, practitioner, or clinician determined appropriate by the Secretary.

(4) HEALTH INFORMATION.—The term "health information" has the meaning given such term in section 1171(4) of the Social Security Act.

(5) HEALTH INFORMATION TECHNOLOGY.—The term "health information technology" means hardware, software, integrated technologies or related licenses, intellectual property, upgrades, or packaged solutions sold as services that are designed for or support the use by health care entities or patients for the electronic creation, maintenance, access, or exchange of health information

(6) HEALTH PLAN.—The term "health plan" has the meaning given such term in section 1171(5) of the Social Security Act.

(7) HIT POLICY COMMITTEE.—The term "HIT Policy Committee" means such Committee established under section 3002(a).

(8) HIT STANDARDS COMMITTEE.—The term "HIT Standards Committee" means such Committee established under section 3003(a).

(9) INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION.—The term "individually identifiable health information" has the meaning given such term in section 1171(6) of the Social Security Act.

(10) LABORATORY.—The term "laboratory" has the meaning given such term in section 353(a).

(11) NATIONAL COORDINATOR.—The term "National Coordinator" means the head of the Office of the National Coordinator for Health Information Technology established under section 3001(a).

(12) PHARMACIST.—The term "pharmacist" has the meaning given such term in section 804(2) of the Federal Food, Drug, and Cosmetic Act.

(13) QUALIFIED ELECTRONIC HEALTH RECORD.—The term "qualified electronic health record" means an electronic record of health-related information on an individual that—

(A) includes patient demographic and clinical health information, such as medical history and problem lists; and

(B) has the capacity—

(i) to provide clinical decision support;

(ii) to support physician order entry;

(iii) to capture and query information relevant to health care quality; and

(iv) to exchange electronic health information with, and integrate such information from other sources.

(14) STATE.—The term "State" means each of the several States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

Subtitle A—Promotion of Health Information Technology

SEC. 3001.[300jj–11] OFFICE OF THE NATIONAL COORDINATOR FOR HEALTH INFORMATION TECHNOLOGY.

(a) ESTABLISHMENT.—There is established within the Department of Health and Human Services an Office of the National Coordinator for Health Information Technology (referred to in this section as the "Office"). The Office shall be headed by a National Coordinator who shall be appointed by the Secretary and shall report directly to the Secretary.

(b) PURPOSE.—The National Coordinator shall perform the duties under subsection (c) in a manner consistent with the development of a nationwide health information technology infrastructure that allows for the electronic use and exchange of information and that—

(1) ensures that each patient's health information is secure and protected, in accordance with applicable law;

(2) improves health care quality, reduces medical errors, reduces health disparities, and advances the delivery of patient-centered medical care;

(3) reduces health care costs resulting from inefficiency, medical errors, inappropriate care, duplicative care, and incomplete information;

(4) provides appropriate information to help guide medical decisions at the time and place of care;

(5) ensures the inclusion of meaningful public input in such development of such infrastructure;

(6) improves the coordination of care and information among hospitals, laboratories, physician offices, and other entities through an effective infrastructure for the secure and authorized exchange of health care information;

(7) improves public health activities and facilitates the early identification and rapid response to public health threats and emergencies, including bioterror events and infectious disease outbreaks;

(8) facilitates health and clinical research and health care quality;

(9) promotes early detection, prevention, and management of chronic diseases;

(10) promotes a more effective marketplace, greater competition, greater systems analysis, increased consumer choice, and improved outcomes in health care services; and

(11) improves efforts to reduce health disparities.

(c) DUTIES OF THE NATIONAL COORDINATOR.—

(1) STANDARDS.—The National Coordinator shall—

(A) review and determine whether to endorse each standard, implementation specification, and certification criterion for the electronic exchange and use of health information that is recommended by the HIT Standards Committee under section 3003 for purposes of adoption under section 3004;

(B) make such determinations under subparagraph (A), and report to the Secretary such determinations, not later than 45 days after the date the recommendation is received by the Coordinator; and

(C) review Federal health information technology investments to ensure that Federal health information technology programs are meeting the objectives of the strategic plan published under paragraph (3).

(2) HIT POLICY COORDINATION.—

(A) IN GENERAL.—The National Coordinator shall coordinate health information technology policy and programs of the Department with those of other relevant executive branch agencies with a goal of avoiding duplication of efforts and of helping to ensure that each agency undertakes health information technology activities primarily within the areas of its greatest expertise and technical capability and in a manner towards a coordinated national goal.

(B) HIT POLICY AND STANDARDS COMMITTEES.—The National Coordinator shall be a leading member in the establishment and operations of the HIT Policy Committee and the HIT Standards Committee and shall serve as a liaison among those two Committees and the Federal Government.

(3) STRATEGIC PLAN.—

(A) IN GENERAL.—The National Coordinator shall, in consultation with other appropriate Federal agencies (including the National Institute of Standards and Technology), update the Federal Health IT Strategic Plan (developed as of June 3, 2008) to include specific objectives, milestones, and metrics with respect to the following:

(i) The electronic exchange and use of health information and the enterprise integration of such information.

(ii) The utilization of an electronic health record for each person in the United States by 2014.

(iii) The incorporation of privacy and security protections for the electronic exchange of an individual's individually identifiable health information.

(iv) Ensuring security methods to ensure appropriate authorization and electronic authentication of health information and specifying technologies or methodologies for rendering health information unusable, unreadable, or indecipherable.

(v) Specifying a framework for coordination and flow of recommendations and policies under this subtitle among the Secretary, the National Coordinator, the HIT Policy Committee, the HIT Standards Committee, and other health information exchanges and other relevant entities.

(vi) Methods to foster the public understanding of health information technology.

(vii) Strategies to enhance the use of health information technology in improving the quality of health

care, reducing medical errors, reducing health disparities, improving public health, increasing prevention and coordination with community resources, and improving the continuity of care among health care settings.

(viii) Specific plans for ensuring that populations with unique needs, such as children, are appropriately addressed in the technology design, as appropriate, which may include technology that automates enrollment and retention for eligible individuals.

(B) COLLABORATION.—The strategic plan shall be updated through collaboration of public and private entities.

(C) MEASURABLE OUTCOME GOALS.—The strategic plan update shall include measurable outcome goals.

(D) PUBLICATION.—The National Coordinator shall republish the strategic plan, including all updates.

(4) WEBSITE.—The National Coordinator shall maintain and frequently update an Internet website on which there is posted information on the work, schedules, reports, recommendations, and other information to ensure transparency in promotion of a nationwide health information technology infrastructure.

(5) CERTIFICATION.—

(A) IN GENERAL.—The National Coordinator, in consultation with the Director of the National Institute of Standards and Technology, shall keep or recognize a program or programs for the voluntary certification of health information technology as being in compliance with applicable certification criteria adopted under this subtitle. Such program shall include, as appropriate, testing of the technology in accordance with section 13201(b) of the Health Information Technology for Economic and Clinical Health Act.

(B) CERTIFICATION CRITERIA DESCRIBED.—In this title, the term "certification criteria" means, with respect to standards and implementation specifications for health information technology, criteria to establish that the technology meets such standards and implementation specifications.

(6) REPORTS AND PUBLICATIONS.—

(A) REPORT ON ADDITIONAL FUNDING OR AUTHORITY NEEDED.—Not later than 12 months after the date of the enactment of this title, the National Coordinator shall submit to the appropriate committees of jurisdiction of the House of Representatives and the Senate a report on any additional funding or authority the Coordinator or the HIT Policy Committee or HIT Standards Committee requires to evaluate and develop standards, implementation specifications, and certification criteria, or to achieve full participation of stakeholders in the adoption of a nationwide health information technology infrastructure that allows for the electronic use and exchange of health information.

(B) IMPLEMENTATION REPORT.—The National Coordinator shall prepare a report that identifies lessons learned

from major public and private health care systems in their implementation of health information technology, including information on whether the technologies and practices developed by such systems may be applicable to and usable in whole or in part by other health care providers.

(C) ASSESSMENT OF IMPACT OF HIT ON COMMUNITIES WITH HEALTH DISPARITIES AND UNINSURED, UNDERINSURED, AND MEDICALLY UNDERSERVED AREAS.—The National Coordinator shall assess and publish the impact of health information technology in communities with health disparities and in areas with a high proportion of individuals who are uninsured, underinsured, and medically underserved individuals (including urban and rural areas) and identify practices to increase the adoption of such technology by health care providers in such communities, and the use of health information technology to reduce and better manage chronic diseases.

(D) EVALUATION OF BENEFITS AND COSTS OF THE ELECTRONIC USE AND EXCHANGE OF HEALTH INFORMATION.—The National Coordinator shall evaluate and publish evidence on the benefits and costs of the electronic use and exchange of health information and assess to whom these benefits and costs accrue.

(E) RESOURCE REQUIREMENTS.—The National Coordinator shall estimate and publish resources required annually to reach the goal of utilization of an electronic health record for each person in the United States by 2014, including—

(i) the required level of Federal funding;

(ii) expectations for regional, State, and private investment;

(iii) the expected contributions by volunteers to activities for the utilization of such records; and

(iv) the resources needed to establish a health information technology workforce sufficient to support this effort (including education programs in medical informatics and health information management).

(7) ASSISTANCE.—The National Coordinator may provide financial assistance to consumer advocacy groups and not-for-profit entities that work in the public interest for purposes of defraying the cost to such groups and entities to participate under, whether in whole or in part, the National Technology Transfer Act of 1995 (15 U.S.C. 272 note).

(8) GOVERNANCE FOR NATIONWIDE HEALTH INFORMATION NETWORK.—The National Coordinator shall establish a governance mechanism for the nationwide health information network.

(d) DETAIL OF FEDERAL EMPLOYEES.—

(1) IN GENERAL.—Upon the request of the National Coordinator, the head of any Federal agency is authorized to detail, with or without reimbursement from the Office, any of the personnel of such agency to the Office to assist it in carrying out its duties under this section.

(2) EFFECT OF DETAIL.—Any detail of personnel under paragraph (1) shall—

(A) not interrupt or otherwise affect the civil service status or privileges of the Federal employee; and

(B) be in addition to any other staff of the Department employed by the National Coordinator.

(3) ACCEPTANCE OF DETAILEES.—Notwithstanding any other provision of law, the Office may accept detailed personnel from other Federal agencies without regard to whether the agency described under paragraph (1) is reimbursed.

(e) CHIEF PRIVACY OFFICER OF THE OFFICE OF THE NATIONAL COORDINATOR.—Not later than 12 months after the date of the enactment of this title, the Secretary shall appoint a Chief Privacy Officer of the Office of the National Coordinator, whose duty it shall be to advise the National Coordinator on privacy, security, and data stewardship of electronic health information and to coordinate with other Federal agencies (and similar privacy officers in such agencies), with State and regional efforts, and with foreign countries with regard to the privacy, security, and data stewardship of electronic individually identifiable health information.

SEC. 3002.[300jj–12] HIT POLICY COMMITTEE.

(a) ESTABLISHMENT.—There is established a HIT Policy Committee to make policy recommendations to the National Coordinator relating to the implementation of a nationwide health information technology infrastructure, including implementation of the strategic plan described in section 3001(c)(3).

(b) DUTIES.—

(1) RECOMMENDATIONS ON HEALTH INFORMATION TECHNOLOGY INFRASTRUCTURE.—The HIT Policy Committee shall recommend a policy framework for the development and adoption of a nationwide health information technology infrastructure that permits the electronic exchange and use of health information as is consistent with the strategic plan under section 3001(c)(3) and that includes the recommendations under paragraph (2). The Committee shall update such recommendations and make new recommendations as appropriate.

(2) SPECIFIC AREAS OF STANDARD DEVELOPMENT.—

(A) IN GENERAL.—The HIT Policy Committee shall recommend the areas in which standards, implementation specifications, and certification criteria are needed for the electronic exchange and use of health information for purposes of adoption under section 3004 and shall recommend an order of priority for the development, harmonization, and recognition of such standards, specifications, and certification criteria among the areas so recommended. Such standards and implementation specifications shall include named standards, architectures, and software schemes for the authentication and security of individually identifiable health information and other information as needed to ensure the reproducible development of common solutions across disparate entities.

(B) AREAS REQUIRED FOR CONSIDERATION.—For purposes of subparagraph (A), the HIT Policy Committee shall make recommendations for at least the following areas:

(i) Technologies that protect the privacy of health information and promote security in a qualified electronic health record, including for the segmentation and protection from disclosure of specific and sensitive individually identifiable health information with the goal of minimizing the reluctance of patients to seek care (or disclose information about a condition) because of privacy concerns, in accordance with applicable law, and for the use and disclosure of limited data sets of such information.

(ii) A nationwide health information technology infrastructure that allows for the electronic use and accurate exchange of health information.

(iii) The utilization of a certified electronic health record for each person in the United States by 2014.

(iv) Technologies that as a part of a qualified electronic health record allow for an accounting of disclosures made by a covered entity (as defined for purposes of regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996) for purposes of treatment, payment, and health care operations (as such terms are defined for purposes of such regulations).

(v) The use of certified electronic health records to improve the quality of health care, such as by promoting the coordination of health care and improving continuity of health care among health care providers, by reducing medical errors, by improving population health, by reducing health disparities, by reducing chronic disease, and by advancing research and education.

(vi) Technologies that allow individually identifiable health information to be rendered unusable, unreadable, or indecipherable to unauthorized individuals when such information is transmitted in the nationwide health information network or physically transported outside of the secured, physical perimeter of a health care provider, health plan, or health care clearinghouse.

(vii) The use of electronic systems to ensure the comprehensive collection of patient demographic data, including, at a minimum, race, ethnicity, primary language, and gender information.

(viii) Technologies that address the needs of children and other vulnerable populations.

(C) OTHER AREAS FOR CONSIDERATION.—In making recommendations under subparagraph (A), the HIT Policy Committee may consider the following additional areas:

(i) The appropriate uses of a nationwide health information infrastructure, including for purposes of—

(I) the collection of quality data and public reporting;

(II) biosurveillance and public health;

(III) medical and clinical research; and

(IV) drug safety.

(ii) Self-service technologies that facilitate the use and exchange of patient information and reduce wait times.

(iii) Telemedicine technologies, in order to reduce travel requirements for patients in remote areas.

(iv) Technologies that facilitate home health care and the monitoring of patients recuperating at home.

(v) Technologies that help reduce medical errors.

(vi) Technologies that facilitate the continuity of care among health settings.

(vii) Technologies that meet the needs of diverse populations.

(viii) Methods to facilitate secure access by an individual to such individual's protected health information.

(ix) Methods, guidelines, and safeguards to facilitate secure access to patient information by a family member, caregiver, or guardian acting on behalf of a patient due to age-related and other disability, cognitive impairment, or dementia.

(x) Any other technology that the HIT Policy Committee finds to be among the technologies with the greatest potential to improve the quality and efficiency of health care.

(3) FORUM.—The HIT Policy Committee shall serve as a forum for broad stakeholder input with specific expertise in policies relating to the matters described in paragraphs (1) and (2).

(4) CONSISTENCY WITH EVALUATION CONDUCTED UNDER MIPPA.—

(A) REQUIREMENT FOR CONSISTENCY.—The HIT Policy Committee shall ensure that recommendations made under paragraph (2)(B)(vi) are consistent with the evaluation conducted under section 1809(a) of the Social Security Act.

(B) SCOPE.—Nothing in subparagraph (A) shall be construed to limit the recommendations under paragraph (2)(B)(vi) to the elements described in section 1809(a)(3) of the Social Security Act.

(C) TIMING.—The requirement under subparagraph (A) shall be applicable to the extent that evaluations have been conducted under section 1809(a) of the Social Security Act, regardless of whether the report described in subsection (b) of such section has been submitted.

(c) MEMBERSHIP AND OPERATIONS.—

(1) IN GENERAL.—The National Coordinator shall take a leading position in the establishment and operations of the HIT Policy Committee.

(2) MEMBERSHIP.—The HIT Policy Committee shall be composed of members to be appointed as follows:

(A) 3 members shall be appointed by the Secretary, 1 of whom shall be appointed to represent the Department of Health and Human Services and 1 of whom shall be a public health official.

(B) 1 member shall be appointed by the majority leader of the Senate.

(C) 1 member shall be appointed by the minority leader of the Senate.

(D) 1 member shall be appointed by the Speaker of the House of Representatives.

(E) 1 member shall be appointed by the minority leader of the House of Representatives.

(F) Such other members as shall be appointed by the President as representatives of other relevant Federal agencies.

(G) 13 members shall be appointed by the Comptroller General of the United States of whom—

(i) 3 members shall advocates for patients or consumers;

(ii) 2 members shall represent health care providers, one of which shall be a physician;

(iii) 1 member shall be from a labor organization representing health care workers;

(iv) 1 member shall have expertise in health information privacy and security;

(v) 1 member shall have expertise in improving the health of vulnerable populations;

(vi) 1 member shall be from the research community;

(vii) 1 member shall represent health plans or other third-party payers;

(viii) 1 member shall represent information technology vendors;

(ix) 1 member shall represent purchasers or employers; and

(x) 1 member shall have expertise in health care quality measurement and reporting.

(3) PARTICIPATION.—The members of the HIT Policy Committee appointed under paragraph (2) shall represent a balance among various sectors of the health care system so that no single sector unduly influences the recommendations of the Policy Committee.

(4) TERMS.—

(A) IN GENERAL.—The terms of the members of the HIT Policy Committee shall be for 3 years, except that the Comptroller General shall designate staggered terms for the members first appointed.

(B) VACANCIES.—Any member appointed to fill a vacancy in the membership of the HIT Policy Committee that occurs prior to the expiration of the term for which the member's predecessor was appointed shall be appointed only for the remainder of that term. A member may serve

after the expiration of that member's term until a successor has been appointed. A vacancy in the HIT Policy Committee shall be filled in the manner in which the original appointment was made.

(5) OUTSIDE INVOLVEMENT.—The HIT Policy Committee shall ensure an opportunity for the participation in activities of the Committee of outside advisors, including individuals with expertise in the development of policies for the electronic exchange and use of health information, including in the areas of health information privacy and security.

(6) QUORUM.—A majority of the member of the HIT Policy Committee shall constitute a quorum for purposes of voting, but a lesser number of members may meet and hold hearings.

(7) FAILURE OF INITIAL APPOINTMENT.—If, on the date that is 45 days after the date of enactment of this title, an official authorized under paragraph (2) to appoint one or more members of the HIT Policy Committee has not appointed the full number of members that such paragraph authorizes such official to appoint, the Secretary is authorized to appoint such members.

(8) CONSIDERATION.—The National Coordinator shall ensure that the relevant and available recommendations and comments from the National Committee on Vital and Health Statistics are considered in the development of policies.

(d) APPLICATION OF FACA.—The Federal Advisory Committee Act (5 U.S.C. App.), other than section 14 of such Act, shall apply to the HIT Policy Committee.

(e) PUBLICATION.—The Secretary shall provide for publication in the Federal Register and the posting on the Internet website of the Office of the National Coordinator for Health Information Technology of all policy recommendations made by the HIT Policy Committee under this section.

SEC. 3003.[300jj–13] HIT STANDARDS COMMITTEE.

(a) ESTABLISHMENT.—There is established a committee to be known as the HIT Standards Committee to recommend to the National Coordinator standards, implementation specifications, and certification criteria for the electronic exchange and use of health information for purposes of adoption under section 3004, consistent with the implementation of the strategic plan described in section 3001(c)(3) and beginning with the areas listed in section 3002(b)(2)(B) in accordance with policies developed by the HIT Policy Committee.

(b) DUTIES.—

(1) STANDARDS DEVELOPMENT.—

(A) IN GENERAL.—The HIT Standards Committee shall recommend to the National Coordinator standards, implementation specifications, and certification criteria described in subsection (a) that have been developed, harmonized, or recognized by the HIT Standards Committee. The HIT Standards Committee shall update such recommendations and make new recommendations as appropriate, including in response to a notification sent under section 3004(a)(2)(B). Such recommendations shall be con-

sistent with the latest recommendations made by the HIT Policy Committee.

(B) HARMONIZATION.—The HIT Standards Committee recognize harmonized or updated standards from an entity or entities for the purpose of harmonizing or updating standards and implementation specifications in order to achieve uniform and consistent implementation of the standards and implementation specifications.

(C) PILOT TESTING OF STANDARDS AND IMPLEMENTATION SPECIFICATIONS.—In the development, harmonization, or recognition of standards and implementation specifications, the HIT Standards Committee shall, as appropriate, provide for the testing of such standards and specifications by the National Institute for Standards and Technology under section 13201(a) of the Health Information Technology for Economic and Clinical Health Act.

(D) CONSISTENCY.—The standards, implementation specifications, and certification criteria recommended under this subsection shall be consistent with the standards for information transactions and data elements adopted pursuant to section 1173 of the Social Security Act.

(2) FORUM.—The HIT Standards Committee shall serve as a forum for the participation of a broad range of stakeholders to provide input on the development, harmonization, and recognition of standards, implementation specifications, and certification criteria necessary for the development and adoption of a nationwide health information technology infrastructure that allows for the electronic use and exchange of health information.

(3) SCHEDULE.—Not later than 90 days after the date of the enactment of this title, the HIT Standards Committee shall develop a schedule for the assessment of policy recommendations developed by the HIT Policy Committee under section 3002. The HIT Standards Committee shall update such schedule annually. The Secretary shall publish such schedule in the Federal Register.

(4) PUBLIC INPUT.—The HIT Standards Committee shall conduct open public meetings and develop a process to allow for public comment on the schedule described in paragraph (3) and recommendations described in this subsection. Under such process comments shall be submitted in a timely manner after the date of publication of a recommendation under this subsection.

(5) CONSIDERATION.—The National Coordinator shall ensure that the relevant and available recommendations and comments from the National Committee on Vital and Health Statistics are considered in the development of standards.

(c) MEMBERSHIP AND OPERATIONS.—

(1) IN GENERAL.—The National Coordinator shall take a leading position in the establishment and operations of the HIT Standards Committee.

(2) MEMBERSHIP.—The membership of the HIT Standards Committee shall at least reflect providers, ancillary healthcare workers, consumers, purchasers, health plans, technology ven-

dors, researchers, relevant Federal agencies, and individuals with technical expertise on health care quality, privacy and security, and on the electronic exchange and use of health information.

(3) PARTICIPATION.—The members of the HIT Standards Committee appointed under this subsection shall represent a balance among various sectors of the health care system so that no single sector unduly influences the recommendations of such Committee.

(4) OUTSIDE INVOLVEMENT.—The HIT Policy Committee shall ensure an opportunity for the participation in activities of the Committee of outside advisors, including individuals with expertise in the development of standards for the electronic exchange and use of health information, including in the areas of health information privacy and security.

(5) BALANCE AMONG SECTORS.—In developing the procedures for conducting the activities of the HIT Standards Committee, the HIT Standards Committee shall act to ensure a balance among various sectors of the health care system so that no single sector unduly influences the actions of the HIT Standards Committee.

(6) ASSISTANCE.—For the purposes of carrying out this section, the Secretary may provide or ensure that financial assistance is provided by the HIT Standards Committee to defray in whole or in part any membership fees or dues charged by such Committee to those consumer advocacy groups and not for profit entities that work in the public interest as a part of their mission.

(d) APPLICATION OF FACA.—The Federal Advisory Committee Act (5 U.S.C. App.), other than section 14, shall apply to the HIT Standards Committee.

(e) PUBLICATION.—The Secretary shall provide for publication in the Federal Register and the posting on the Internet website of the Office of the National Coordinator for Health Information Technology of all recommendations made by the HIT Standards Committee under this section.

SEC. 3004.[300jj–14] PROCESS FOR ADOPTION OF ENDORSED RECOMMENDATIONS; ADOPTION OF INITIAL SET OF STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA.

(a) PROCESS FOR ADOPTION OF ENDORSED RECOMMENDATIONS.—

(1) REVIEW OF ENDORSED STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA.—Not later than 90 days after the date of receipt of standards, implementation specifications, or certification criteria endorsed under section 3001(c), the Secretary, in consultation with representatives of other relevant Federal agencies, shall jointly review such standards, implementation specifications, or certification criteria and shall determine whether or not to propose adoption of such standards, implementation specifications, or certification criteria.

(2) DETERMINATION TO ADOPT STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA.—If the Secretary determines—

(A) to propose adoption of any grouping of such standards, implementation specifications, or certification criteria, the Secretary shall, by regulation under section 553 of title 5, United States Code, determine whether or not to adopt such grouping of standards, implementation specifications, or certification criteria; or

(B) not to propose adoption of any grouping of standards, implementation specifications, or certification criteria, the Secretary shall notify the National Coordinator and the HIT Standards Committee in writing of such determination and the reasons for not proposing the adoption of such recommendation.

(3) PUBLICATION.—The Secretary shall provide for publication in the Federal Register of all determinations made by the Secretary under paragraph (1).

(b) ADOPTION OF STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA.—

(1) IN GENERAL.—Not later than December 31, 2009, the Secretary shall, through the rulemaking process consistent with subsection (a)(2)(A), adopt an initial set of standards, implementation specifications, and certification criteria for the areas required for consideration under section 3002(b)(2)(B). The rulemaking for the initial set of standards, implementation specifications, and certification criteria may be issued on an interim, final basis.

(2) APPLICATION OF CURRENT STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA.—The standards, implementation specifications, and certification criteria adopted before the date of the enactment of this title through the process existing through the Office of the National Coordinator for Health Information Technology may be applied towards meeting the requirement of paragraph (1).

(3) SUBSEQUENT STANDARDS ACTIVITY.—The Secretary shall adopt additional standards, implementation specifications, and certification criteria as necessary and consistent with the schedule published under section 3003(b)(2).

SEC. 3005.[300jj–15] APPLICATION AND USE OF ADOPTED STANDARDS AND IMPLEMENTATION SPECIFICATIONS BY FEDERAL AGENCIES.

For requirements relating to the application and use by Federal agencies of the standards and implementation specifications adopted under section 3004, see section 13111 of the Health Information Technology for Economic and Clinical Health Act.

SEC. 3006.[300jj–16] VOLUNTARY APPLICATION AND USE OF ADOPTED STANDARDS AND IMPLEMENTATION SPECIFICATIONS BY PRIVATE ENTITIES.

(a) IN GENERAL.—Except as provided under section 13112 of the HITECH Act, nothing in such Act or in the amendments made by such Act shall be construed—

(1) to require a private entity to adopt or comply with a standard or implementation specification adopted under section 3004; or

(2) to provide a Federal agency authority, other than the authority such agency may have under other provisions of law, to require a private entity to comply with such a standard or implementation specification.

(b) RULE OF CONSTRUCTION.—Nothing in this subtitle shall be construed to require that a private entity that enters into a contract with the Federal Government apply or use the standards and implementation specifications adopted under section 3004 with respect to activities not related to the contract.

SEC. 3007.[300jj–17] FEDERAL HEALTH INFORMATION TECHNOLOGY.

(a) IN GENERAL.—The National Coordinator shall support the development and routine updating of qualified electronic health record technology (as defined in section 3000) consistent with subsections (b) and (c) and make available such qualified electronic health record technology unless the Secretary determines through an assessment that the needs and demands of providers are being substantially and adequately met through the marketplace.

(b) CERTIFICATION.—In making such electronic health record technology publicly available, the National Coordinator shall ensure that the qualified electronic health record technology described in subsection (a) is certified under the program developed under section 3001(c)(3) to be in compliance with applicable standards adopted under section 3003(a).

(c) AUTHORIZATION TO CHARGE A NOMINAL FEE.—The National Coordinator may impose a nominal fee for the adoption by a health care provider of the health information technology system developed or approved under subsection (a) and (b). Such fee shall take into account the financial circumstances of smaller providers, low income providers, and providers located in rural or other medically underserved areas.

(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to require that a private or government entity adopt or use the technology provided under this section.

SEC. 3008.[300jj–18] TRANSITIONS.

(a) ONCHIT.—To the extent consistent with section 3001, all functions, personnel, assets, liabilities, and administrative actions applicable to the National Coordinator for Health Information Technology appointed under Executive Order No. 13335 or the Office of such National Coordinator on the date before the date of the enactment of this title shall be transferred to the National Coordinator appointed under section 3001(a) and the Office of such National Coordinator as of the date of the enactment of this title.

(b) NATIONAL EHEALTH COLLABORATIVE.—Nothing in sections 3002 or 3003 or this subsection shall be construed as prohibiting the AHIC Successor, Inc. doing business as the National eHealth Collaborative from modifying its charter, duties, membership, and any other structure or function required to be consistent with section 3002 and 3003 so as to allow the Secretary to recognize such AHIC Successor, Inc. as the HIT Policy Committee or the HIT Standards Committee.

(c) CONSISTENCY OF RECOMMENDATIONS.—In carrying out section 3003(b)(1)(A), until recommendations are made by the HIT Policy Committee, recommendations of the HIT Standards Committee shall be consistent with the most recent recommendations made by such AHIC Successor, Inc.

SEC. 3009.[300jj–19] MISCELLANEOUS PROVISIONS.

(a) RELATION TO HIPAA PRIVACY AND SECURITY LAW.—

(1) IN GENERAL.—With respect to the relation of this title to HIPAA privacy and security law:

(A) This title may not be construed as having any effect on the authorities of the Secretary under HIPAA privacy and security law.

(B) The purposes of this title include ensuring that the health information technology standards and implementation specifications adopted under section 3004 take into account the requirements of HIPAA privacy and security law.

(2) DEFINITION.—For purposes of this section, the term "HIPAA privacy and security law" means—

(A) the provisions of part C of title XI of the Social Security Act, section 264 of the Health Insurance Portability and Accountability Act of 1996, and subtitle D of title IV of the Health Information Technology for Economic and Clinical Health Act; and

(B) regulations under such provisions.

(b) FLEXIBILITY.—In administering the provisions of this title, the Secretary shall have flexibility in applying the definition of health care provider under section 3000(3), including the authority to omit certain entities listed in such definition when applying such definition under this title, where appropriate.

Subtitle B—Incentives for the Use of Health Information Technology

SEC. 3011.[300jj–31] IMMEDIATE FUNDING TO STRENGTHEN THE HEALTH INFORMATION TECHNOLOGY INFRASTRUCTURE.

(a) IN GENERAL.—The Secretary shall, using amounts appropriated under section 3018, invest in the infrastructure necessary to allow for and promote the electronic exchange and use of health information for each individual in the United States consistent with the goals outlined in the strategic plan developed by the National Coordinator (and as available) under section 3001. The Secretary shall invest funds through the different agencies with expertise in such goals, such as the Office of the National Coordinator for Health Information Technology, the Health Resources and Services Administration, the Agency for Healthcare Research and Quality, the Centers of Medicare & Medicaid Services, the Centers for Disease Control and Prevention, and the Indian Health Service to support the following:

(1) Health information technology architecture that will support the nationwide electronic exchange and use of health information in a secure, private, and accurate manner, including connecting health information exchanges, and which may

include updating and implementing the infrastructure necessary within different agencies of the Department of Health and Human Services to support the electronic use and exchange of health information.

(2) Development and adoption of appropriate certified electronic health records for categories of health care providers not eligible for support under title XVIII or XIX of the Social Security Act for the adoption of such records.

(3) Training on and dissemination of information on best practices to integrate health information technology, including electronic health records, into a provider's delivery of care, consistent with best practices learned from the Health Information Technology Research Center developed under section 3012(b), including community health centers receiving assistance under section 330, covered entities under section 340B, and providers participating in one or more of the programs under titles XVIII, XIX, and XXI of the Social Security Act (relating to Medicare, Medicaid, and the State Children's Health Insurance Program).

(4) Infrastructure and tools for the promotion of telemedicine, including coordination among Federal agencies in the promotion of telemedicine.

(5) Promotion of the interoperability of clinical data repositories or registries.

(6) Promotion of technologies and best practices that enhance the protection of health information by all holders of individually identifiable health information.

(7) Improvement and expansion of the use of health information technology by public health departments.

(b) COORDINATION.—The Secretary shall ensure funds under this section are used in a coordinated manner with other health information promotion activities.

(c) ADDITIONAL USE OF FUNDS.—In addition to using funds as provided in subsection (a), the Secretary may use amounts appropriated under section 3018 to carry out health information technology activities that are provided for under laws in effect on the date of the enactment of this title.

(d) STANDARDS FOR ACQUISITION OF HEALTH INFORMATION TECHNOLOGY.—To the greatest extent practicable, the Secretary shall ensure that where funds are expended under this section for the acquisition of health information technology, such funds shall be used to acquire health information technology that meets applicable standards adopted under section 3004. Where it is not practicable to expend funds on health information technology that meets such applicable standards, the Secretary shall ensure that such health information technology meets applicable standards otherwise adopted by the Secretary.

SEC. 3012.[300jj–32] HEALTH INFORMATION TECHNOLOGY IMPLEMENTATION ASSISTANCE.

(a) HEALTH INFORMATION TECHNOLOGY EXTENSION PROGRAM.—To assist health care providers to adopt, implement, and effectively use certified EHR technology that allows for the electronic exchange and use of health information, the Secretary, acting through the Office of the National Coordinator, shall establish a

health information technology extension program to provide health information technology assistance services to be carried out through the Department of Health and Human Services. The National Coordinator shall consult with other Federal agencies with demonstrated experience and expertise in information technology services, such as the National Institute of Standards and Technology, in developing and implementing this program.

(b) HEALTH INFORMATION TECHNOLOGY RESEARCH CENTER.—

(1) IN GENERAL.—The Secretary shall create a Health Information Technology Research Center (in this section referred to as the "Center") to provide technical assistance and develop or recognize best practices to support and accelerate efforts to adopt, implement, and effectively utilize health information technology that allows for the electronic exchange and use of information in compliance with standards, implementation specifications, and certification criteria adopted under section 3004.

(2) INPUT.—The Center shall incorporate input from—

(A) other Federal agencies with demonstrated experience and expertise in information technology services such as the National Institute of Standards and Technology;

(B) users of health information technology, such as providers and their support and clerical staff and others involved in the care and care coordination of patients, from the health care and health information technology industry; and

(C) others as appropriate.

(3) PURPOSES.—The purposes of the Center are to—

(A) provide a forum for the exchange of knowledge and experience;

(B) accelerate the transfer of lessons learned from existing public and private sector initiatives, including those currently receiving Federal financial support;

(C) assemble, analyze, and widely disseminate evidence and experience related to the adoption, implementation, and effective use of health information technology that allows for the electronic exchange and use of information including through the regional centers described in subsection (c);

(D) provide technical assistance for the establishment and evaluation of regional and local health information networks to facilitate the electronic exchange of information across health care settings and improve the quality of health care;

(E) provide technical assistance for the development and dissemination of solutions to barriers to the exchange of electronic health information; and

(F) learn about effective strategies to adopt and utilize health information technology in medically underserved communities.

(c) HEALTH INFORMATION TECHNOLOGY REGIONAL EXTENSION CENTERS.—

(1) IN GENERAL.—The Secretary shall provide assistance for the creation and support of regional centers (in this sub-

section referred to as "regional centers") to provide technical assistance and disseminate best practices and other information learned from the Center to support and accelerate efforts to adopt, implement, and effectively utilize health information technology that allows for the electronic exchange and use of information in compliance with standards, implementation specifications, and certification criteria adopted under section 3004. Activities conducted under this subsection shall be consistent with the strategic plan developed by the National Coordinator, (and, as available) under section 3001.

(2) AFFILIATION.—Regional centers shall be affiliated with any United States-based nonprofit institution or organization, or group thereof, that applies and is awarded financial assistance under this section. Individual awards shall be decided on the basis of merit.

(3) OBJECTIVE.—The objective of the regional centers is to enhance and promote the adoption of health information technology through—

(A) assistance with the implementation, effective use, upgrading, and ongoing maintenance of health information technology, including electronic health records, to healthcare providers nationwide;

(B) broad participation of individuals from industry, universities, and State governments;

(C) active dissemination of best practices and research on the implementation, effective use, upgrading, and ongoing maintenance of health information technology, including electronic health records, to health care providers in order to improve the quality of healthcare and protect the privacy and security of health information;

(D) participation, to the extent practicable, in health information exchanges;

(E) utilization, when appropriate, of the expertise and capability that exists in Federal agencies other than the Department; and

(F) integration of health information technology, including electronic health records, into the initial and ongoing training of health professionals and others in the healthcare industry that would be instrumental to improving the quality of healthcare through the smooth and accurate electronic use and exchange of health information.

(4) REGIONAL ASSISTANCE.—Each regional center shall aim to provide assistance and education to all providers in a region, but shall prioritize any direct assistance first to the following:

(A) Public or not-for-profit hospitals or critical access hospitals.

(B) Federally qualified health centers (as defined in section 1861(aa)(4) of the Social Security Act).

(C) Entities that are located in rural and other areas that serve uninsured, underinsured, and medically underserved individuals (regardless of whether such area is urban or rural).

(D) Individual or small group practices (or a consortium thereof) that are primarily focused on primary care.

(5) FINANCIAL SUPPORT.—The Secretary may provide financial support to any regional center created under this subsection for a period not to exceed four years. The Secretary may not provide more than 50 percent of the capital and annual operating and maintenance funds required to create and maintain such a center, except in an instance of national economic conditions which would render this cost-share requirement detrimental to the program and upon notification to Congress as to the justification to waive the cost-share requirement.

(6) NOTICE OF PROGRAM DESCRIPTION AND AVAILABILITY OF FUNDS.—The Secretary shall publish in the Federal Register, not later than 90 days after the date of the enactment of this title, a draft description of the program for establishing regional centers under this subsection. Such description shall include the following:

(A) A detailed explanation of the program and the programs goals.

(B) Procedures to be followed by the applicants.

(C) Criteria for determining qualified applicants.

(D) Maximum support levels expected to be available to centers under the program.

(7) APPLICATION REVIEW.—The Secretary shall subject each application under this subsection to merit review. In making a decision whether to approve such application and provide financial support, the Secretary shall consider at a minimum the merits of the application, including those portions of the application regarding—

(A) the ability of the applicant to provide assistance under this subsection and utilization of health information technology appropriate to the needs of particular categories of health care providers;

(B) the types of service to be provided to health care providers;

(C) geographical diversity and extent of service area; and

(D) the percentage of funding and amount of in-kind commitment from other sources.

(8) BIENNIAL EVALUATION.—Each regional center which receives financial assistance under this subsection shall be evaluated biennially by an evaluation panel appointed by the Secretary. Each evaluation panel shall be composed of private experts, none of whom shall be connected with the center involved, and of Federal officials. Each evaluation panel shall measure the involved center's performance against the objective specified in paragraph (3). The Secretary shall not continue to provide funding to a regional center unless its evaluation is overall positive.

(9) CONTINUING SUPPORT.—After the second year of assistance under this subsection, a regional center may receive additional support under this subsection if it has received positive evaluations and a finding by the Secretary that continuation of Federal funding to the center was in the best interest of provision of health information technology extension services.

SEC. 3013.[300jj–33] STATE GRANTS TO PROMOTE HEALTH INFORMATION TECHNOLOGY.

(a) IN GENERAL.—The Secretary, acting through the National Coordinator, shall establish a program in accordance with this section to facilitate and expand the electronic movement and use of health information among organizations according to nationally recognized standards.

(b) PLANNING GRANTS.—The Secretary may award a grant to a State or qualified State-designated entity (as described in subsection (f)) that submits an application to the Secretary at such time, in such manner, and containing such information as the Secretary may specify, for the purpose of planning activities described in subsection (d).

(c) IMPLEMENTATION GRANTS.—The Secretary may award a grant to a State or qualified State designated entity that—

(1) has submitted, and the Secretary has approved, a plan described in subsection (e) (regardless of whether such plan was prepared using amounts awarded under subsection (b); and

(2) submits an application at such time, in such manner, and containing such information as the Secretary may specify.

(d) USE OF FUNDS.—Amounts received under a grant under subsection (c) shall be used to conduct activities to facilitate and expand the electronic movement and use of health information among organizations according to nationally recognized standards through activities that include—

(1) enhancing broad and varied participation in the authorized and secure nationwide electronic use and exchange of health information;

(2) identifying State or local resources available towards a nationwide effort to promote health information technology;

(3) complementing other Federal grants, programs, and efforts towards the promotion of health information technology;

(4) providing technical assistance for the development and dissemination of solutions to barriers to the exchange of electronic health information;

(5) promoting effective strategies to adopt and utilize health information technology in medically underserved communities;

(6) assisting patients in utilizing health information technology;

(7) encouraging clinicians to work with Health Information Technology Regional Extension Centers as described in section 3012, to the extent they are available and valuable;

(8) supporting public health agencies' authorized use of and access to electronic health information;

(9) promoting the use of electronic health records for quality improvement including through quality measures reporting; and

(10) such other activities as the Secretary may specify.

(e) PLAN.—

(1) IN GENERAL.—A plan described in this subsection is a plan that describes the activities to be carried out by a State or by the qualified State-designated entity within such State to

facilitate and expand the electronic movement and use of health information among organizations according to nationally recognized standards and implementation specifications.

(2) REQUIRED ELEMENTS.—A plan described in paragraph (1) shall—

(A) be pursued in the public interest;

(B) be consistent with the strategic plan developed by the National Coordinator, (and, as available) under section 3001;

(C) include a description of the ways the State or qualified State-designated entity will carry out the activities described in subsection (b); and

(D) contain such elements as the Secretary may require.

(f) QUALIFIED STATE-DESIGNATED ENTITY.—For purposes of this section, to be a qualified State-designated entity, with respect to a State, an entity shall—

(1) be designated by the State as eligible to receive awards under this section;

(2) be a not-for-profit entity with broad stakeholder representation on its governing board;

(3) demonstrate that one of its principal goals is to use information technology to improve health care quality and efficiency through the authorized and secure electronic exchange and use of health information;

(4) adopt nondiscrimination and conflict of interest policies that demonstrate a commitment to open, fair, and nondiscriminatory participation by stakeholders; and

(5) conform to such other requirements as the Secretary may establish.

(g) REQUIRED CONSULTATION.—In carrying out activities described in subsections (b) and (c), a State or qualified State-designated entity shall consult with and consider the recommendations of—

(1) health care providers (including providers that provide services to low income and underserved populations);

(2) health plans;

(3) patient or consumer organizations that represent the population to be served;

(4) health information technology vendors;

(5) health care purchasers and employers;

(6) public health agencies;

(7) health professions schools, universities and colleges;

(8) clinical researchers;

(9) other users of health information technology such as the support and clerical staff of providers and others involved in the care and care coordination of patients; and

(10) such other entities, as may be determined appropriate by the Secretary.

(h) CONTINUOUS IMPROVEMENT.—The Secretary shall annually evaluate the activities conducted under this section and shall, in awarding grants under this section, implement the lessons learned from such evaluation in a manner so that awards made subsequent to each such evaluation are made in a manner that, in the deter-

mination of the Secretary, will lead towards the greatest improvement in quality of care, decrease in costs, and the most effective authorized and secure electronic exchange of health information.

(i) REQUIRED MATCH.—

(1) IN GENERAL.—For a fiscal year (beginning with fiscal year 2011), the Secretary may not make a grant under this section to a State unless the State agrees to make available non-Federal contributions (which may include in-kind contributions) toward the costs of a grant awarded under subsection (c) in an amount equal to—

(A) for fiscal year 2011, not less than $1 for each $10 of Federal funds provided under the grant;

(B) for fiscal year 2012, not less than $1 for each $7 of Federal funds provided under the grant; and

(C) for fiscal year 2013 and each subsequent fiscal year, not less than $1 for each $3 of Federal funds provided under the grant.

(2) AUTHORITY TO REQUIRE STATE MATCH FOR FISCAL YEARS BEFORE FISCAL YEAR 2011.—For any fiscal year during the grant program under this section before fiscal year 2011, the Secretary may determine the extent to which there shall be required a non-Federal contribution from a State receiving a grant under this section.

SEC. 3014.[300jj–34] COMPETITIVE GRANTS TO STATES AND INDIAN TRIBES FOR THE DEVELOPMENT OF LOAN PROGRAMS TO FACILITATE THE WIDESPREAD ADOPTION OF CERTIFIED EHR TECHNOLOGY.

(a) IN GENERAL.—The National Coordinator may award competitive grants to eligible entities for the establishment of programs for loans to health care providers to conduct the activities described in subsection (e).

(b) ELIGIBLE ENTITY DEFINED.—For purposes of this subsection, the term "eligible entity" means a State or Indian tribe (as defined in the Indian Self-Determination and Education Assistance Act) that—

(1) submits to the National Coordinator an application at such time, in such manner, and containing such information as the National Coordinator may require;

(2) submits to the National Coordinator a strategic plan in accordance with subsection (d) and provides to the National Coordinator assurances that the entity will update such plan annually in accordance with such subsection;

(3) provides assurances to the National Coordinator that the entity will establish a Loan Fund in accordance with subsection (c);

(4) provides assurances to the National Coordinator that the entity will not provide a loan from the Loan Fund to a health care provider unless the provider agrees to—

(A) submit reports on quality measures adopted by the Federal Government (by not later than 90 days after the date on which such measures are adopted), to—

(i) the Administrator of the Centers for Medicare & Medicaid Services (or his or her designee), in the case of an entity participating in the Medicare pro-

gram under title XVIII of the Social Security Act or the Medicaid program under title XIX of such Act; or

(ii) the Secretary in the case of other entities;

(B) demonstrate to the satisfaction of the Secretary (through criteria established by the Secretary) that any certified EHR technology purchased, improved, or otherwise financially supported under a loan under this section is used to exchange health information in a manner that, in accordance with law and standards (as adopted under section 3004) applicable to the exchange of information, improves the quality of health care, such as promoting care coordination; and

(C) comply with such other requirements as the entity or the Secretary may require;

(D) include a plan on how health care providers involved intend to maintain and support the certified EHR technology over time;

(E) include a plan on how the health care providers involved intend to maintain and support the certified EHR technology that would be purchased with such loan, including the type of resources expected to be involved and any such other information as the State or Indian Tribe, respectively, may require; and

(5) agrees to provide matching funds in accordance with subsection (h).

(c) ESTABLISHMENT OF FUND.—For purposes of subsection (b)(3), an eligible entity shall establish a certified EHR technology loan fund (referred to in this subsection as a "Loan Fund") and comply with the other requirements contained in this section. A grant to an eligible entity under this section shall be deposited in the Loan Fund established by the eligible entity. No funds authorized by other provisions of this title to be used for other purposes specified in this title shall be deposited in any Loan Fund.

(d) STRATEGIC PLAN.—

(1) IN GENERAL.—For purposes of subsection (b)(2), a strategic plan of an eligible entity under this subsection shall identify the intended uses of amounts available to the Loan Fund of such entity.

(2) CONTENTS.—A strategic plan under paragraph (1), with respect to a Loan Fund of an eligible entity, shall include for a year the following:

(A) A list of the projects to be assisted through the Loan Fund during such year.

(B) A description of the criteria and methods established for the distribution of funds from the Loan Fund during the year.

(C) A description of the financial status of the Loan Fund as of the date of submission of the plan.

(D) The short-term and long-term goals of the Loan Fund.

(e) USE OF FUNDS.—Amounts deposited in a Loan Fund, including loan repayments and interest earned on such amounts, shall be used only for awarding loans or loan guarantees, making reimbursements described in subsection (g)(4)(A), or as a source of

reserve and security for leveraged loans, the proceeds of which are deposited in the Loan Fund established under subsection (c). Loans under this section may be used by a health care provider to—

(1) facilitate the purchase of certified EHR technology;

(2) enhance the utilization of certified EHR technology (which may include costs associated with upgrading health information technology so that it meets criteria necessary to be a certified EHR technology);

(3) train personnel in the use of such technology; or

(4) improve the secure electronic exchange of health information.

(f) TYPES OF ASSISTANCE.—Except as otherwise limited by applicable State law, amounts deposited into a Loan Fund under this section may only be used for the following:

(1) To award loans that comply with the following:

(A) The interest rate for each loan shall not exceed the market interest rate.

(B) The principal and interest payments on each loan shall commence not later than 1 year after the date the loan was awarded, and each loan shall be fully amortized not later than 10 years after the date of the loan.

(C) The Loan Fund shall be credited with all payments of principal and interest on each loan awarded from the Loan Fund.

(2) To guarantee, or purchase insurance for, a local obligation (all of the proceeds of which finance a project eligible for assistance under this subsection) if the guarantee or purchase would improve credit market access or reduce the interest rate applicable to the obligation involved.

(3) As a source of revenue or security for the payment of principal and interest on revenue or general obligation bonds issued by the eligible entity if the proceeds of the sale of the bonds will be deposited into the Loan Fund.

(4) To earn interest on the amounts deposited into the Loan Fund.

(5) To make reimbursements described in subsection (g)(4)(A).

(g) ADMINISTRATION OF LOAN FUNDS.—

(1) COMBINED FINANCIAL ADMINISTRATION.—An eligible entity may (as a convenience and to avoid unnecessary administrative costs) combine, in accordance with applicable State law, the financial administration of a Loan Fund established under this subsection with the financial administration of any other revolving fund established by the entity if otherwise not prohibited by the law under which the Loan Fund was established.

(2) COST OF ADMINISTERING FUND.—Each eligible entity may annually use not to exceed 4 percent of the funds provided to the entity under a grant under this section to pay the reasonable costs of the administration of the programs under this section, including the recovery of reasonable costs expended to establish a Loan Fund which are incurred after the date of the enactment of this title.

(3) GUIDANCE AND REGULATIONS.—The National Coordinator shall publish guidance and promulgate regulations as may be necessary to carry out the provisions of this section, including—

(A) provisions to ensure that each eligible entity commits and expends funds allotted to the entity under this section as efficiently as possible in accordance with this title and applicable State laws; and

(B) guidance to prevent waste, fraud, and abuse.

(4) PRIVATE SECTOR CONTRIBUTIONS.—

(A) IN GENERAL.—A Loan Fund established under this section may accept contributions from private sector entities, except that such entities may not specify the recipient or recipients of any loan issued under this subsection. An eligible entity may agree to reimburse a private sector entity for any contribution made under this subparagraph, except that the amount of such reimbursement may not be greater than the principal amount of the contribution made.

(B) AVAILABILITY OF INFORMATION.—An eligible entity shall make publicly available the identity of, and amount contributed by, any private sector entity under subparagraph (A) and may issue letters of commendation or make other awards (that have no financial value) to any such entity.

(h) MATCHING REQUIREMENTS.—

(1) IN GENERAL.—The National Coordinator may not make a grant under subsection (a) to an eligible entity unless the entity agrees to make available (directly or through donations from public or private entities) non-Federal contributions in cash to the costs of carrying out the activities for which the grant is awarded in an amount equal to not less than $1 for each $5 of Federal funds provided under the grant.

(2) DETERMINATION OF AMOUNT OF NON-FEDERAL CONTRIBUTION.—In determining the amount of non-Federal contributions that an eligible entity has provided pursuant to subparagraph (A), the National Coordinator may not include any amounts provided to the entity by the Federal Government.

(i) EFFECTIVE DATE.—The Secretary may not make an award under this section prior to January 1, 2010.

SEC. 3015.[300jj–35] DEMONSTRATION PROGRAM TO INTEGRATE INFORMATION TECHNOLOGY INTO CLINICAL EDUCATION.

(a) IN GENERAL.—The Secretary may award grants under this section to carry out demonstration projects to develop academic curricula integrating certified EHR technology in the clinical education of health professionals. Such awards shall be made on a competitive basis and pursuant to peer review.

(b) ELIGIBILITY.—To be eligible to receive a grant under subsection (a), an entity shall—

(1) submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require;

(2) submit to the Secretary a strategic plan for integrating certified EHR technology in the clinical education of health

professionals to reduce medical errors, increase access to prevention, reduce chronic diseases, and enhance health care quality;

(3) be—

(A) a school of medicine, osteopathic medicine, dentistry, or pharmacy, a graduate program in behavioral or mental health, or any other graduate health professions school;

(B) a graduate school of nursing or physician assistant studies;

(C) a consortium of two or more schools described in subparagraph (A) or (B); or

(D) an institution with a graduate medical education program in medicine, osteopathic medicine, dentistry, pharmacy, nursing, or physician assistance studies;

(4) provide for the collection of data regarding the effectiveness of the demonstration project to be funded under the grant in improving the safety of patients, the efficiency of health care delivery, and in increasing the likelihood that graduates of the grantee will adopt and incorporate certified EHR technology, in the delivery of health care services; and

(5) provide matching funds in accordance with subsection (d).

(c) USE OF FUNDS.—

(1) IN GENERAL.—With respect to a grant under subsection (a), an eligible entity shall—

(A) use grant funds in collaboration with 2 or more disciplines; and

(B) use grant funds to integrate certified EHR technology into community-based clinical education.

(2) LIMITATION.—An eligible entity shall not use amounts received under a grant under subsection (a) to purchase hardware, software, or services.

(d) FINANCIAL SUPPORT.—The Secretary may not provide more than 50 percent of the costs of any activity for which assistance is provided under subsection (a), except in an instance of national economic conditions which would render the cost-share requirement under this subsection detrimental to the program and upon notification to Congress as to the justification to waive the cost-share requirement.

(e) EVALUATION.—The Secretary shall take such action as may be necessary to evaluate the projects funded under this section and publish, make available, and disseminate the results of such evaluations on as wide a basis as is practicable.

(f) REPORTS.—Not later than 1 year after the date of enactment of this title, and annually thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Finance of the Senate, and the Committee on Energy and Commerce of the House of Representatives a report that—

(1) describes the specific projects established under this section; and

(2) contains recommendations for Congress based on the evaluation conducted under subsection (e).

SEC. 3016.[300jj–36] INFORMATION TECHNOLOGY PROFESSIONALS IN HEALTH CARE.

(a) IN GENERAL.—The Secretary, in consultation with the Director of the National Science Foundation, shall provide assistance to institutions of higher education (or consortia thereof) to establish or expand medical health informatics education programs, including certification, undergraduate, and masters degree programs, for both health care and information technology students to ensure the rapid and effective utilization and development of health information technologies (in the United States health care infrastructure).

(b) ACTIVITIES.—Activities for which assistance may be provided under subsection (a) may include the following:

(1) Developing and revising curricula in medical health informatics and related disciplines.

(2) Recruiting and retaining students to the program involved.

(3) Acquiring equipment necessary for student instruction in these programs, including the installation of testbed networks for student use.

(4) Establishing or enhancing bridge programs in the health informatics fields between community colleges and universities.

(c) PRIORITY.—In providing assistance under subsection (a), the Secretary shall give preference to the following:

(1) Existing education and training programs.

(2) Programs designed to be completed in less than six months.

SEC. 3017.[300jj–37] GENERAL GRANT AND LOAN PROVISIONS.

(a) REPORTS.—The Secretary may require that an entity receiving assistance under this subtitle shall submit to the Secretary, not later than the date that is 1 year after the date of receipt of such assistance, a report that includes—

(1) an analysis of the effectiveness of the activities for which the entity receives such assistance, as compared to the goals for such activities; and

(2) an analysis of the impact of the project on health care quality and safety.

(b) REQUIREMENT TO IMPROVE QUALITY OF CARE AND DECREASE IN COSTS.—The National Coordinator shall annually evaluate the activities conducted under this subtitle and shall, in awarding grants, implement the lessons learned from such evaluation in a manner so that awards made subsequent to each such evaluation are made in a manner that, in the determination of the National Coordinator, will result in the greatest improvement in the quality and efficiency of health care.

SEC. 3018.[300jj–38] AUTHORIZATION FOR APPROPRIATIONS.

For the purposes of carrying out this subtitle, there is authorized to be appropriated such sums as may be necessary for each of the fiscal years 2009 through 2013.

Subtitle C—Other Provisions

SEC. 3021.[300jj–51] HEALTH INFORMATION TECHNOLOGY ENROLLMENT STANDARDS AND PROTOCOLS.

(a) IN GENERAL.—

(1) STANDARDS AND PROTOCOLS.—Not later than 180 days after the date of enactment of this title, the Secretary, in consultation with the HIT Policy Committee and the HIT Standards Committee, shall develop interoperable and secure standards and protocols that facilitate enrollment of individuals in Federal and State health and human services programs, as determined by the Secretary.

(2) METHODS.—The Secretary shall facilitate enrollment in such programs through methods determined appropriate by the Secretary, which shall include providing individuals and third parties authorized by such individuals and their designees notification of eligibility and verification of eligibility required under such programs.

(b) CONTENT.—The standards and protocols for electronic enrollment in the Federal and State programs described in subsection (a) shall allow for the following:

(1) Electronic matching against existing Federal and State data, including vital records, employment history, enrollment systems, tax records, and other data determined appropriate by the Secretary to serve as evidence of eligibility and in lieu of paper-based documentation.

(2) Simplification and submission of electronic documentation, digitization of documents, and systems verification of eligibility.

(3) Reuse of stored eligibility information (including documentation) to assist with retention of eligible individuals.

(4) Capability for individuals to apply, recertify and manage their eligibility information online, including at home, at points of service, and other community-based locations.

(5) Ability to expand the enrollment system to integrate new programs, rules, and functionalities, to operate at increased volume, and to apply streamlined verification and eligibility processes to other Federal and State programs, as appropriate.

(6) Notification of eligibility, recertification, and other needed communication regarding eligibility, which may include communication via email and cellular phones.

(7) Other functionalities necessary to provide eligibles with streamlined enrollment process.

(c) APPROVAL AND NOTIFICATION.—With respect to any standard or protocol developed under subsection (a) that has been approved by the HIT Policy Committee and the HIT Standards Committee, the Secretary—

(1) shall notify States of such standards or protocols; and

(2) may require, as a condition of receiving Federal funds for the health information technology investments, that States or other entities incorporate such standards and protocols into such investments.

(d) GRANTS FOR IMPLEMENTATION OF APPROPRIATE ENROLLMENT HIT.—

(1) IN GENERAL.—The Secretary shall award grant to eligible entities to develop new, and adapt existing, technology systems to implement the HIT enrollment standards and protocols developed under subsection (a) (referred to in this subsection as "appropriate HIT technology").

(2) ELIGIBLE ENTITIES.—To be eligible for a grant under this subsection, an entity shall—

(A) be a State, political subdivision of a State, or a local governmental entity; and

(B) submit to the Secretary an application at such time, in such manner, and containing—

(i) a plan to adopt and implement appropriate enrollment technology that includes—

(I) proposed reduction in maintenance costs of technology systems;

(II) elimination or updating of legacy systems; and

(III) demonstrated collaboration with other entities that may receive a grant under this section that are located in the same State, political subdivision, or locality;

(ii) an assurance that the entity will share such appropriate enrollment technology in accordance with paragraph (4); and

(iii) such other information as the Secretary may require.

(3) SHARING.—

(A) IN GENERAL.—The Secretary shall ensure that appropriate enrollment HIT adopted under grants under this subsection is made available to other qualified State, qualified political subdivisions of a State, or other appropriate qualified entities (as described in subparagraph (B)) at no cost.

(B) QUALIFIED ENTITIES.—The Secretary shall determine what entities are qualified to receive enrollment HIT under subparagraph (A), taking into consideration the recommendations of the HIT Policy Committee and the HIT Standards Committee.

PUBLIC HEALTH SERVICE ACT

As Amended Through P.L. 112–240, Enacted January 2, 2013

TITLE XXXI—DATA COLLECTION, ANALYSIS, AND QUALITY

SEC. 3101.[300kk] DATA COLLECTION, ANALYSIS, AND QUALITY.

(a) DATA COLLECTION.—

(1) IN GENERAL.—The Secretary shall ensure that, by not later than 2 years after the date of enactment of this title, any federally conducted or supported health care or public health program, activity or survey (including Current Population Surveys and American Community Surveys conducted by the Bureau of Labor Statistics and the Bureau of the Census) collects and reports, to the extent practicable—

(A) data on race, ethnicity, sex, primary language, and disability status for applicants, recipients, or participants;

(B) data at the smallest geographic level such as State, local, or institutional levels if such data can be aggregated;

(C) sufficient data to generate statistically reliable estimates by racial, ethnic, sex, primary language, and disability status subgroups for applicants, recipients or participants using, if needed, statistical oversamples of these subpopulations; and

(D) any other demographic data as deemed appropriate by the Secretary regarding health disparities.

(2) COLLECTION STANDARDS.—In collecting data described in paragraph (1), the Secretary or designee shall—

(A) use Office of Management and Budget standards, at a minimum, for race and ethnicity measures;

(B) develop standards for the measurement of sex, primary language, and disability status;

(C) develop standards for the collection of data described in paragraph (1) that, at a minimum—

(i) collects self-reported data by the applicant, recipient, or participant; and

(ii) collects data from a parent or legal guardian if the applicant, recipient, or participant is a minor or legally incapacitated;

(D) survey health care providers and establish other procedures in order to assess access to care and treatment for individuals with disabilities and to identify—

(i) locations where individuals with disabilities access primary, acute (including intensive), and long-term care;

(ii) the number of providers with accessible facilities and equipment to meet the needs of the individuals with disabilities, including medical diagnostic equipment that meets the minimum technical criteria set forth in section 510 of the Rehabilitation Act of 1973; and

(iii) the number of employees of health care providers trained in disability awareness and patient care of individuals with disabilities; and

(E) require that any reporting requirement imposed for purposes of measuring quality under any ongoing or federally conducted or supported health care or public health program, activity, or survey includes requirements for the collection of data on individuals receiving health care items or services under such programs activities by race, ethnicity, sex, primary language, and disability status.

(3) DATA MANAGEMENT.—In collecting data described in paragraph (1), the Secretary, acting through the National Coordinator for Health Information Technology shall—

(A) develop national standards for the management of data collected; and

(B) develop interoperability and security systems for data management.

(b)[1] DATA ANALYSIS.—

(1) IN GENERAL.—For each federally conducted or supported health care or public health program or activity, the Secretary shall analyze data collected under paragraph (a) to detect and monitor trends in health disparities (as defined for purposes of section 485E) at the Federal and State levels.

(c) DATA REPORTING AND DISSEMINATION.—

(1) IN GENERAL.—The Secretary shall make the analyses described in (b) available to—

(A) the Office of Minority Health;

(B) the National Center on Minority Health and Health Disparities;

(C) the Agency for Healthcare Research and Quality;

(D) the Centers for Disease Control and Prevention;

(E) the Centers for Medicare & Medicaid Services;

(F) the Indian Health Service and epidemiology centers funded under the Indian Health Care Improvement Act;

(G) the Office of Rural health;

(H) other agencies within the Department of Health and Human Services; and

(I) other entities as determined appropriate by the Secretary.

(2) REPORTING OF DATA.—The Secretary shall report data and analyses described in (a) and (b) through—

(A) public postings on the Internet websites of the Department of Health and Human Services; and

[1] So in law. Subsection (b) includes a paragraph (1) but there are no subsequent paragraphs.

(B) any other reporting or dissemination mechanisms determined appropriate by the Secretary.

(3) AVAILABILITY OF DATA.—The Secretary may make data described in (a) and (b) available for additional research, analyses, and dissemination to other Federal agencies, non-governmental entities, and the public, in accordance with any Federal agency's data user agreements.

(d) LIMITATIONS ON USE OF DATA.—Nothing in this section shall be construed to permit the use of information collected under this section in a manner that would adversely affect any individual.

(e) PROTECTION AND SHARING OF DATA.—

(1) PRIVACY AND OTHER SAFEGUARDS.—The Secretary shall ensure (through the promulgation of regulations or otherwise) that—

(A) all data collected pursuant to subsection (a) is protected—

(i) under privacy protections that are at least as broad as those that the Secretary applies to other health data under the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191; 110 Stat. 2033); and

(ii) from all inappropriate internal use by any entity that collects, stores, or receives the data, including use of such data in determinations of eligibility (or continued eligibility) in health plans, and from other inappropriate uses, as defined by the Secretary; and

(B) all appropriate information security safeguards are used in the collection, analysis, and sharing of data collected pursuant to subsection (a).

(2) DATA SHARING.—The Secretary shall establish procedures for sharing data collected pursuant to subsection (a), measures relating to such data, and analyses of such data, with other relevant Federal and State agencies including the agencies, centers, and entities within the Department of Health and Human Services specified in subsection (c)(1)..

(f) DATA ON RURAL UNDERSERVED POPULATIONS.—The Secretary shall ensure that any data collected in accordance with this section regarding racial and ethnic minority groups are also collected regarding underserved rural and frontier populations.

(g) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of fiscal years 2010 through 2014.

(h) REQUIREMENT FOR IMPLEMENTATION.—Notwithstanding any other provision of this section, data may not be collected under this section unless funds are directly appropriated for such purpose in an appropriations Act.

(i) CONSULTATION.—The Secretary shall consult with the Director of the Office of Personnel Management, the Secretary of Defense, the Secretary of Veterans Affairs, the Director of the Bureau of the Census, the Commissioner of Social Security, and the head of other appropriate Federal agencies in carrying out this section.

December 13, 2013

PUBLIC HEALTH SERVICE ACT

As Amended Through P.L. 112–240, Enacted January 2, 2013

TITLE XXXIII—WORLD TRADE CENTER HEALTH PROGRAM

Subtitle A—Establishment of Program; Advisory Committee

SEC. 3301.[42 U.S.C. 300mm] ESTABLISHMENT OF WORLD TRADE CENTER HEALTH PROGRAM.

(a) IN GENERAL.—There is hereby established within the Department of Health and Human Services a program to be known as the World Trade Center Health Program, which shall be administered by the WTC Program Administrator, to provide beginning on July 1, 2011—

(1) medical monitoring and treatment benefits to eligible emergency responders and recovery and cleanup workers (including those who are Federal employees) who responded to the September 11, 2001, terrorist attacks; and

(2) initial health evaluation, monitoring, and treatment benefits to residents and other building occupants and area workers in New York City who were directly impacted and adversely affected by such attacks.

(b) COMPONENTS OF PROGRAM.—The WTC Program includes the following components:

(1) MEDICAL MONITORING FOR RESPONDERS.—Medical monitoring under section 3311, including clinical examinations and long-term health monitoring and analysis for enrolled WTC responders who were likely to have been exposed to airborne toxins that were released, or to other hazards, as a result of the September 11, 2001, terrorist attacks.

(2) INITIAL HEALTH EVALUATION FOR SURVIVORS.—An initial health evaluation under section 3321, including an evaluation to determine eligibility for followup monitoring and treatment.

(3) FOLLOWUP MONITORING AND TREATMENT FOR WTC-RELATED HEALTH CONDITIONS FOR RESPONDERS AND SURVIVORS.—Provision under sections 3312, 3322, and 3323 of followup monitoring and treatment and payment, subject to the provisions of subsection (d), for all medically necessary health and mental health care expenses of an individual with respect to a WTC-related health condition (including necessary prescription drugs).

(4) OUTREACH.—Establishment under section 3303 of an education and outreach program to potentially eligible individuals concerning the benefits under this title.

(5) CLINICAL DATA COLLECTION AND ANALYSIS.—Collection and analysis under section 3304 of health and mental health data relating to individuals receiving monitoring or treatment benefits in a uniform manner in collaboration with the collection of epidemiological data under section 3342.

(6) RESEARCH ON HEALTH CONDITIONS.—Establishment under subtitle C of a research program on health conditions resulting from the September 11, 2001, terrorist attacks.

(c) NO COST SHARING.—Monitoring and treatment benefits and initial health evaluation benefits are provided under subtitle B without any deductibles, copayments, or other cost sharing to an enrolled WTC responder or certified-eligible WTC survivor. Initial health evaluation benefits are provided under subtitle B without any deductibles, copayments, or other cost sharing to a screening-eligible WTC survivor.

(d) PREVENTING FRAUD AND UNREASONABLE ADMINISTRATIVE COSTS.—

(1) FRAUD.—The Inspector General of the Department of Health and Human Services shall develop and implement a program to review the WTC Program's health care expenditures to detect fraudulent or duplicate billing and payment for inappropriate services. This title is a Federal health care program (as defined in section 1128B(f) of the Social Security Act) and is a health plan (as defined in section 1128C(c) of such Act) for purposes of applying sections 1128 through 1128E of such Act.

(2) UNREASONABLE ADMINISTRATIVE COSTS.—The Inspector General of the Department of Health and Human Services shall develop and implement a program to review the WTC Program for unreasonable administrative costs, including with respect to infrastructure, administration, and claims processing.

(e) QUALITY ASSURANCE.—The WTC Program Administrator working with the Clinical Centers of Excellence shall develop and implement a quality assurance program for the monitoring and treatment delivered by such Centers of Excellence and any other participating health care providers. Such program shall include—

(1) adherence to monitoring and treatment protocols;

(2) appropriate diagnostic and treatment referrals for participants;

(3) prompt communication of test results to participants; and

(4) such other elements as the Administrator specifies in consultation with the Clinical Centers of Excellence.

(f) ANNUAL PROGRAM REPORT.—

(1) IN GENERAL.—Not later than 6 months after the end of each fiscal year in which the WTC Program is in operation, the WTC Program Administrator shall submit an annual report to the Congress on the operations of this title for such fiscal year and for the entire period of operation of the program.

(2) CONTENTS INCLUDED IN REPORT.—Each annual report under paragraph (1) shall include at least the following:

(A) ELIGIBLE INDIVIDUALS.—Information for each clinical program described in paragraph (3)—

(i) on the number of individuals who applied for certification under subtitle B and the number of such individuals who were so certified;

(ii) of the individuals who were certified, on the number who received monitoring under the program and the number of such individuals who received medical treatment under the program;

(iii) with respect to individuals so certified who received such treatment, on the WTC-related health conditions for which they were treated; and

(iv) on the projected number of individuals who will be certified under subtitle B in the succeeding fiscal year and the succeeding 10-year period.

(B) MONITORING, INITIAL HEALTH EVALUATION, AND TREATMENT COSTS.—For each clinical program so described—

(i) information on the costs of monitoring and initial health evaluation and the costs of treatment and on the estimated costs of such monitoring, evaluation, and treatment in the succeeding fiscal year; and

(ii) an estimate of the cost of medical treatment for WTC-related health conditions that have been paid for or reimbursed by workers' compensation, by public or private health plans, or by New York City under section 3331.

(C) ADMINISTRATIVE COSTS.—Information on the cost of administering the program, including costs of program support, data collection and analysis, and research conducted under the program.

(D) ADMINISTRATIVE EXPERIENCE.—Information on the administrative performance of the program, including—

(i) the performance of the program in providing timely evaluation of and treatment to eligible individuals; and

(ii) a list of the Clinical Centers of Excellence and other providers that are participating in the program.

(E) SCIENTIFIC REPORTS.—A summary of the findings of any new scientific reports or studies on the health effects associated with exposure described in section 3306(1), including the findings of research conducted under section 3341(a).

(F) ADVISORY COMMITTEE RECOMMENDATIONS.—A list of recommendations by the WTC Scientific/Technical Advisory Committee on additional WTC Program eligibility criteria and on additional WTC-related health conditions and the action of the WTC Program Administrator concerning each such recommendation.

(3) SEPARATE CLINICAL PROGRAMS DESCRIBED.—In paragraph (2), each of the following shall be treated as a separate clinical program of the WTC Program:

(A) FIREFIGHTERS AND RELATED PERSONNEL.—The benefits provided for enrolled WTC responders described in section 3311(a)(2)(A).

(B) OTHER WTC RESPONDERS.—The benefits provided for enrolled WTC responders not described in subparagraph (A).

(C) WTC SURVIVORS.—The benefits provided for screening-eligible WTC survivors and certified-eligible WTC survivors in section 3321(a).

(g) NOTIFICATION TO CONGRESS UPON REACHING 80 PERCENT OF ELIGIBILITY NUMERICAL LIMITS.—The Secretary shall promptly notify the Congress of each of the following:

(1) When the number of enrollments of WTC responders subject to the limit established under section 3311(a)(4) has reached 80 percent of such limit.

(2) When the number of certifications for certified-eligible WTC survivors subject to the limit established under section 3321(a)(3) has reached 80 percent of such limit.

(h) CONSULTATION.—The WTC Program Administrator shall engage in ongoing outreach and consultation with relevant stakeholders, including the WTC Health Program Steering Committees and the Advisory Committee under section 3302, regarding the implementation and improvement of programs under this title.

SEC. 3302.[42 U.S.C. 300mm–1] WTC HEALTH PROGRAM SCIENTIFIC/TECHNICAL ADVISORY COMMITTEE; WTC HEALTH PROGRAM STEERING COMMITTEES.

(a) ADVISORY COMMITTEE.—

(1) ESTABLISHMENT.—The WTC Program Administrator shall establish an advisory committee to be known as the WTC Health Program Scientific/Technical Advisory Committee (in this subsection referred to as the "Advisory Committee") to review scientific and medical evidence and to make recommendations to the Administrator on additional WTC Program eligibility criteria and on additional WTC-related health conditions.

(2) COMPOSITION.—The WTC Program Administrator shall appoint the members of the Advisory Committee and shall include at least—

(A) 4 occupational physicians, at least 2 of whom have experience treating WTC rescue and recovery workers;

(B) 1 physician with expertise in pulmonary medicine;

(C) 2 environmental medicine or environmental health specialists;

(D) 2 representatives of WTC responders;

(E) 2 representatives of certified-eligible WTC survivors;

(F) an industrial hygienist;

(G) a toxicologist;

(H) an epidemiologist; and

(I) a mental health professional.

(3) MEETINGS.—The Advisory Committee shall meet at such frequency as may be required to carry out its duties.

(4) REPORTS.—The WTC Program Administrator shall provide for publication of recommendations of the Advisory Com-

mittee on the public Web site established for the WTC Program.

(5) DURATION.—Notwithstanding any other provision of law, the Advisory Committee shall continue in operation during the period in which the WTC Program is in operation.

(6) APPLICATION OF FACA.—Except as otherwise specifically provided, the Advisory Committee shall be subject to the Federal Advisory Committee Act.

(b) WTC HEALTH PROGRAM STEERING COMMITTEES.—

(1) CONSULTATION.—The WTC Program Administrator shall consult with 2 steering committees (each in this section referred to as a "Steering Committee") that are established as follows:

(A) WTC RESPONDERS STEERING COMMITTEE.—One Steering Committee, to be known as the WTC Responders Steering Committee, for the purpose of receiving input from affected stakeholders and facilitating the coordination of monitoring and treatment programs for the enrolled WTC responders under part 1 of subtitle B.

(B) WTC SURVIVORS STEERING COMMITTEE.—One Steering Committee, to be known as the WTC Survivors Steering Committee, for the purpose of receiving input from affected stakeholders and facilitating the coordination of initial health evaluations, monitoring, and treatment programs for screening-eligible and certified-eligible WTC survivors under part 2 of subtitle B.

(2) MEMBERSHIP.—

(A) WTC RESPONDERS STEERING COMMITTEE.—

(i) REPRESENTATION.—The WTC Responders Steering Committee shall include—

(I) representatives of the Centers of Excellence providing services to WTC responders;

(II) representatives of labor organizations representing firefighters, police, other New York City employees, and recovery and cleanup workers who responded to the September 11, 2001, terrorist attacks; and

(III) 3 representatives of New York City, 1 of whom will be selected by the police commissioner of New York City, 1 by the health commissioner of New York City, and 1 by the mayor of New York City.

(ii) INITIAL MEMBERSHIP.—The WTC Responders Steering Committee shall initially be composed of members of the WTC Monitoring and Treatment Program Steering Committee (as in existence on the day before the date of the enactment of this title).

(B) WTC SURVIVORS STEERING COMMITTEE.—

(i) REPRESENTATION.—The WTC Survivors Steering Committee shall include representatives of—

(I) the Centers of Excellence providing services to screening-eligible and certified-eligible WTC survivors;

(II) the population of residents, students, and area and other workers affected by the September 11, 2001, terrorist attacks;

(III) screening-eligible and certified-eligible survivors receiving initial health evaluations, monitoring, or treatment under part 2 of subtitle B and organizations advocating on their behalf; and

(IV) New York City.

(ii) INITIAL MEMBERSHIP.—The WTC Survivors Steering Committee shall initially be composed of members of the WTC Environmental Health Center Survivor Advisory Committee (as in existence on the day before the date of the enactment of this title).

(C) ADDITIONAL APPOINTMENTS.—Each Steering Committee may recommend, if approved by a majority of voting members of the Committee, additional members to the Committee.

(D) VACANCIES.—A vacancy in a Steering Committee shall be filled by an individual recommended by the Steering Committee.

SEC. 3303.[42 U.S.C. 300mm–2] EDUCATION AND OUTREACH.

The WTC Program Administrator shall institute a program that provides education and outreach on the existence and availability of services under the WTC Program. The outreach and education program—

(1) shall include—

(A) the establishment of a public Web site with information about the WTC Program;

(B) meetings with potentially eligible populations;

(C) development and dissemination of outreach materials informing people about the program; and

(D) the establishment of phone information services; and

(2) shall be conducted in a manner intended—

(A) to reach all affected populations; and

(B) to include materials for culturally and linguistically diverse populations.

SEC. 3304.[42 U.S.C. 300mm–3] UNIFORM DATA COLLECTION AND ANALYSIS.

(a) IN GENERAL.—The WTC Program Administrator shall provide for the uniform collection of data, including claims data (and analysis of data and regular reports to the Administrator) on the prevalence of WTC-related health conditions and the identification of new WTC-related health conditions. Such data shall be collected for all individuals provided monitoring or treatment benefits under subtitle B and regardless of their place of residence or Clinical Center of Excellence through which the benefits are provided. The WTC Program Administrator shall provide, through the Data Centers or otherwise, for the integration of such data into the monitoring and treatment program activities under this title.

(b) COORDINATING THROUGH CENTERS OF EXCELLENCE.—Each Clinical Center of Excellence shall collect data described in sub-

section (a) and report such data to the corresponding Data Center for analysis by such Data Center.

(c) COLLABORATION WITH WTC HEALTH REGISTRY.—The WTC Program Administrator shall provide for collaboration between the Data Centers and the World Trade Center Health Registry described in section 3342.

(d) PRIVACY.—The data collection and analysis under this section shall be conducted and maintained in a manner that protects the confidentiality of individually identifiable health information consistent with applicable statutes and regulations, including, as applicable, HIPAA privacy and security law (as defined in section 3009(a)(2)) and section 552a of title 5, United States Code.

SEC. 3305.[42 U.S.C. 300mm–4] CLINICAL CENTERS OF EXCELLENCE AND DATA CENTERS.

(a) IN GENERAL.—

(1) CONTRACTS WITH CLINICAL CENTERS OF EXCELLENCE.—The WTC Program Administrator shall, subject to subsection (b)(1)(B), enter into contracts with Clinical Centers of Excellence (as defined in subsection (b)(1)(A))—

(A) for the provision of monitoring and treatment benefits and initial health evaluation benefits under subtitle B;

(B) for the provision of outreach activities to individuals eligible for such monitoring and treatment benefits, for initial health evaluation benefits, and for followup to individuals who are enrolled in the monitoring program;

(C) for the provision of counseling for benefits under subtitle B, with respect to WTC-related health conditions, for individuals eligible for such benefits;

(D) for the provision of counseling for benefits for WTC-related health conditions that may be available under workers' compensation or other benefit programs for work-related injuries or illnesses, health insurance, disability insurance, or other insurance plans or through public or private social service agencies and assisting eligible individuals in applying for such benefits;

(E) for the provision of translational and interpretive services for program participants who are not English language proficient; and

(F) for the collection and reporting of data, including claims data, in accordance with section 3304.

(2) CONTRACTS WITH DATA CENTERS.—

(A) IN GENERAL.—The WTC Program Administrator shall enter into contracts with one or more Data Centers (as defined in subsection (b)(2))—

(i) for receiving, analyzing, and reporting to the WTC Program Administrator on data, in accordance with section 3304, that have been collected and reported to such Data Centers by the corresponding Clinical Centers of Excellence under subsection (b)(1)(B)(iii);

(ii) for the development of monitoring, initial health evaluation, and treatment protocols, with respect to WTC-related health conditions;

(iii) for coordinating the outreach activities conducted under paragraph (1)(B) by each corresponding Clinical Center of Excellence;

(iv) for establishing criteria for the credentialing of medical providers participating in the nationwide network under section 3313;

(v) for coordinating and administering the activities of the WTC Health Program Steering Committees established under section 3002(b); and

(vi) for meeting periodically with the corresponding Clinical Centers of Excellence to obtain input on the analysis and reporting of data collected under clause (i) and on the development of monitoring, initial health evaluation, and treatment protocols under clause (ii).

(B) MEDICAL PROVIDER SELECTION.—The medical providers under subparagraph (A)(iv) shall be selected by the WTC Program Administrator on the basis of their experience treating or diagnosing the health conditions included in the list of WTC-related health conditions.

(C) CLINICAL DISCUSSIONS.—In carrying out subparagraph (A)(ii), a Data Center shall engage in clinical discussions across the WTC Program to guide treatment approaches for individuals with a WTC-related health condition.

(D) TRANSPARENCY OF DATA.—A contract entered into under this subsection with a Data Center shall require the Data Center to make any data collected and reported to such Center under subsection (b)(1)(B)(iii) available to health researchers and others as provided in the CDC/ATSDR Policy on Releasing and Sharing Data.

(3) AUTHORITY FOR CONTRACTS TO BE CLASS SPECIFIC.—A contract entered into under this subsection with a Clinical Center of Excellence or a Data Center may be with respect to one or more class of enrolled WTC responders, screening-eligible WTC survivors, or certified-eligible WTC survivors.

(4) USE OF COOPERATIVE AGREEMENTS.—Any contract under this title between the WTC Program Administrator and a Data Center or a Clinical Center of Excellence may be in the form of a cooperative agreement.

(5) REVIEW ON FEASIBILITY OF CONSOLIDATING DATA CENTERS.—Not later than July 1, 2011, the Comptroller General of the United States shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the feasibility of consolidating Data Centers into a single Data Center.

(b) CENTERS OF EXCELLENCE.—

(1) CLINICAL CENTERS OF EXCELLENCE.—

(A) DEFINITION.—For purposes of this title, the term "Clinical Center of Excellence" means a Center that demonstrates to the satisfaction of the Administrator that the Center—

(i) uses an integrated, centralized health care provider approach to create a comprehensive suite of health services under this title that are accessible to enrolled WTC responders, screening-eligible WTC survivors, or certified-eligible WTC survivors;

(ii) has experience in caring for WTC responders and screening-eligible WTC survivors or includes health care providers who have been trained pursuant to section 3313(c);

(iii) employs health care provider staff with expertise that includes, at a minimum, occupational medicine, environmental medicine, trauma-related psychiatry and psychology, and social services counseling; and

(iv) meets such other requirements as specified by the Administrator.

(B) CONTRACT REQUIREMENTS.—The WTC Program Administrator shall not enter into a contract with a Clinical Center of Excellence under subsection (a)(1) unless the Center agrees to do each of the following:

(i) Establish a formal mechanism for consulting with and receiving input from representatives of eligible populations receiving monitoring and treatment benefits under subtitle B from such Center.

(ii) Coordinate monitoring and treatment benefits under subtitle B with routine medical care provided for the treatment of conditions other than WTC-related health conditions.

(iii) Collect and report to the corresponding Data Center data, including claims data, in accordance with section 3304(b).

(iv) Have in place safeguards against fraud that are satisfactory to the Administrator, in consultation with the Inspector General of the Department of Health and Human Services.

(v) Treat or refer for treatment all individuals who are enrolled WTC responders or certified-eligible WTC survivors with respect to such Center who present themselves for treatment of a WTC-related health condition.

(vi) Have in place safeguards, consistent with section 3304(c), to ensure the confidentiality of an individual's individually identifiable health information, including requiring that such information not be disclosed to the individual's employer without the authorization of the individual.

(vii) Use amounts paid under subsection (c)(1) only for costs incurred in carrying out the activities described in subsection (a), other than those described in subsection (a)(1)(A).

(viii) Utilize health care providers with occupational and environmental medicine expertise to conduct physical and mental health assessments, in ac-

cordance with protocols developed under subsection (a)(2)(A)(ii).

(ix) Communicate with WTC responders and screening-eligible and certified-eligible WTC survivors in appropriate languages and conduct outreach activities with relevant stakeholder worker or community associations.

(x) Meet all the other applicable requirements of this title, including regulations implementing such requirements.

(C) TRANSITION RULE TO ENSURE CONTINUITY OF CARE.—The WTC Program Administrator shall to the maximum extent feasible ensure continuity of care in any period of transition from monitoring and treatment of an enrolled WTC responder or certified-eligible WTC survivor by a provider to a Clinical Center of Excellence or a health care provider participating in the nationwide network under section 3313.

(2) DATA CENTERS.—For purposes of this title, the term "Data Center" means a Center that the WTC Program Administrator determines has the capacity to carry out the responsibilities for a Data Center under subsection (a)(2).

(3) CORRESPONDING CENTERS.—For purposes of this title, a Clinical Center of Excellence and a Data Center shall be treated as "corresponding" to the extent that such Clinical Center and Data Center serve the same population group.

(c) PAYMENT FOR INFRASTRUCTURE COSTS.—

(1) IN GENERAL.—The WTC Program Administrator shall reimburse a Clinical Center of Excellence for the fixed infrastructure costs of such Center in carrying out the activities described in subtitle B at a rate negotiated by the Administrator and such Centers. Such negotiated rate shall be fair and appropriate and take into account the number of enrolled WTC responders receiving services from such Center under this title.

(2) FIXED INFRASTRUCTURE COSTS.—For purposes of paragraph (1), the term "fixed infrastructure costs" means, with respect to a Clinical Center of Excellence, the costs incurred by such Center that are not otherwise reimbursable by the WTC Program Administrator under section 3312(c) for patient evaluation, monitoring, or treatment but which are needed to operate the WTC program such as the costs involved in outreach to participants or recruiting participants, data collection and analysis, social services for counseling patients on other available assistance outside the WTC program, and the development of treatment protocols. Such term does not include costs for new construction or other capital costs.

(d) GAO ANALYSIS.—Not later than July 1, 2011, the Comptroller General shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate an analysis on whether Clinical Centers of Excellence with which the WTC Program Administrator enters into a contract under this section have financial systems that will allow for the timely submission of

claims data for purposes of section 3304 and subsections (a)(1)(F) and (b)(1)(B)(iii).

SEC. 3306.[42 U.S.C. 300mm–5] DEFINITIONS.

In this title:

(1) The term "aggravating" means, with respect to a health condition, a health condition that existed on September 11, 2001, and that, as a result of exposure to airborne toxins, any other hazard, or any other adverse condition resulting from the September 11, 2001, terrorist attacks, requires medical treatment that is (or will be) in addition to, more frequent than, or of longer duration than the medical treatment that would have been required for such condition in the absence of such exposure.

(2) The term "certified-eligible WTC survivor" has the meaning given such term in section 3321(a)(2).

(3) The terms "Clinical Center of Excellence" and "Data Center" have the meanings given such terms in section 3305.

(4) The term "enrolled WTC responder" means a WTC responder enrolled under section 3311(a)(3).

(5) The term "initial health evaluation" includes, with respect to an individual, a medical and exposure history, a physical examination, and additional medical testing as needed to evaluate whether the individual has a WTC-related health condition and is eligible for treatment under the WTC Program.

(6) The term "list of WTC-related health conditions" means—

(A) for WTC responders, the health conditions listed in section 3312(a)(3); and

(B) for screening-eligible and certified-eligible WTC survivors, the health conditions listed in section 3322(b).

(7) The term "New York City disaster area" means the area within New York City that is—

(A) the area of Manhattan that is south of Houston Street; and

(B) any block in Brooklyn that is wholly or partially contained within a 1.5-mile radius of the former World Trade Center site.

(8) The term "New York metropolitan area" means an area, specified by the WTC Program Administrator, within which WTC responders and eligible WTC screening-eligible survivors who reside in such area are reasonably able to access monitoring and treatment benefits and initial health evaluation benefits under this title through a Clinical Center of Excellence described in subparagraphs (A), (B), or (C) of section 3305(b)(1).

(9) The term "screening-eligible WTC survivor" has the meaning given such term in section 3321(a)(1).

(10) Any reference to "September 11, 2001" shall be deemed a reference to the period on such date subsequent to the terrorist attacks at the World Trade Center, Shanksville, Pennsylvania, or the Pentagon, as applicable, on such date.

(11) The term "September 11, 2001, terrorist attacks" means the terrorist attacks that occurred on September 11,

2001, in New York City, in Shanksville, Pennsylvania, and at the Pentagon, and includes the aftermath of such attacks.

(12) The term "WTC Health Program Steering Committee" means such a Steering Committee established under section 3302(b).

(13) The term "WTC Program" means the Word Trade Center Health Program established under section 3301(a).

(14)(A) The term "WTC Program Administrator" means—

(i) subject to subparagraph (B), with respect to paragraphs (3) and (4) of section 3311(a) (relating to enrollment of WTC responders), section 3312(c) and the corresponding provisions of section 3322 (relating to payment for initial health evaluation, monitoring, and treatment, paragraphs (1)(C), (2)(B), and (3) of section 3321(a) (relating to determination or certification of screening-eligible or certified-eligible WTC responders), and part 3 of subtitle B (relating to payor provisions), an official in the Department of Health and Human Services, to be designated by the Secretary; and

(ii) with respect to any other provision of this title, the Director of the National Institute for Occupational Safety and Health, or a designee of such Director.

(B) In no case may the Secretary designate under subparagraph (A)(i) the Director of the National Institute for Occupational Safety and Health or a designee of such Director with respect to section 3322 (relating to payment for initial health evaluation, monitoring, and treatment).

(15) The term "WTC-related health condition" is defined in section 3312(a).

(16) The term "WTC responder" is defined in section 3311(a).

(17) The term "WTC Scientific/Technical Advisory Committee" means such Committee established under section 3302(a).

Subtitle B—Program of Monitoring, Initial Health Evaluations, and Treatment

PART 1—WTC RESPONDERS

SEC. 3311.[42 U.S.C. 300mm–21] IDENTIFICATION OF WTC RESPONDERS AND PROVISION OF WTC-RELATED MONITORING SERVICES.

(a) WTC RESPONDER DEFINED.—

(1) IN GENERAL.—For purposes of this title, the term "WTC responder" means any of the following individuals, subject to paragraph (4):

(A) CURRENTLY IDENTIFIED RESPONDER.—An individual who has been identified as eligible for monitoring under the arrangements as in effect on the date of the enactment of this title between the National Institute for Occupational Safety and Health and—

(i) the consortium coordinated by Mt. Sinai Hospital in New York City that coordinates the monitoring and treatment for enrolled WTC responders other than with respect to those covered under the arrangement with the Fire Department of New York City; or

(ii) the Fire Department of New York City.

(B) RESPONDER WHO MEETS CURRENT ELIGIBILITY CRITERIA.—An individual who meets the current eligibility criteria described in paragraph (2).

(C) RESPONDER WHO MEETS MODIFIED ELIGIBILITY CRITERIA.—An individual who—

(i) performed rescue, recovery, demolition, debris cleanup, or other related services in the New York City disaster area in response to the September 11, 2001, terrorist attacks, regardless of whether such services were performed by a State or Federal employee or member of the National Guard or otherwise; and

(ii) meets such eligibility criteria relating to exposure to airborne toxins, other hazards, or adverse conditions resulting from the September 11, 2001, terrorist attacks as the WTC Program Administrator, after consultation with the WTC Scientific/Technical Advisory Committee, determines appropriate.

The WTC Program Administrator shall not modify such eligibility criteria on or after the date that the number of enrollments of WTC responders has reached 80 percent of the limit described in paragraph (4) or on or after the date that the number of certifications for certified-eligible WTC survivors under section 3321(a)(2)(B) has reached 80 percent of the limit described in section 3321(a)(3).

(2) CURRENT ELIGIBILITY CRITERIA.—The eligibility criteria described in this paragraph for an individual is that the individual is described in any of the following categories:

(A) FIREFIGHTERS AND RELATED PERSONNEL.—The individual—

(i) was a member of the Fire Department of New York City (whether fire or emergency personnel, active or retired) who participated at least one day in the rescue and recovery effort at any of the former World Trade Center sites (including Ground Zero, Staten Island Landfill, and the New York City Chief Medical Examiner's Office) for any time during the period beginning on September 11, 2001, and ending on July 31, 2002; or

(ii)(I) is a surviving immediate family member of an individual who was a member of the Fire Department of New York City (whether fire or emergency personnel, active or retired) and was killed at the World Trade site on September 11, 2001; and

(II) received any treatment for a WTC-related health condition described in section 3312(a)(1)(A)(ii)

(relating to mental health conditions) on or before September 1, 2008.

(B) LAW ENFORCEMENT OFFICERS AND WTC RESCUE, RECOVERY, AND CLEANUP WORKERS.—The individual—

(i) worked or volunteered onsite in rescue, recovery, debris cleanup, or related support services in lower Manhattan (south of Canal St.), the Staten Island Landfill, or the barge loading piers, for at least 4 hours during the period beginning on September 11, 2001, and ending on September 14, 2001, for at least 24 hours during the period beginning on September 11, 2001, and ending on September 30, 2001, or for at least 80 hours during the period beginning on September 11, 2001, and ending on July 31, 2002;

(ii)(I) was a member of the Police Department of New York City (whether active or retired) or a member of the Port Authority Police of the Port Authority of New York and New Jersey (whether active or retired) who participated onsite in rescue, recovery, debris cleanup, or related services in lower Manhattan (south of Canal St.), including Ground Zero, the Staten Island Landfill, or the barge loading piers, for at least 4 hours during the period beginning September 11, 2001, and ending on September 14, 2001;

(II) participated onsite in rescue, recovery, debris cleanup, or related services at Ground Zero, the Staten Island Landfill, or the barge loading piers, for at least one day during the period beginning on September 11, 2001, and ending on July 31, 2002;

(III) participated onsite in rescue, recovery, debris cleanup, or related services in lower Manhattan (south of Canal St.) for at least 24 hours during the period beginning on September 11, 2001, and ending on September 30, 2001; or

(IV) participated onsite in rescue, recovery, debris cleanup, or related services in lower Manhattan (south of Canal St.) for at least 80 hours during the period beginning on September 11, 2001, and ending on July 31, 2002;

(iii) was an employee of the Office of the Chief Medical Examiner of New York City involved in the examination and handling of human remains from the World Trade Center attacks, or other morgue worker who performed similar post-September 11 functions for such Office staff, during the period beginning on September 11, 2001, and ending on July 31, 2002;

(iv) was a worker in the Port Authority Trans-Hudson Corporation Tunnel for at least 24 hours during the period beginning on February 1, 2002, and ending on July 1, 2002; or

(v) was a vehicle-maintenance worker who was exposed to debris from the former World Trade Center while retrieving, driving, cleaning, repairing, and maintaining vehicles contaminated by airborne toxins

from the September 11, 2001, terrorist attacks during a duration and period described in subparagraph (A).

(C) RESPONDERS TO THE SEPTEMBER 11 ATTACKS AT THE PENTAGON AND SHANKSVILLE, PENNSYLVANIA.—The individual—

(i)(I) was a member of a fire or police department (whether fire or emergency personnel, active or retired), worked for a recovery or cleanup contractor, or was a volunteer; and performed rescue, recovery, demolition, debris cleanup, or other related services at the Pentagon site of the terrorist-related aircraft crash of September 11, 2001, during the period beginning on September 11, 2001, and ending on the date on which the cleanup of the site was concluded, as determined by the WTC Program Administrator; or

(II) was a member of a fire or police department (whether fire or emergency personnel, active or retired), worked for a recovery or cleanup contractor, or was a volunteer; and performed rescue, recovery, demolition, debris cleanup, or other related services at the Shanksville, Pennsylvania, site of the terrorist-related aircraft crash of September 11, 2001, during the period beginning on September 11, 2001, and ending on the date on which the cleanup of the site was concluded, as determined by the WTC Program Administrator; and

(ii) is determined by the WTC Program Administrator to be at an increased risk of developing a WTC-related health condition as a result of exposure to airborne toxins, other hazards, or adverse conditions resulting from the September 11, 2001, terrorist attacks, and meets such eligibility criteria related to such exposures, as the WTC Program Administrator determines are appropriate, after consultation with the WTC Scientific/Technical Advisory Committee.

(3) ENROLLMENT PROCESS.—

(A) IN GENERAL.—The WTC Program Administrator shall establish a process for enrolling WTC responders in the WTC Program. Under such process—

(i) WTC responders described in paragraph (1)(A) shall be deemed to be enrolled in such Program;

(ii) subject to clause (iii), the Administrator shall enroll in such program individuals who are determined to be WTC responders;

(iii) the Administrator shall deny such enrollment to an individual if the Administrator determines that the numerical limitation in paragraph (4) on enrollment of WTC responders has been met;

(iv) there shall be no fee charged to the applicant for making an application for such enrollment;

(v) the Administrator shall make a determination on such an application not later than 60 days after the date of filing the application; and

(vi) an individual who is denied enrollment in such Program shall have an opportunity to appeal such determination in a manner established under such process.

(B) TIMING.—

(i) CURRENTLY IDENTIFIED RESPONDERS.—In accordance with subparagraph (A)(i), the WTC Program Administrator shall enroll an individual described in paragraph (1)(A) in the WTC Program not later than July 1, 2011.

(ii) OTHER RESPONDERS.—In accordance with subparagraph (A)(ii) and consistent with paragraph (4), the WTC Program Administrator shall enroll any other individual who is determined to be a WTC responder in the WTC Program at the time of such determination.

(4) NUMERICAL LIMITATION ON ELIGIBLE WTC RESPONDERS.—

(A) IN GENERAL.—The total number of individuals not described in paragraph (1)(A) or (2)(A)(ii) who may be enrolled under paragraph (3)(A)(ii) shall not exceed 25,000 at any time, of which no more than 2,500 may be individuals enrolled based on modified eligibility criteria established under paragraph (1)(C).

(B) PROCESS.—In implementing subparagraph (A), the WTC Program Administrator shall—

(i) limit the number of enrollments made under paragraph (3)—

(I) in accordance with such subparagraph; and

(II) to such number, as determined by the Administrator based on the best available information and subject to amounts available under section 3351, that will ensure sufficient funds will be available to provide treatment and monitoring benefits under this title, with respect to all individuals who are enrolled through the end of fiscal year 2020; and

(ii) provide priority (subject to paragraph (3)(A)(i)) in such enrollments in the order in which individuals apply for enrollment under paragraph (3).

(5) DISQUALIFICATION OF INDIVIDUALS ON TERRORIST WATCH LIST.—No individual who is on the terrorist watch list maintained by the Department of Homeland Security shall qualify as an eligible WTC responder. Before enrolling any individual as a WTC responder in the WTC Program under paragraph (3), the Administrator, in consultation with the Secretary of Homeland Security, shall determine whether the individual is on such list.

(b) MONITORING BENEFITS.—

(1) IN GENERAL.—In the case of an enrolled WTC responder (other than one described in subsection (a)(2)(A)(ii)), the WTC Program shall provide for monitoring benefits that include monitoring consistent with protocols approved by the WTC Program Administrator and including clinical examina-

tions and long-term health monitoring and analysis. In the case of an enrolled WTC responder who is an active member of the Fire Department of New York City, the responder shall receive such benefits as part of the individual's periodic company medical exams.

(2) PROVISION OF MONITORING BENEFITS.—The monitoring benefits under paragraph (1) shall be provided through the Clinical Center of Excellence for the type of individual involved or, in the case of an individual residing outside the New York metropolitan area, under an arrangement under section 3313.

SEC. 3312.[42 U.S.C. 300mm–22] TREATMENT OF ENROLLED WTC RESPONDERS FOR WTC-RELATED HEALTH CONDITIONS.

(a) WTC-RELATED HEALTH CONDITION DEFINED.—

(1) IN GENERAL.—For purposes of this title, the term "WTC-related health condition" means a condition that—

(A)(i) is an illness or health condition for which exposure to airborne toxins, any other hazard, or any other adverse condition resulting from the September 11, 2001, terrorist attacks, based on an examination by a medical professional with experience in treating or diagnosing the health conditions included in the applicable list of WTC-related health conditions, is substantially likely to be a significant factor in aggravating, contributing to, or causing the illness or health condition, as determined under paragraph (2); or

(ii) is a mental health condition for which such attacks, based on an examination by a medical professional with experience in treating or diagnosing the health conditions included in the applicable list of WTC-related health conditions, is substantially likely to be a significant factor in aggravating, contributing to, or causing the condition, as determined under paragraph (2); and

(B) is included in the applicable list of WTC-related health conditions or—

(i) with respect to a WTC responder, is provided certification of coverage under subsection (b)(2)(B)(iii); or

(ii) with respect to a screening-eligible WTC survivor or certified-eligible WTC survivor, is provided certification of coverage under subsection (b)(2)(B)(iii), as applied under section 3322(a).

In the case of a WTC responder described in section 3311(a)(2)(A)(ii) (relating to a surviving immediate family member of a firefighter), such term does not include an illness or health condition described in subparagraph (A)(i).

(2) DETERMINATION.—The determination under paragraph (1) or subsection (b) of whether the September 11, 2001, terrorist attacks were substantially likely to be a significant factor in aggravating, contributing to, or causing an individual's illness or health condition shall be made based on an assessment of the following:

(A) The individual's exposure to airborne toxins, any other hazard, or any other adverse condition resulting from the terrorist attacks. Such exposure shall be—

(i) evaluated and characterized through the use of a standardized, population-appropriate questionnaire approved by the Director of the National Institute for Occupational Safety and Health; and

(ii) assessed and documented by a medical professional with experience in treating or diagnosing health conditions included on the list of WTC-related health conditions.

(B) The type of symptoms and temporal sequence of symptoms. Such symptoms shall be—

(i) assessed through the use of a standardized, population-appropriate medical questionnaire approved by the Director of the National Institute for Occupational Safety and Health and a medical examination; and

(ii) diagnosed and documented by a medical professional described in subparagraph (A)(ii).

(3) LIST OF HEALTH CONDITIONS FOR WTC RESPONDERS.—The list of health conditions for WTC responders consists of the following:

(A) AERODIGESTIVE DISORDERS.—

(i) Interstitial lung diseases.

(ii) Chronic respiratory disorder—fumes/vapors.

(iii) Asthma.

(iv) Reactive airways dysfunction syndrome (RADS).

(v) WTC-exacerbated chronic obstructive pulmonary disease (COPD).

(vi) Chronic cough syndrome.

(vii) Upper airway hyperreactivity.

(viii) Chronic rhinosinusitis.

(ix) Chronic nasopharyngitis.

(x) Chronic laryngitis.

(xi) Gastroesophageal reflux disorder (GERD).

(xii) Sleep apnea exacerbated by or related to a condition described in a previous clause.

(B) MENTAL HEALTH CONDITIONS.—

(i) Posttraumatic stress disorder (PTSD).

(ii) Major depressive disorder.

(iii) Panic disorder.

(iv) Generalized anxiety disorder.

(v) Anxiety disorder (not otherwise specified).

(vi) Depression (not otherwise specified).

(vii) Acute stress disorder.

(viii) Dysthymic disorder.

(ix) Adjustment disorder.

(x) Substance abuse.

(C) MUSCULOSKELETAL DISORDERS FOR CERTAIN WTC RESPONDERS.—In the case of a WTC responder described in paragraph (4), a condition described in such paragraph.

(D) ADDITIONAL CONDITIONS.—Any cancer (or type of cancer) or other condition added, pursuant to paragraph (5) or (6), to the list under this paragraph.

(4) MUSCULOSKELETAL DISORDERS.—

(A) IN GENERAL.—For purposes of this title, in the case of a WTC responder who received any treatment for a WTC-related musculoskeletal disorder on or before September 11, 2003, the list of health conditions in paragraph (3) shall include:

(i) Low back pain.

(ii) Carpal tunnel syndrome (CTS).

(iii) Other musculoskeletal disorders.

(B) DEFINITION.—The term "WTC-related musculoskeletal disorder" means a chronic or recurrent disorder of the musculoskeletal system caused by heavy lifting or repetitive strain on the joints or musculoskeletal system occurring during rescue or recovery efforts in the New York City disaster area in the aftermath of the September 11, 2001, terrorist attacks.

(5) CANCER.—

(A) IN GENERAL.—The WTC Program Administrator shall periodically conduct a review of all available scientific and medical evidence, including findings and recommendations of Clinical Centers of Excellence, published in peer-reviewed journals to determine if, based on such evidence, cancer or a certain type of cancer should be added to the applicable list of WTC-related health conditions. The WTC Program Administrator shall conduct the first review under this subparagraph not later than 180 days after the date of the enactment of this title.

(B) PROPOSED REGULATIONS AND RULEMAKING.—Based on the periodic reviews under subparagraph (A), if the WTC Program Administrator determines that cancer or a certain type of cancer should be added to such list of WTC-related health conditions, the WTC Program Administrator shall propose regulations, through rulemaking, to add cancer or the certain type of cancer to such list.

(C) FINAL REGULATIONS.—Based on all the available evidence in the rulemaking record, the WTC Program Administrator shall make a final determination of whether cancer or a certain type of cancer should be added to such list of WTC-related health conditions. If such a determination is made to make such an addition, the WTC Program Administrator shall by regulation add cancer or the certain type of cancer to such list.

(D) DETERMINATIONS NOT TO ADD CANCER OR CERTAIN TYPES OF CANCER.—In the case that the WTC Program Administrator determines under subparagraph (B) or (C) that cancer or a certain type of cancer should not be added to such list of WTC-related health conditions, the WTC Program Administrator shall publish an explanation for such determination in the Federal Register. Any such determination to not make such an addition shall not preclude the addition of cancer or the certain type of cancer to such list at a later date.

(6) ADDITION OF HEALTH CONDITIONS TO LIST FOR WTC RESPONDERS.—

(A) IN GENERAL.—Whenever the WTC Program Administrator determines that a proposed rule should be promulgated to add a health condition to the list of health conditions in paragraph (3), the Administrator may request a recommendation of the Advisory Committee or may publish such a proposed rule in the Federal Register in accordance with subparagraph (D).

(B) ADMINISTRATOR'S OPTIONS AFTER RECEIPT OF PETITION.—In the case that the WTC Program Administrator receives a written petition by an interested party to add a health condition to the list of health conditions in paragraph (3), not later than 60 days after the date of receipt of such petition the Administrator shall—

(i) request a recommendation of the Advisory Committee;

(ii) publish a proposed rule in the Federal Register to add such health condition, in accordance with subparagraph (D);

(iii) publish in the Federal Register the Administrator's determination not to publish such a proposed rule and the basis for such determination; or

(iv) publish in the Federal Register a determination that insufficient evidence exists to take action under clauses (i) through (iii).

(C) ACTION BY ADVISORY COMMITTEE.—In the case that the Administrator requests a recommendation of the Advisory Committee under this paragraph, with respect to adding a health condition to the list in paragraph (3), the Advisory Committee shall submit to the Administrator such recommendation not later than 60 days after the date of such request or by such date (not to exceed 180 days after such date of request) as specified by the Administrator. Not later than 60 days after the date of receipt of such recommendation, the Administrator shall, in accordance with subparagraph (D), publish in the Federal Register a proposed rule with respect to such recommendation or a determination not to propose such a proposed rule and the basis for such determination.

(D) PUBLICATION.—The WTC Program Administrator shall, with respect to any proposed rule under this paragraph—

(i) publish such proposed rule in accordance with section 553 of title 5, United States Code; and

(ii) provide interested parties a period of 30 days after such publication to submit written comments on the proposed rule.

The WTC Program Administrator may extend the period described in clause (ii) upon a finding of good cause. In the case of such an extension, the Administrator shall publish such extension in the Federal Register.

(E) INTERESTED PARTY DEFINED.—For purposes of this paragraph, the term "interested party" includes a representative of any organization representing WTC responders, a nationally recognized medical association, a Clinical

or Data Center, a State or political subdivision, or any other interested person.

(b) COVERAGE OF TREATMENT FOR WTC-RELATED HEALTH CONDITIONS.—

(1) DETERMINATION FOR ENROLLED WTC RESPONDERS BASED ON A WTC-RELATED HEALTH CONDITION.—

(A) IN GENERAL.—If a physician at a Clinical Center of Excellence that is providing monitoring benefits under section 3311 for an enrolled WTC responder makes a determination that the responder has a WTC-related health condition that is in the list in subsection (a)(3) and that exposure to airborne toxins, other hazards, or adverse conditions resulting from the September 1, 2001, terrorist attacks is substantially likely to be a significant factor in aggravating, contributing to, or causing the condition—

(i) the physician shall promptly transmit such determination to the WTC Program Administrator and provide the Administrator with the medical facts supporting such determination; and

(ii) on and after the date of such transmittal and subject to subparagraph (B), the WTC Program shall provide for payment under subsection (c) for medically necessary treatment for such condition.

(B) REVIEW; CERTIFICATION; APPEALS.—

(i) REVIEW.—A Federal employee designated by the WTC Program Administrator shall review determinations made under subparagraph (A).

(ii) CERTIFICATION.—The Administrator shall provide a certification of such condition based upon reviews conducted under clause (i). Such a certification shall be provided unless the Administrator determines that the responder's condition is not a WTC-related health condition in the list in subsection (a)(3) or that exposure to airborne toxins, other hazards, or adverse conditions resulting from the September 1, 2001, terrorist attacks is not substantially likely to be a significant factor in aggravating, contributing to, or causing the condition.

(iii) APPEAL PROCESS.—The Administrator shall establish, by rule, a process for the appeal of determinations under clause (ii).

(2) DETERMINATION BASED ON MEDICALLY ASSOCIATED WTC-RELATED HEALTH CONDITIONS.—

(A) IN GENERAL.—If a physician at a Clinical Center of Excellence determines pursuant to subsection (a) that the enrolled WTC responder has a health condition described in subsection (a)(1)(A) that is not in the list in subsection (a)(3) but which is medically associated with a WTC-related health condition—

(i) the physician shall promptly transmit such determination to the WTC Program Administrator and provide the Administrator with the facts supporting such determination; and

(ii) the Administrator shall make a determination under subparagraph (B) with respect to such physician's determination.

(B) PROCEDURES FOR REVIEW, CERTIFICATION, AND APPEAL.—The WTC Program Administrator shall, by rule, establish procedures for the review and certification of physician determinations under subparagraph (A). Such rule shall provide for—

(i) the timely review of such a determination by a physician panel with appropriate expertise for the condition and recommendations to the WTC Program Administrator;

(ii) not later than 60 days after the date of the transmittal under subparagraph (A)(i), a determination by the WTC Program Administrator on whether or not the condition involved is described in subsection (a)(1)(A) and is medically associated with a WTC-related health condition;

(iii) certification in accordance with paragraph (1)(B)(ii) of coverage of such condition if determined to be described in subsection (a)(1)(A) and medically associated with a WTC-related health condition; and

(iv) a process for appeals of determinations relating to such conditions.

(C) INCLUSION IN LIST OF HEALTH CONDITIONS.—If the WTC Program Administrator provides certification under subparagraph (B)(iii) for coverage of a condition, the Administrator may, pursuant to subsection (a)(6), add the condition to the list in subsection (a)(3).

(D) CONDITIONS ALREADY DECLINED FOR INCLUSION IN LIST.—If the WTC Program Administrator publishes a determination under subsection (a)(6)(B) not to include a condition in the list in subsection (a)(3), the WTC Program Administrator shall not provide certification under subparagraph (B)(iii) for coverage of the condition. In the case of an individual who is certified under subparagraph (B)(iii) with respect to such condition before the date of the publication of such determination the previous sentence shall not apply.

(3) REQUIREMENT OF MEDICAL NECESSITY.—

(A) IN GENERAL.—In providing treatment for a WTC-related health condition, a physician or other provider shall provide treatment that is medically necessary and in accordance with medical treatment protocols established under subsection (d).

(B) REGULATIONS RELATING TO MEDICAL NECESSITY.—For the purpose of this title, the WTC Program Administrator shall issue regulations specifying a standard for determining medical necessity with respect to health care services and prescription pharmaceuticals, a process for determining whether treatment furnished and pharmaceuticals prescribed under this title meet such standard (including any prior authorization requirement), and a

process for appeal of a determination under subsection (c)(3).

(4) SCOPE OF TREATMENT COVERED.—

(A) IN GENERAL.—The scope of treatment covered under this subsection includes services of physicians and other health care providers, diagnostic and laboratory tests, prescription drugs, inpatient and outpatient hospital services, and other medically necessary treatment.

(B) PHARMACEUTICAL COVERAGE.—With respect to ensuring coverage of medically necessary outpatient prescription drugs, such drugs shall be provided, under arrangements made by the WTC Program Administrator, directly through participating Clinical Centers of Excellence or through one or more outside vendors.

(C) TRANSPORTATION EXPENSES FOR NATIONWIDE NETWORK.—The WTC Program Administrator may provide for necessary and reasonable transportation and expenses incident to the securing of medically necessary treatment through the nationwide network under section 3313 involving travel of more than 250 miles and for which payment is made under this section in the same manner in which individuals may be furnished necessary and reasonable transportation and expenses incident to services involving travel of more than 250 miles under regulations implementing section 3629(c) of the Energy Employees Occupational Illness Compensation Program Act of 2000 (title XXXVI of Public Law 106–398; 42 U.S.C. 7384t(c)).

(5) PROVISION OF TREATMENT PENDING CERTIFICATION.—With respect to an enrolled WTC responder for whom a determination is made by an examining physician under paragraph (1) or (2), but for whom the WTC Program Administrator has not yet determined whether to certify the determination, the WTC Program Administrator may establish by rule a process through which the Administrator may approve the provision of medical treatment under this subsection (and payment under subsection (c)) with respect to such responder and such responder's WTC-related health condition (under such terms and conditions as the Administrator may provide) until the Administrator makes a decision on whether to certify the determination.

(c) PAYMENT FOR INITIAL HEALTH EVALUATION, MONITORING, AND TREATMENT OF WTC-RELATED HEALTH CONDITIONS.—

(1) MEDICAL TREATMENT.—

(A) USE OF FECA PAYMENT RATES.—

(i) IN GENERAL.—Subject to clause (ii):

(I) Subject to subparagraphs (B) and (C), the WTC Program Administrator shall reimburse costs for medically necessary treatment under this title for WTC-related health conditions according to the payment rates that would apply to the provision of such treatment and services by the facility under the Federal Employees Compensation Act.

(II) For treatment not covered under subclause (i) or subparagraph (B), the WTC Program Administrator shall establish by regulation a reimbursement rate for such treatment.

(ii) EXCEPTION.—In no case shall payments for products or services under clause (i) be made at a rate higher than the Office of Worker's Compensation Programs in the Department Labor would pay for such products or services rendered at the time such products or services were provided.

(B) PHARMACEUTICALS.—

(i) IN GENERAL.—The WTC Program Administrator shall establish a program for paying for the medically necessary outpatient prescription pharmaceuticals prescribed under this title for WTC-related health conditions through one or more contracts with outside vendors.

(ii) COMPETITIVE BIDDING.—Under such program the Administrator shall—

(I) select one or more appropriate vendors through a Federal competitive bid process; and

(II) select the lowest bidder (or bidders) meeting the requirements for providing pharmaceutical benefits for participants in the WTC Program.

(iii) TREATMENT OF FDNY PARTICIPANTS.—Under such program the Administrator may enter into an agreement with a separate vendor to provide pharmaceutical benefits to enrolled WTC responders for whom the Clinical Center of Excellence is described in section 3305 if such an arrangement is deemed necessary and beneficial to the program by the WTC Program Administrator.

(iv) PHARMACEUTICALS.—Not later than July 1, 2011, the Comptroller General of the United States shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on whether existing Federal pharmaceutical purchasing programs can provide pharmaceutical benefits more efficiently and effectively than through the WTC program.

(C) IMPROVING QUALITY AND EFFICIENCY THROUGH MODIFICATION OF PAYMENT AMOUNTS AND METHODOLOGIES.—The WTC Program Administrator may modify the amounts and methodologies for making payments for initial health evaluations, monitoring, or treatment, if, taking into account utilization and quality data furnished by the Clinical Centers of Excellence under section 3305(b)(1)(B)(iii), the Administrator determines that a bundling, capitation, pay for performance, or other payment methodology would better ensure high quality and efficient delivery of initial health evaluations, monitoring, or treatment to an enrolled WTC responder, screening-eligible WTC survivor, or certified-eligible WTC survivor.

(2) MONITORING AND INITIAL HEALTH EVALUATION.—The WTC Program Administrator shall reimburse the costs of monitoring and the costs of an initial health evaluation provided under this title at a rate set by the Administrator by regulation.

(3) DETERMINATION OF MEDICAL NECESSITY.—

(A) REVIEW OF MEDICAL NECESSITY AND PROTOCOLS.—As part of the process for reimbursement or payment under this subsection, the WTC Program Administrator shall provide for the review of claims for reimbursement or payment for the provision of medical treatment to determine if such treatment is medically necessary and in accordance with medical treatment protocols established under subsection (d).

(B) WITHHOLDING OF PAYMENT FOR MEDICALLY UNNECESSARY TREATMENT.—The Administrator shall withhold such reimbursement or payment for treatment that the Administrator determines is not medically necessary or is not in accordance with such medical treatment protocols.

(d) MEDICAL TREATMENT PROTOCOLS.—

(1) DEVELOPMENT.—The Data Centers shall develop medical treatment protocols for the treatment of enrolled WTC responders and certified-eligible WTC survivors for health conditions included in the applicable list of WTC-related health conditions.

(2) APPROVAL.—The medical treatment protocols developed under paragraph (1) shall be subject to approval by the WTC Program Administrator.

SEC. 3313.[42 U.S.C. 300mm–23] NATIONAL ARRANGEMENT FOR BENEFITS FOR ELIGIBLE INDIVIDUALS OUTSIDE NEW YORK.

(a) IN GENERAL.—In order to ensure reasonable access to benefits under this subtitle for individuals who are enrolled WTC responders, screening-eligible WTC survivors, or certified-eligible WTC survivors and who reside in any State, as defined in section 2(f), outside the New York metropolitan area, the WTC Program Administrator shall establish a nationwide network of health care providers to provide monitoring and treatment benefits and initial health evaluations near such individuals' areas of residence in such States. Nothing in this subsection shall be construed as preventing such individuals from being provided such monitoring and treatment benefits or initial health evaluation through any Clinical Center of Excellence.

(b) NETWORK REQUIREMENTS.—Any health care provider participating in the network under subsection (a) shall—

(1) meet criteria for credentialing established by the Data Centers;

(2) follow the monitoring, initial health evaluation, and treatment protocols developed under section 3305(a)(2)(A)(ii);

(3) collect and report data in accordance with section 3304; and

(4) meet such fraud, quality assurance, and other requirements as the WTC Program Administrator establishes, including sections 1128 through 1128E of the Social Security Act, as applied by section 3301(d).

(c) TRAINING AND TECHNICAL ASSISTANCE.—The WTC Program Administer may provide, including through contract, for the provision of training and technical assistance to health care providers participating in the network under subsection (a).

(d) PROVISION OF SERVICES THROUGH THE VA.—

(1) IN GENERAL.—The WTC Program Administrator may enter into an agreement with the Secretary of Veterans Affairs for the Secretary to provide services under this section through facilities of the Department of Veterans Affairs.

(2) NATIONAL PROGRAM.—Not later than July 1, 2011, the Comptroller General of the United States shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on whether the Department of Veterans Affairs can provide monitoring and treatment services to individuals under this section more efficiently and effectively than through the nationwide network to be established under subsection (a).

PART 2—WTC SURVIVORS

SEC. 3321.[42 U.S.C. 300mm–31] IDENTIFICATION AND INITIAL HEALTH EVALUATION OF SCREENING-ELIGIBLE AND CERTIFIED-ELIGIBLE WTC SURVIVORS.

(a) IDENTIFICATION OF SCREENING-ELIGIBLE WTC SURVIVORS AND CERTIFIED-ELIGIBLE WTC SURVIVORS.—

(1) SCREENING-ELIGIBLE WTC SURVIVORS.—

(A) DEFINITION.—In this title, the term "screening-eligible WTC survivor" means, subject to subparagraph (C) and paragraph (3), an individual who is described in any of the following clauses:

(i) CURRENTLY IDENTIFIED SURVIVOR.—An individual, including a WTC responder, who has been identified as eligible for medical treatment and monitoring by the WTC Environmental Health Center as of the date of enactment of this title.

(ii) SURVIVOR WHO MEETS CURRENT ELIGIBILITY CRITERIA.—An individual who is not a WTC responder, for purposes of the initial health evaluation under subsection (b), claims symptoms of a WTC-related health condition and meets any of the current eligibility criteria described in subparagraph (B).

(iii) SURVIVOR WHO MEETS MODIFIED ELIGIBILITY CRITERIA.—An individual who is not a WTC responder, for purposes of the initial health evaluation under subsection (b), claims symptoms of a WTC-related health condition and meets such eligibility criteria relating to exposure to airborne toxins, other hazards, or adverse conditions resulting from the September 11, 2001, terrorist attacks as the WTC Administrator determines, after consultation with the Data Centers described in section 3305 and the WTC Scientific/Technical Advisory Committee and WTC Health Program Steering Committees under section 3302.

The Administrator shall not modify such criteria under clause (iii) on or after the date that the number of certifications for certified-eligible WTC survivors under paragraph (2)(B) has reached 80 percent of the limit described in paragraph (3) or on or after the date that the number of enrollments of WTC responders has reached 80 percent of the limit described in section 3311(a)(4).

(B) CURRENT ELIGIBILITY CRITERIA.—The eligibility criteria described in this subparagraph for an individual are that the individual is described in any of the following clauses:

(i) A person who was present in the New York City disaster area in the dust or dust cloud on September 11, 2001.

(ii) A person who worked, resided, or attended school, childcare, or adult daycare in the New York City disaster area for—

(I) at least 4 days during the 4-month period beginning on September 11, 2001, and ending on January 10, 2002; or

(II) at least 30 days during the period beginning on September 11, 2001, and ending on July 31, 2002.

(iii) Any person who worked as a cleanup worker or performed maintenance work in the New York City disaster area during the 4-month period described in subparagraph (B)(i) and had extensive exposure to WTC dust as a result of such work.

(iv) A person who was deemed eligible to receive a grant from the Lower Manhattan Development Corporation Residential Grant Program, who possessed a lease for a residence or purchased a residence in the New York City disaster area, and who resided in such residence during the period beginning on September 11, 2001, and ending on May 31, 2003.

(v) A person whose place of employment—

(I) at any time during the period beginning on September 11, 2001, and ending on May 31, 2003, was in the New York City disaster area; and

(II) was deemed eligible to receive a grant from the Lower Manhattan Development Corporation WTC Small Firms Attraction and Retention Act program or other government incentive program designed to revitalize the lower Manhattan economy after the September 11, 2001, terrorist attacks.

(C) APPLICATION AND DETERMINATION PROCESS FOR SCREENING ELIGIBILITY.—

(i) IN GENERAL.—The WTC Program Administrator in consultation with the Data Centers shall establish a process for individuals, other than individuals described in subparagraph (A)(i), to be determined to be screening-eligible WTC survivors. Under such process—

(I) there shall be no fee charged to the applicant for making an application for such determination;

(II) the Administrator shall make a determination on such an application not later than 60 days after the date of filing the application;

(III) the Administrator shall make such a determination relating to an applicant's compliance with this title and shall not determine that an individual is not so eligible or deny written documentation under clause (ii) to such individual unless the Administrator determines that—

(aa) based on the application submitted, the individual does not meet the eligibility criteria; or

(bb) the numerical limitation on certifications of certified-eligible WTC survivors set forth in paragraph (3) has been met; and

(IV) an individual who is determined not to be a screening-eligible WTC survivor shall have an opportunity to appeal such determination in a manner established under such process.

(ii) WRITTEN DOCUMENTATION OF SCREENING-ELIGIBILITY.—

(I) IN GENERAL.—In the case of an individual who is described in subparagraph (A)(i) or who is determined under clause (i) (consistent with paragraph (3)) to be a screening-eligible WTC survivor, the WTC Program Administrator shall provide an appropriate written documentation of such fact.

(II) TIMING.—

(aa) CURRENTLY IDENTIFIED SURVIVORS.—In the case of an individual who is described in subparagraph (A)(i), the WTC Program Administrator shall provide the written documentation under subclause (I) not later than July 1, 2011.

(bb) OTHER MEMBERS.—In the case of another individual who is determined under clause (i) and consistent with paragraph (3) to be a screening-eligible WTC survivor, the WTC Program Administrator shall provide the written documentation under subclause (I) at the time of such determination.

(2) CERTIFIED-ELIGIBLE WTC SURVIVORS.—

(A) DEFINITION.—The term "certified-eligible WTC survivor" means, subject to paragraph (3), a screening-eligible WTC survivor who the WTC Program Administrator certifies under subparagraph (B) to be eligible for followup monitoring and treatment under this part.

(B) CERTIFICATION OF ELIGIBILITY FOR MONITORING AND TREATMENT.—

(i) IN GENERAL.—The WTC Program Administrator shall establish a certification process under

which the Administrator shall provide appropriate certification to screening-eligible WTC survivors who, pursuant to the initial health evaluation under subsection (b), are determined to be eligible for followup monitoring and treatment under this part.

(ii) TIMING.—

(I) CURRENTLY IDENTIFIED SURVIVORS.—In the case of an individual who is described in paragraph (1)(A)(i), the WTC Program Administrator shall provide the certification under clause (i) not later than July 1, 2011.

(II) OTHER MEMBERS.—In the case of another individual who is determined under clause (i) to be eligible for followup monitoring and treatment, the WTC Program Administrator shall provide the certification under such clause at the time of such determination.

(3) NUMERICAL LIMITATION ON CERTIFIED-ELIGIBLE WTC SURVIVORS.—

(A) IN GENERAL.—The total number of individuals not described in paragraph (1)(A)(i) who may be certified as certified-eligible WTC survivors under paragraph (2)(B) shall not exceed 25,000 at any time.

(B) PROCESS.—In implementing subparagraph (A), the WTC Program Administrator shall—

(i) limit the number of certifications provided under paragraph (2)(B)—

(I) in accordance with such subparagraph; and

(II) to such number, as determined by the Administrator based on the best available information and subject to amounts made available under section 3351, that will ensure sufficient funds will be available to provide treatment and monitoring benefits under this title, with respect to all individuals receiving such certifications through the end of fiscal year 2020; and

(ii) provide priority in such certifications in the order in which individuals apply for a determination under paragraph (2)(B).

(4) DISQUALIFICATION OF INDIVIDUALS ON TERRORIST WATCH LIST.—No individual who is on the terrorist watch list maintained by the Department of Homeland Security shall qualify as a screening-eligible WTC survivor or a certified-eligible WTC survivor. Before determining any individual to be a screening-eligible WTC survivor under paragraph (1) or certifying any individual as a certified eligible WTC survivor under paragraph (2), the Administrator, in consultation with the Secretary of Homeland Security, shall determine whether the individual is on such list.

(b) INITIAL HEALTH EVALUATION TO DETERMINE ELIGIBILITY FOR FOLLOWUP MONITORING OR TREATMENT.—

(1) IN GENERAL.—In the case of a screening-eligible WTC survivor, the WTC Program shall provide for an initial health evaluation to determine if the survivor has a WTC-related

health condition and is eligible for followup monitoring and treatment benefits under the WTC Program. Initial health evaluation protocols under section 3305(a)(2)(A)(ii) shall be subject to approval by the WTC Program Administrator.

(2) INITIAL HEALTH EVALUATION PROVIDERS.—The initial health evaluation described in paragraph (1) shall be provided through a Clinical Center of Excellence with respect to the individual involved.

(3) LIMITATION ON INITIAL HEALTH EVALUATION BENEFITS.—Benefits for an initial health evaluation under this part for a screening-eligible WTC survivor shall consist only of a single medical initial health evaluation consistent with initial health evaluation protocols described in paragraph (1). Nothing in this paragraph shall be construed as preventing such an individual from seeking additional medical initial health evaluations at the expense of the individual.

SEC. 3322.[42 U.S.C. 300mm–32] FOLLOWUP MONITORING AND TREATMENT OF CERTIFIED-ELIGIBLE WTC SURVIVORS FOR WTC-RELATED HEALTH CONDITIONS.

(a) IN GENERAL.—Subject to subsection (b), the provisions of sections 3311 and 3312 shall apply to followup monitoring and treatment of WTC-related health conditions for certified-eligible WTC survivors in the same manner as such provisions apply to the monitoring and treatment of WTC-related health conditions for enrolled WTC responders.

(b) LIST OF WTC-RELATED HEALTH CONDITIONS FOR SURVIVORS.—The list of health conditions for screening-eligible WTC survivors and certified-eligible WTC survivors consists of the following:

(1) AERODIGESTIVE DISORDERS.—

(A) Interstitial lung diseases.

(B) Chronic respiratory disorder—fumes/vapors.

(C) Asthma.

(D) Reactive airways dysfunction syndrome (RADS).

(E) WTC-exacerbated chronic obstructive pulmonary disease (COPD).

(F) Chronic cough syndrome.

(G) Upper airway hyperreactivity.

(H) Chronic rhinosinusitis.

(I) Chronic nasopharyngitis.

(J) Chronic laryngitis.

(K) Gastroesophageal reflux disorder (GERD).

(L) Sleep apnea exacerbated by or related to a condition described in a previous clause.

(2) MENTAL HEALTH CONDITIONS.—

(A) Posttraumatic stress disorder (PTSD).

(B) Major depressive disorder.

(C) Panic disorder.

(D) Generalized anxiety disorder.

(E) Anxiety disorder (not otherwise specified).

(F) Depression (not otherwise specified).

(G) Acute stress disorder.

(H) Dysthymic disorder.

(I) Adjustment disorder.

(J) Substance abuse.

(3) ADDITIONAL CONDITIONS.—Any cancer (or type of cancer) or other condition added to the list in section 3312(a)(3) pursuant to paragraph (5) or (6) of section 3312(a), as such provisions are applied under subsection (a) with respect to certified-eligible WTC survivors.

SEC. 3323.[42 U.S.C. 300mm–33] FOLLOWUP MONITORING AND TREATMENT OF OTHER INDIVIDUALS WITH WTC-RELATED HEALTH CONDITIONS.

(a) IN GENERAL.—Subject to subsection (c), the provisions of section 3322 shall apply to the followup monitoring and treatment of WTC-related health conditions in the case of individuals described in subsection (b) in the same manner as such provisions apply to the followup monitoring and treatment of WTC-related health conditions for certified-eligible WTC survivors.

(b) INDIVIDUALS DESCRIBED.—An individual described in this subsection is an individual who, regardless of location of residence—

(1) is not an enrolled WTC responder or a certified-eligible WTC survivor; and

(2) is diagnosed at a Clinical Center of Excellence with a WTC-related health condition for certified-eligible WTC survivors.

(c) LIMITATION.—

(1) IN GENERAL.—The WTC Program Administrator shall limit benefits for any fiscal year under subsection (a) in a manner so that payments under this section for such fiscal year do not exceed the amount specified in paragraph (2) for such fiscal year.

(2) LIMITATION.—The amount specified in this paragraph for—

(A) the last calendar quarter of fiscal year 2011 is $5,000,000;

(B) fiscal year 2012 is $20,000,000; or

(C) a succeeding fiscal year is the amount specified in this paragraph for the previous fiscal year increased by the annual percentage increase in the medical care component of the consumer price index for all urban consumers.

PART 3—PAYOR PROVISIONS

SEC. 3331.[42 U.S.C. 300mm–41] PAYMENT OF CLAIMS.

(a) IN GENERAL.—Except as provided in subsections (b) and (c), the cost of monitoring and treatment benefits and initial health evaluation benefits provided under parts 1 and 2 of this subtitle shall be paid for by the WTC Program from the World Trade Center Health Program Fund.

(b) WORKERS' COMPENSATION PAYMENT.—

(1) IN GENERAL.—Subject to paragraph (2), payment for treatment under parts 1 and 2 of this subtitle of a WTC-related health condition of an individual that is work-related shall be reduced or recouped to the extent that the WTC Program Administrator determines that payment has been made, or can reasonably be expected to be made, under a workers'

compensation law or plan of the United States, a State, or a locality, or other work-related injury or illness benefit plan of the employer of such individual, for such treatment. The provisions of clauses (iii), (iv), (v), and (vi) of paragraph (2)(B) of section 1862(b) of the Social Security Act and paragraphs (3) and (4) of such section shall apply to the recoupment under this subsection of a payment to the WTC Program (with respect to a workers' compensation law or plan, or other work-related injury or illness plan of the employer involved, and such individual) in the same manner as such provisions apply to the reimbursement of a payment under section 1862(b)(2) of such Act to the Secretary (with respect to such a law or plan and an individual entitled to benefits under title XVIII of such Act) except that any reference in such paragraph (4) to payment rates under title XVIII of the Social Security Act shall be deemed a reference to payment rates under this title.

(2) EXCEPTION.—Paragraph (1) shall not apply for any quarter, with respect to any workers' compensation law or plan, including line of duty compensation, to which New York City is obligated to make payments, if, in accordance with terms specified under the contract under subsection (d)(1)(A), New York City has made the full payment required under such contract for such quarter.

(3) RULES OF CONSTRUCTION.—Nothing in this title shall be construed to affect, modify, or relieve any obligations under a worker's compensation law or plan, other work-related injury or illness benefit plan of an employer, or any health insurance plan.

(c) HEALTH INSURANCE COVERAGE.—

(1) IN GENERAL.—In the case of an individual who has a WTC-related health condition that is not work-related and has health coverage for such condition through any public or private health plan (including health benefits under title XVIII, XIX, or XXI of the Social Security Act) the provisions of section 1862(b) of the Social Security Act shall apply to such a health plan and such individual in the same manner as they apply to group health plan and an individual entitled to benefits under title XVIII of such Act pursuant to section 226(a) of such Act. Any costs for items and services covered under such plan that are not reimbursed by such health plan, due to the application of deductibles, copayments, coinsurance, other cost sharing, or otherwise, are reimbursable under this title to the extent that they are covered under the WTC Program. The program under this title shall not be treated as a legally liable party for purposes of applying section 1902(a)(25) of the Social Security Act.

(2) RECOVERY BY INDIVIDUAL PROVIDERS.—Nothing in paragraph (1) shall be construed as requiring an entity providing monitoring and treatment under this title to seek reimbursement under a health plan with which the entity has no contract for reimbursement.

(3) MAINTENANCE OF REQUIRED MINIMUM ESSENTIAL COVERAGE.—No payment may be made for monitoring and treatment under this title for an individual for a month (beginning with July 2014) if with respect to such month the individual—

(A) is an applicable individual (as defined in subsection (d) of section 5000A of Internal Revenue Code of 1986) for whom the exemption under subsection (e) of such section does not apply; and

(B) is not covered under minimum essential coverage, as required under subsection (a) of such section.

(d) REQUIRED CONTRIBUTION BY NEW YORK CITY IN PROGRAM COSTS.—

(1) CONTRACT REQUIREMENT.—

(A) IN GENERAL.—No funds may be disbursed from the World Trade Center Health Program Fund under section 3351 unless New York City has entered into a contract with the WTC Program Administrator under which New York City agrees, in a form and manner specified by the Administrator, to pay the full contribution described in subparagraph (B) in accordance with this subsection on a timely basis, plus any interest owed pursuant to subparagraph (E)(i). Such contract shall specify the terms under which New York City shall be considered to have made the full payment required for a quarter for purposes of subsection (b)(2).

(B) FULL CONTRIBUTION AMOUNT.—Under such contract, with respect to the last calendar quarter of fiscal year 2011 and each calendar quarter in fiscal years 2012 through 2015 the full contribution amount under this subparagraph shall be equal to 10 percent of the expenditures in carrying out this title for the respective quarter and with respect to calendar quarters in fiscal year 2016, such full contribution amount shall be equal to 1/9 of the Federal expenditures in carrying out this title for the respective quarter.

(C) SATISFACTION OF PAYMENT OBLIGATION.—The payment obligation under such contract may not be satisfied through any of the following:

(i) An amount derived from Federal sources.

(ii) An amount paid before the date of the enactment of this title.

(iii) An amount paid to satisfy a judgment or as part of a settlement related to injuries or illnesses arising out of the September 11, 2001, terrorist attacks.

(D) TIMING OF CONTRIBUTION.—The payment obligation under such contract for a calendar quarter in a fiscal year shall be paid not later than the last day of the second succeeding calendar quarter.

(E) COMPLIANCE.—

(i) INTEREST FOR LATE PAYMENT.—If New York City fails to pay to the WTC Program Administrator pursuant to such contract the amount required for any calendar quarter by the day specified in subparagraph (D), interest shall accrue on the amount not so paid at the rate (determined by the Administrator) based on the average yield to maturity, plus 1 percentage point,

on outstanding municipal bonds issued by New York City with a remaining maturity of at least 1 year.

(ii) RECOVERY OF AMOUNTS OWED.—The amounts owed to the WTC Program Administrator under such contract shall be recoverable by the United States in an action in the same manner as payments made under title XVIII of the Social Security Act may be recoverable in an action brought under section 1862(b)(2)(B)(iii) of such Act.

(F) DEPOSIT IN FUND.—The WTC Program Administer shall deposit amounts paid under such contract into the World Trade Center Health Program Fund under section 3351.

(2) PAYMENT OF NEW YORK CITY SHARE OF MONITORING AND TREATMENT COSTS.—With respect to each calendar quarter for which a contribution is required by New York City under the contract under paragraph (1), the WTC Program Administrator shall—

(A) provide New York City with an estimate of such amount of the required contribution at the beginning of such quarter and with an updated estimate of such amount at the beginning of each of the subsequent 2 quarters;

(B) bill such amount directly to New York City; and

(C) certify periodically, for purposes of this subsection, whether or not New York City has paid the amount so billed.

Such amount shall initially be estimated by the WTC Program Administrator and shall be subject to adjustment and reconciliation based upon actual expenditures in carrying out this title.

(3) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed as authorizing the WTC Administrator, with respect to a fiscal year, to reduce the numerical limitation under section 3311(a)(4) or 3321(a)(3) for such fiscal year if New York City fails to comply with paragraph (1) for a calendar quarter in such fiscal year.

(e) WORK-RELATED DESCRIBED.—For the purposes of this section, a WTC-related health condition shall be treated as a condition that is work-related if—

(1) the condition is diagnosed in an enrolled WTC responder, or in an individual who qualifies as a certified-eligible WTC survivor on the basis of being a rescue, recovery, or cleanup worker; or

(2) with respect to the condition the individual has filed and had established a claim under a workers' compensation law or plan of the United States or a State, or other work-related injury or illness benefit plan of the employer of such individual.

SEC. 3332.[42 U.S.C. 300mm–42] ADMINISTRATIVE ARRANGEMENT AUTHORITY.

The WTC Program Administrator may enter into arrangements with other government agencies, insurance companies, or other third-party administrators to provide for timely and accurate processing of claims under sections 3312, 3313, 3322, and 3323.

Subtitle C—Research Into Conditions

SEC. 3341.[42 U.S.C. 300mm–51] RESEARCH REGARDING CERTAIN HEALTH CONDITIONS RELATED TO SEPTEMBER 11 TERRORIST ATTACKS.

(a) IN GENERAL.—With respect to individuals, including enrolled WTC responders and certified-eligible WTC survivors, receiving monitoring or treatment under subtitle B, the WTC Program Administrator shall conduct or support—

(1) research on physical and mental health conditions that may be related to the September 11, 2001, terrorist attacks;

(2) research on diagnosing WTC-related health conditions of such individuals, in the case of conditions for which there has been diagnostic uncertainty; and

(3) research on treating WTC-related health conditions of such individuals, in the case of conditions for which there has been treatment uncertainty.

The Administrator may provide such support through continuation and expansion of research that was initiated before the date of the enactment of this title and through the World Trade Center Health Registry (referred to in section 3342), through a Clinical Center of Excellence, or through a Data Center.

(b) TYPES OF RESEARCH.—The research under subsection (a)(1) shall include epidemiologic and other research studies on WTC-related health conditions or emerging conditions—

(1) among enrolled WTC responders and certified-eligible WTC survivors under treatment; and

(2) in sampled populations outside the New York City disaster area in Manhattan as far north as 14th Street and in Brooklyn, along with control populations, to identify potential for long-term adverse health effects in less exposed populations.

(c) CONSULTATION.—The WTC Program Administrator shall carry out this section in consultation with the WTC Scientific/Technical Advisory Committee.

(d) APPLICATION OF PRIVACY AND HUMAN SUBJECT PROTECTIONS.—The privacy and human subject protections applicable to research conducted under this section shall not be less than such protections applicable to research conducted or funded by the Department of Health and Human Services.

SEC. 3342.[42 U.S.C. 300mm–52] WORLD TRADE CENTER HEALTH REGISTRY.

For the purpose of ensuring ongoing data collection relating to victims of the September 11, 2001, terrorist attacks, the WTC Program Administrator shall ensure that a registry of such victims is maintained that is at least as comprehensive as the World Trade Center Health Registry maintained under the arrangements in effect as of April 20, 2009, with the New York City Department of Health and Mental Hygiene.

Subtitle D—Funding

SEC. 3351.[42 U.S.C. 300mm–61] WORLD TRADE CENTER HEALTH PROGRAM FUND.

(a) ESTABLISHMENT OF FUND.—

(1) IN GENERAL.—There is established a fund to be known as the World Trade Center Health Program Fund (referred to in this section as the "Fund").

(2) FUNDING.—Out of any money in the Treasury not otherwise appropriated, there shall be deposited into the Fund for each of fiscal years 2012 through 2016 (and the last calendar quarter of fiscal year 2011)—

(A) the Federal share, consisting of an amount equal to the lesser of—

(i) 90 percent of the expenditures in carrying out this title for the respective fiscal year (initially based on estimates, subject to subsequent reconciliation based on actual expenditures); or

(ii)(I) $71,000,000 for the last calendar quarter of fiscal year 2011, $318,000,000 for fiscal year 2012, $354,000,000 for fiscal year 2013, $382,000,000 for fiscal year 2014, and $431,000,000 for fiscal year 2015; and

(II) subject to paragraph (4), an additional amount for fiscal year 2016 from unexpended amounts for previous fiscal years; plus

(B) the New York City share, consisting of the amount contributed under the contract under section 3331(d).

(3) CONTRACT REQUIREMENT.—

(A) IN GENERAL.—No funds may be disbursed from the Fund unless New York City has entered into a contract with the WTC Program Administrator under section 3331(d)(1).

(B) BREACH OF CONTRACT.—In the case of a failure to pay the amount so required under the contract—

(i) the amount is recoverable under subparagraph (E)(ii) of such section;

(ii) such failure shall not affect the disbursement of amounts from the Fund; and

(iii) the Federal share described in paragraph (2)(A) shall not be increased by the amount so unpaid.

(4) AGGREGATE LIMITATION ON FUNDING BEGINNING WITH FISCAL YEAR 2016.—Beginning with fiscal year 2016, in no case shall the share of Federal funds deposited into the Fund under paragraph (2) for such fiscal year and previous fiscal years and quarters exceed the sum of the amounts specified in paragraph (2)(A)(ii)(I).

(b) MANDATORY FUNDS FOR MONITORING, INITIAL HEALTH EVALUATIONS, TREATMENT, AND CLAIMS PROCESSING.—

(1) IN GENERAL.—The amounts deposited into the Fund under subsection (a)(2) shall be available, without further appropriation, consistent with paragraph (2) and subsection (c),

to carry out subtitle B and sections 3302(a), 3303, 3304, 3305(a)(2), 3305(c), 3341, and 3342.

(2) LIMITATION ON MANDATORY FUNDING.—This title does not establish any Federal obligation for payment of amounts in excess of the amounts available from the Fund for such purpose.

(3) LIMITATION ON AUTHORIZATION FOR FURTHER APPROPRIATIONS.—This title does not establish any authorization for appropriation of amounts in excess of the amounts available from the Fund under paragraph (1).

(c) LIMITS ON SPENDING FOR CERTAIN PURPOSES.—Of the amounts made available under subsection (b)(1), not more than each of the following amounts may be available for each of the following purposes:

(1) SURVIVING IMMEDIATE FAMILY MEMBERS OF FIREFIGHTERS.—For the purposes of carrying out subtitle B with respect to WTC responders described in section 3311(a)(2)(A)(ii)—

(A) for the last calendar quarter of fiscal year 2011, $100,000;

(B) for fiscal year 2012, $400,000; and

(C) for each subsequent fiscal year, the amount specified under this paragraph for the previous fiscal year increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) as estimated by the Secretary for the 12-month period ending with March of the previous year.

(2) WTC HEALTH PROGRAM SCIENTIFIC/TECHNICAL ADVISORY COMMITTEE.—For the purpose of carrying out section 3302(a)—

(A) for the last calendar quarter of fiscal year 2011, $25,000;

(B) for fiscal year 2012, $100,000; and

(C) for each subsequent fiscal year, the amount specified under this paragraph for the previous fiscal year increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) as estimated by the Secretary for the 12-month period ending with March of the previous year.

(3) EDUCATION AND OUTREACH.—For the purpose of carrying out section 3303—

(A) for the last calendar quarter of fiscal year 2011, $500,000;

(B) for fiscal year 2012, $2,000,000; and

(C) for each subsequent fiscal year, the amount specified under this paragraph for the previous fiscal year increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) as estimated by the Secretary for the 12-month period ending with March of the previous year.

(4) UNIFORM DATA COLLECTION.—For the purpose of carrying out section 3304 and for reimbursing Data Centers (as defined in section 3305(b)(2)) for the costs incurred by such Centers in carrying out activities under contracts entered into under section 3305(a)(2)—

(A) for the last calendar quarter of fiscal year 2011, $2,500,000;

(B) for fiscal year 2012, $10,000,000; and

(C) for each subsequent fiscal year, the amount specified under this paragraph for the previous fiscal year increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) as estimated by the Secretary for the 12-month period ending with March of the previous year.

(5) RESEARCH REGARDING CERTAIN HEALTH CONDITIONS.—For the purpose of carrying out section 3341—

(A) for the last calendar quarter of fiscal year 2011, $3,750,000;

(B) for fiscal year 2012, $15,000,000; and

(C) for each subsequent fiscal year, the amount specified under this paragraph for the previous fiscal year increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) as estimated by the Secretary for the 12-month period ending with March of the previous year.

(6) WORLD TRADE CENTER HEALTH REGISTRY.—For the purpose of carrying out section 3342—

(A) for the last calendar quarter of fiscal year 2011, $1,750,000;

(B) for fiscal year 2012, $7,000,000; and

(C) for each subsequent fiscal year, the amount specified under this paragraph for the previous fiscal year increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) as estimated by the Secretary for the 12-month period ending with March of the previous year.