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109TH CONGRESS
*1st Session*

COMMITTEE PRINT

COMMITTEE
PRINT 109–B

# COMPILATION OF SELECTED ACTS WITHIN THE JURISDICTION OF THE COMMITTEE ON ENERGY AND COMMERCE

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## HEALTH LAW

As Amended Through December 31, 2004

INCLUDING

PUBLIC HEALTH SERVICE ACT
DEVELOPMENTAL DISABILITIES ASSISTANCE AND BILL OF RIGHTS ACT OF 2000
MENTAL HEALTH SYSTEMS ACT
CONSUMER-PATIENT RADIATION HEALTH AND SAFETY ACT OF 1981
DRUG ABUSE PREVENTION, TREATMENT, AND REHABILITATION ACT
PROTECTION AND ADVOCACY FOR MENTALLY ILL INDIVIDUALS ACT OF 1986
HEALTH CARE QUALITY IMPROVEMENT ACT OF 1986
ALZHEIMER'S DISEASE AND RELATED DEMENTIAS RESEARCH ACT OF 1992
ABANDONED INFANTS ASSISTANCE ACT OF 1988
APPENDIX

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PREPARED FOR THE USE OF THE

COMMITTEE ON ENERGY AND COMMERCE
U.S. HOUSE OF REPRESENTATIVES



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AUGUST 2005

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# PUBLIC HEALTH SERVICE ACT

**NOTE.**—Reorganization Plan No. 3 of 1966 transferred all statutory powers and functions of the Surgeon General and other officers of the Public Health Service and of all agencies of or in the Service to the Secretary of Health, Education, and Welfare. The Department of Education Organization Act designated the Secretary of Health, Education, and Welfare as the Secretary of Health and Human Services. References in the Act to the Surgeon General, other officers of the Service, the Secretary of Health, Education, and Welfare, and the Department of Health, Education, and Welfare, should be read in the light of the transfer of statutory functions and the redesignation.

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# PUBLIC HEALTH SERVICE ACT

**(References in brackets [ ] are to title 42, United States Code)**

## 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) [Repealed.]

(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.

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

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[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).

COMMISSIONED CORPS

SEC. 203. [204] There shall be in the Service a commissioned Regular Corps and, for the purpose of securing a reserve for duty in the Service in time of national emergency, a Reserve Corps. All commissioned officers shall be citizens and shall be appointed without regard to the civil-service laws and compensated without regard to the Classification Act of 1923,[1] as amended. Commissioned officers of the Reserve Corps shall be appointed by the President and commissioned officers of the Regular Corps shall be appointed by him by and with the advice and consent of the Senate. Commissioned officers of the 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 and active duty for the purpose of determining their fitness for appointment in the Regular Corps. 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.

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

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

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 section 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. [1]

(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, [1] 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.

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

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

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, [1] nor more than (1) the highest rate of grade 18 of the General Schedule of such Act,

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

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 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, by and with the advice and consent of the Senate, 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 promotion; 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 pro-

motions 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).[1]

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

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

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,[1] 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) 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).

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

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

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 regula-

[1] 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.

tions 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 migrant health centers and other entities under grants and contracts under section 329.[1]

(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.[1] 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

[1] 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.

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 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) [1] 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.

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.

[1] 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).

(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.

(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.

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 [1] 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

(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

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

(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 perform-

ance 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,[1] 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

[1] 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,".)

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.

(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 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 individual 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 vac-

cine 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) [1] 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 [2]—

(I) such countermeasure was administered;

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

(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);

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

[2] 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.

(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 [1]—

(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 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. [2] [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

[1] 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.

[2] 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.

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 representatives, 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; [1]

(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.

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

(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.

(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 para-

graph 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.

## 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 income 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). [1]

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.

[1] 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,[1] 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.

[1] 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 standard 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 government 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. [1]

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

[1] Public Law 105–12 (111 Stat. 23).

(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 occur-

rence 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 Countermeasures 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)[1] 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.

**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

[1] 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.

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 survivors 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.

# 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.

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 authorized 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 consultants 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.

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

[2] See footnote for section 306.

(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.[1] [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,

(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, ex-

[1] 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.

tended 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 [1] 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.

(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.

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

(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 sup-

ported 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) For the purpose of advancing the status of the health sciences in the United States (and thereby the health of the American people), the Secretary may participate with other countries in cooperative endeavors in biomedical research, health care technology, and the health services research and statistical activities authorized by section 306 and by title IX.

(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; and

The Secretary may not, in the exercise of his authority under this section, provide financial assistance for the construction of any facility in any foreign country.

(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 any purpose. [1]

(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 1990 (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, 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.

[1] So in law. Section 310 of Public Law 102–531 (106 Stat. 3503) amended subsection (b) by adding a paragraph (8) at the end. The paragraph probably should have been inserted after paragraph (7).

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 employee 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.[1] **[**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

[1] Former section 309 was repealed by section 6103(d)(1)(B) of Public Law 101–239 (103 Stat. 2205).

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.

## 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 reason-

able 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 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 fiscal year 2003, and such sums as may be necessary for each of the fiscal years 2004 through 2006. 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

(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)[1] 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 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.

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[1] 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.

(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) comprehen-

sive 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.[1] [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).

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] 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).

(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, documents, 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 for each of the fiscal years 1998 through 2005. 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, after October 1, 1997, 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).

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 [1], 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

[1] Enacted October 27, 1992.

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;

(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 defects 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 [1].

(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; mental retardation; 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 sub-

[1] Public Law 106–310, enacted October 17, 2000.

paragraph (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, 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 [1].

(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

[1] So in law. Probably should be "subsection".

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.

(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[1] 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.

[1] So in law.

(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 installments 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).

PREVENTIVE HEALTH SERVICES REGARDING 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, DEMONSTRATION PROJECTS, EDUCATION, AND TRAINING.—With respect to the prevention, 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 concerning strains of tuberculosis resistant to drugs and research concerning cases of tuberculosis that affect certain populations.

(2) Demonstration projects.

(3) Public information and education programs.

(4) Education, training, and clinical skills improvement activities for health professionals, including allied health personnel and emergency response employees.

(5) Support of centers to carry out activities under paragraphs (1) through (4).

(6) Collaboration with international organizations and foreign countries in carrying out such activities.

(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 activities 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.

(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) GENERAL DUTIES.—The Council shall provide advice and recommendations regarding the elimination of tuberculosis to the Secretary, the Assistant Secretary for Health, and the Director of the Centers for Disease Control and Prevention.

(3) CERTAIN ACTIVITIES.—With respect to the elimination of tuberculosis, the Council shall—

(A) in making recommendations under paragraph (2), make recommendations regarding policies, strategies, objectives, and priorities;

(B) address the development and application of new technologies; and

(C) review the extent to which progress has been made toward eliminating tuberculosis.

(4) COMPOSITION.—The Secretary shall determine the size and composition of the Council, and the frequency and scope of official meetings of the Council.

(5) 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) FUNDING.—

(1) IN GENERAL; ALLOCATION FOR EMERGENCY GRANTS.—

(A) For the purpose of making grants under subsection (a), there are authorized to be appropriated $200,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 through 2002.

(B) 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 in which there is, relative to other areas, a substantial number of cases of tuberculosis or a substantial rate of increase in such cases.

(2) RESEARCH, DEMONSTRATION PROJECTS, EDUCATION, AND TRAINING.—For the purpose of carrying out subsection (b), there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1994 through 2002.

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 consider-

ation 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)[1] 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.

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[1]So in law. Subsection (c) does not contain a paragraph (2). See section 901 of Public Law 106–310 (114 Stat. 1126).

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)—

(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, may award grants to States and Indian tribes 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) 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.

(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.

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 activities 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

SEC. 317P. [247b–17] (a) SURVEILLANCE.—

(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 dis-

seminate 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.—

(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.

**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 epidemio-

logical 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 subsection, 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) 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 2002, and such sums as may be necessary for each of the fiscal years 2003 through 2006.

**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 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 control 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).

PROJECTS AND PROGRAMS FOR THE PREVENTION AND CONTROL OF SEXUALLY TRANSMITTED DISEASES [1]

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.

(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 eval-

[1] 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".

uation 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 pur-

pose 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 specification 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.

**SEC. 319A. [247d–1] NATIONAL NEEDS TO COMBAT THREATS TO PUBLIC HEALTH.**

(a) CAPACITIES.—

(1) IN GENERAL.—Not later than 1 year after the date of the enactment of this section, the Secretary, and such Administrators, Directors, or Commissioners, as may be appropriate, and in collaboration with State and local health officials, shall establish reasonable capacities that are appropriate for national, State, and local public health systems and the personnel or work forces of such systems. Such capacities shall be revised every five years, or more frequently as the Secretary determines to be necessary.

(2) BASIS.—The capacities established under paragraph (1) shall improve, enhance or expand the capacity of national, State and local public health agencies to detect and respond effectively to significant public health threats, including major outbreaks of infectious disease, pathogens resistant to antimicrobial agents and acts of bioterrorism. Such capacities may include the capacity to—

(A) recognize the clinical signs and epidemiological characteristic of significant outbreaks of infectious disease;

(B) identify disease-causing pathogens rapidly and accurately;

(C) develop and implement plans to provide medical care for persons infected with disease-causing agents and

to provide preventive care as needed for individuals likely to be exposed to disease-causing agents;

(D) communicate information relevant to significant public health threats rapidly to local, State and national health agencies, and health care providers; or

(E) develop or implement policies to prevent the spread of infectious disease or antimicrobial resistance.

(b) 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.

(c) TECHNICAL ASSISTANCE.—The Secretary shall provide technical assistance to the States to assist such States in fulfilling the requirements of this section.

(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $4,000,000 for fiscal year 2001, and such sums as may be necessary for each subsequent fiscal year through 2006.

**SEC. 319B. [247d–2] ASSESSMENT OF PUBLIC HEALTH NEEDS.**

(a) PROGRAM AUTHORIZED.—Not later than 1 year after the date of the enactment of this section and every five years thereafter, the Secretary shall award grants to States, or consortia of two or more States or political subdivisions of States, to perform, in collaboration with local public health agencies, an evaluation to determine the extent to which the States or local public health agencies can achieve the capacities applicable to State and local public health agencies described in subsection (a) of section 319A. The Secretary shall provide technical assistance to States, or consortia of two or more States or political subdivisions of States, in addition to awarding such grants.

(b) PROCEDURE.—

(1) IN GENERAL.—A State, or a consortium of two or more States or political subdivisions of States, may contract with an outside entity to perform the evaluation described in subsection (a).

(2) METHODS.—To the extent practicable, the evaluation described in subsection (a) shall be completed by using methods, to be developed by the Secretary in collaboration with State and local health officials, that facilitate the comparison of evaluations conducted by a State to those conducted by other States receiving funds under this section.

(c) REPORT.—Not later than 1 year after the date on which a State, or a consortium of two or more States or political subdivisions of States, receives a grant under this subsection, such State, or a consortium of two or more States or political subdivisions of States, shall prepare and submit to the Secretary a report describing the results of the evaluation described in subsection (a) with respect to such State, or consortia of two or more States or political subdivisions of States.

(d) 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.

(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $45,000,000 for fiscal year 2001, and such sums as may be necessary for each subsequent fiscal year through 2003.

**SEC. 319C. [247d–3] GRANTS TO IMPROVE STATE AND LOCAL PUBLIC HEALTH AGENCIES.**

(a) PROGRAM AUTHORIZED.—The Secretary shall award competitive grants to eligible entities to address core public health capacity needs using the capacities developed under section 319A, with a particular focus on building capacity to identify, detect, monitor, and respond to threats to the public health.

(b) ELIGIBLE ENTITIES.—A State or political subdivision of a State, or a consortium of two or more States or political subdivisions of States, that has completed an evaluation under section 319B(a), or an evaluation that is substantially equivalent as determined by the Secretary under section 319B(a), shall be eligible for grants under subsection (a).

(c) USE OF FUNDS.—An eligible entity that receives a grant under subsection (a), may use funds received under such grant to—

(1) train public health personnel;

(2) develop, enhance, coordinate, or improve participation in an electronic network by which disease detection and public health related information can be rapidly shared among national, regional, State, and local public health agencies and health care providers;

(3) develop a plan for responding to public health emergencies, including significant outbreaks of infectious diseases or bioterrorism attacks, which is coordinated with the capacities of applicable national, State, and local health agencies and health care providers; and

(4) enhance laboratory capacity and facilities.

(d) REPORT.—No later than January 1, 2005, 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 that describes the activities carried out under sections 319A, 319B, and 319C.

(e) 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.

**SEC. 319C–1. [247d–3a] GRANTS TO IMPROVE STATE, LOCAL, AND HOSPITAL PREPAREDNESS FOR AND RESPONSE TO BIOTERRORISM AND OTHER PUBLIC HEALTH EMERGENCIES.**

(a) IN GENERAL.—To enhance the security of the United States with respect to bioterrorism and other public health emergencies, the Secretary shall make awards of grants or cooperative agreements to eligible entities to enable such entities to conduct the activities described in subsection (d).

(b) ELIGIBLE ENTITIES.—

(1) IN GENERAL.—To be eligible to receive an award under subsection (a), an entity shall—

(A)(i) be a State; and

(ii) 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 an assurance that the State—

(I) has completed an evaluation under section 319B(a), or an evaluation that is substantially equivalent to an evaluation described in such section (as determined by the Secretary);

(II) has prepared, or will (within 60 days of receiving an award under this section) prepare, a Bioterrorism and Other Public Health Emergency Preparedness and Response Plan in accordance with subsection (c);

(III) has established a means by which to obtain public comment and input on the plan prepared under subclause (II), and on the implementation of such plan, that shall include an advisory committee or other similar mechanism for obtaining comment from the public at large as well as from other State and local stakeholders;

(IV) will use amounts received under the award in accordance with the plan prepared under subclause (II), including making expenditures to carry out the strategy contained in the plan; and

(V) with respect to the plan prepared under subclause (II), will establish reasonable criteria to evaluate the effective performance of entities that receive funds under the award and include relevant benchmarks in the plan; or

(B)(i) be a political subdivision of a State or a consortium of 2 or more such subdivisions; and

(ii) prepare and submit to the Secretary an application at such time, and in such manner, and containing such information as the Secretary may require.

(2) COORDINATION WITH STATEWIDE PLANS.—An award under subsection (a) to an eligible entity described in paragraph (1)(B) may not be made unless the application of such entity is in coordination with, and consistent with, applicable Statewide plans described in subsection (d)(1).

(c) BIOTERRORISM AND OTHER PUBLIC HEALTH EMERGENCY PREPAREDNESS AND RESPONSE PLAN.—Not later than 60 days after receiving amounts under an award under subsection (a), an eligible entity described in subsection (b)(1)(A) shall prepare and submit to the Secretary a Bioterrorism and Other Public Health Emergency Preparedness and Response Plan. Recognizing the assessment of public health needs conducted under section 319B, such plan shall include a description of activities to be carried out by the entity to address the needs identified in such assessment (or an equivalent assessment).

(d) USE OF FUNDS.—An award under subsection (a) may be expended for activities that may include the following and similar activities:

(1) To develop Statewide plans (including the development of the Bioterrorism and Other Public Health Emergency Pre-

paredness and Response Plan required under subsection (c)), and community-wide plans for responding to bioterrorism and other public health emergencies that are coordinated with the capacities of applicable national, State, and local health agencies and health care providers, including poison control centers.

(2) To address deficiencies identified in the assessment conducted under section 319B.

(3) To purchase or upgrade equipment (including stationary or mobile communications equipment), supplies, pharmaceuticals or other priority countermeasures to enhance preparedness for and response to bioterrorism or other public health emergencies, consistent with the plan described in subsection (c).

(4) To conduct exercises to test the capability and timeliness of public health emergency response activities.

(5) To develop and implement the trauma care and burn center care components of the State plans for the provision of emergency medical services.

(6) To improve training or workforce development to enhance public health laboratories.

(7) To train public health and health care personnel to enhance the ability of such personnel—

(A) to detect, provide accurate identification of, and recognize the symptoms and epidemiological characteristics of exposure to a biological agent that may cause a public health emergency; and

(B) to provide treatment to individuals who are exposed to such an agent.

(8) To develop, enhance, coordinate, or improve participation in systems by which disease detection and information about biological attacks and other public health emergencies can be rapidly communicated among national, State, and local health agencies, emergency response personnel, and health care providers and facilities to detect and respond to a bioterrorist attack or other public health emergency, including activities to improve information technology and communications equipment available to health care and public health officials for use in responding to a biological threat or attack or other public health emergency.

(9) To enhance communication to the public of information on bioterrorism and other public health emergencies, including through the use of 2–1–1 call centers.

(10) To address the health security needs of children and other vulnerable populations with respect to bioterrorism and other public health emergencies.

(11) To provide training and develop, enhance, coordinate, or improve methods to enhance the safety of workers and workplaces in the event of bioterrorism.

(12) To prepare and plan for contamination prevention efforts related to public health that may be implemented in the event of a bioterrorist attack, including training and planning to protect the health and safety of workers conducting the activities described in this paragraph.

(13) To prepare a plan for triage and transport management in the event of bioterrorism or other public health emergencies.

(14) To enhance the training of health care professionals to recognize and treat the mental health consequences of bioterrorism or other public health emergencies.

(15) To enhance the training of health care professionals to assist in providing appropriate health care for large numbers of individuals exposed to a bioweapon.

(16) To enhance training and planning to protect the health and safety of personnel, including health care professionals, involved in responding to a biological attack.

(17) To improve surveillance, detection, and response activities to prepare for emergency response activities including biological threats or attacks, including training personnel in these and other necessary functions and including early warning and surveillance networks that use advanced information technology to provide early detection of biological threats or attacks.

(18) To develop, enhance, and coordinate or improve the ability of existing telemedicine programs to provide health care information and advice as part of the emergency public health response to bioterrorism or other public health emergencies.

Nothing in this subsection may be construed as establishing new regulatory authority or as modifying any existing regulatory authority.

(e) PRIORITIES IN USE OF GRANTS.—

(1) IN GENERAL.—

(A) PRIORITIES.—Except as provided in subparagraph (B), the Secretary shall, in carrying out the activities described in this section, address the following hazards in the following priority:

(i) Bioterrorism or acute outbreaks of infectious diseases.

(ii) Other public health threats and emergencies.

(B) DETERMINATION OF THE SECRETARY.—In the case of the hazard involved, the degree of priority that would apply to the hazard based on the categories specified in clauses (i) and (ii) of subparagraph (A) may be modified by the Secretary if the following conditions are met:

(i) The Secretary determines that the modification is appropriate on the basis of the following factors:

(I) The extent to which eligible entities are adequately prepared for responding to hazards within the category specified in clause (i) of subparagraph (A).

(II) There has been a significant change in the assessment of risks to the public health posed by hazards within the category specified in clause (ii) of such subparagraph.

(ii) Prior to modifying the priority, the Secretary notifies the appropriate committees of the Congress of the determination of the Secretary under clause (i) of this subparagraph.

(2) AREAS OF EMPHASIS WITHIN CATEGORIES.—The Secretary shall determine areas of emphasis within the category of hazards specified in clause (i) of paragraph (1)(A), and shall determine areas of emphasis within the category of hazards specified in clause (ii) of such paragraph, based on an assessment of the risk and likely consequences of such hazards and on an evaluation of Federal, State, and local needs, and may also take into account the extent to which receiving an award under subsection (a) will develop capacities that can be used for public health emergencies of varying types.

(f) CERTAIN ACTIVITIES.—In administering activities under section 319C(c)(4) or similar activities, the Secretary shall, where appropriate, give priority to activities that include State or local government financial commitments, that seek to incorporate multiple public health and safety services or diagnostic databases into an integrated public health entity, and that cover geographic areas lacking advanced diagnostic and laboratory capabilities.

(g) COORDINATION WITH LOCAL MEDICAL RESPONSE SYSTEM.—An eligible entity and local Metropolitan Medical Response Systems shall, to the extent practicable, ensure that activities carried out under an award under subsection (a) are coordinated with activities that are carried out by local Metropolitan Medical Response Systems.

(h) COORDINATION OF FEDERAL ACTIVITIES.—In making awards under subsection (a), the Secretary shall—

(1) annually notify the Director of the Federal Emergency Management Agency, the Director of the Office of Justice Programs, and the Director of the National Domestic Preparedness Office, as to the amount, activities covered under, and status of such awards; and

(2) coordinate such awards with other activities conducted or supported by the Secretary to enhance preparedness for bioterrorism and other public health emergencies.

(i) DEFINITION.—For purposes of this section, the term "eligible entity" means an entity that meets the conditions described in subparagraph (A) or (B) of subsection (b)(1).

(j) FUNDING.—

(1) AUTHORIZATIONS OF APPROPRIATIONS.—

(A) FISCAL YEAR 2003.—

(i) AUTHORIZATIONS.—For the purpose of carrying out this section, there is authorized to be appropriated $1,600,000,000 for fiscal year 2003, of which—

(I) $1,080,000,000 is authorized to be appropriated for awards pursuant to paragraph (3) (subject to the authority of the Secretary to make awards pursuant to paragraphs (4) and (5)); and

(II) $520,000,000 is authorized to be appropriated—

(aa) for awards under subsection (a) to States, notwitstanding the eligibility conditions under subsection (b), for the purpose of enhancing the preparedness of hospitals (including children's hospitals), clinics, health centers, and primary care facilities for bioter-

rorism and other public health emergencies; and

(bb) for Federal, State, and local planning and administrative activities related to such purpose.

(ii) CONTINGENT ADDITIONAL AUTHORIZATION.—If a significant change in circumstances warrants an increase in the amount authorized to be appropriated under clause (i) for fiscal year 2003, there are authorized to be appropriated such sums as may be necessary for such year for carrying out this section, in addition to the amount authorized in clause (i).

(B) OTHER FISCAL YEARS.—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 2004 through 2006.

(2) SUPPLEMENT NOT SUPPLANT.—Amounts appropriated under paragraph (1) shall be used to supplement and not supplant other State and local public funds provided for activities under this section.

(3) STATE BIOTERRORISM AND OTHER PUBLIC HEALTH EMERGENCY PREPAREDNESS AND RESPONSE BLOCK GRANT FOR FISCAL YEAR 2003.—

(A) IN GENERAL.—For fiscal year 2003, the Secretary shall, in an amount determined in accordance with subparagraphs (B) through (D), make an award under subsection (a) to each State, notwithstanding the eligibility conditions described in subsection (b), that submits to the Secretary an application for the award 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. No other awards may be made under subsection (a) for such fiscal year, except as provided in paragraph (1)(A)(i)(II) and paragraphs (4) and (5).

(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)(i)(I) 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)(i)(I), 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)(i)(I) 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 2003, the Secretary may, before making awards pursuant to paragraph (3) for such year, reserve from the amount appropriated under paragraph (1)(A)(i)(I) 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 (c).

(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 2002.

(5) SIGNIFICANT UNMET NEEDS; DEGREE OF RISK.—

(A) IN GENERAL.—For fiscal year 2003, the Secretary may, before making awards pursuant to paragraph (3) for such year, reserve from the amount appropriated under paragraph (1)(A)(i)(I) 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.—For fiscal year 2003, the Secretary shall in making awards under this section ensure that appropriate portions of such awards are made available to political subdivisions, local departments of public health, hospitals (including children's hospitals), clinics, health centers, or primary care facilities, or consortia of such entities.

**SEC. 319C–2. [247d–3b] PARTNERSHIPS FOR COMMUNITY AND HOSPITAL PREPAREDNESS.**

(a) GRANTS.—The Secretary shall make awards of grants or cooperative agreements to eligible entities to enable such entities to improve community and hospital preparedness for bioterrorism and other public health emergencies.

(b) ELIGIBILITY.—To be eligible for an award under subsection (a), an entity shall—

(1) be a partnership consisting of—

(A) one or more hospitals (including children's hospitals), clinics, health centers, or primary care facilities; and

(B)(i) one or more political subdivisions of States;

(ii) one or more States; or

(iii) one or more States and one or more political subdivisions of States; and

(2) prepare, in consultation with the Chief Executive Officer of the State, District, or territory in which the hospital, clinic, health center, or primary care facility described in paragraph (1)(A) is located, and submit to the Secretary, an appli-

cation at such time, in such manner, and containing such information as the Secretary may require.

(c) 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, will—

(1) enhance coordination—

(A) among the entities described in subsection (b)(1)(A); and

(B) between such entities and the entities described in subsection (b)(1)(B); and

(2) serve the needs of a defined geographic area.

(d) CONSISTENCY OF PLANNED ACTIVITIES.—An entity described in subsection (b)(1) shall utilize amounts received under an award under subsection (a) in a manner that is coordinated and consistent, as determined by the Secretary, with an applicable State Bioterrorism and Other Public Health Emergency Preparedness and Response Plan.

(e) USE OF FUNDS.—An award under subsection (a) may be expended for activities that may include the following and similar activities—

(1) planning and administration for such award;

(2) preparing a plan for triage and transport management in the event of bioterrorism or other public health emergencies;

(3) enhancing the training of health care professionals to improve the ability of such professionals to recognize the symptoms of exposure to a potential bioweapon, to make appropriate diagnosis, and to provide treatment to those individuals so exposed;

(4) enhancing the training of health care professionals to recognize and treat the mental health consequences of bioterrorism or other public health emergencies;

(5) enhancing the training of health care professionals to assist in providing appropriate health care for large numbers of individuals exposed to a bioweapon;

(6) enhancing training and planning to protect the health and safety of personnel involved in responding to a biological attack;

(7) developing and implementing the trauma care and burn center care components of the State plans for the provision of emergency medical services; or

(8) conducting such activities as are described in section 319C–1(d) that are appropriate for hospitals (including children's hospitals), clinics, health centers, or primary care facilities.

(f) LIMITATION ON AWARDS.—A political subdivision of a State shall not participate in more than one partnership described in subsection (b)(1).

(g) PRIORITIES IN USE OF GRANTS.—

(1) IN GENERAL.—

(A) PRIORITIES.—Except as provided in subparagraph (B), the Secretary shall, in carrying out the activities described in this section, address the following hazards in the following priority:

(i) Bioterrorism or acute outbreaks of infectious diseases.

(ii) Other public health threats and emergencies.

(B) DETERMINATION OF THE SECRETARY.—In the case of the hazard involved, the degree of priority that would apply to the hazard based on the categories specified in clauses (i) and (ii) of subparagraph (A) may be modified by the Secretary if the following conditions are met:

(i) The Secretary determines that the modification is appropriate on the basis of the following factors:

(I) The extent to which eligible entities are adequately prepared for responding to hazards within the category specified in clause (i) of subparagraph (A).

(II) There has been a significant change in the assessment of risks to the public health posed by hazards within the category specified in clause (ii) of such subparagraph.

(ii) Prior to modifying the priority, the Secretary notifies the appropriate committees of the Congress of the determination of the Secretary under clause (i) of this subparagraph.

(2) AREAS OF EMPHASIS WITHIN CATEGORIES.—The Secretary shall determine areas of emphasis within the category of hazards specified in clause (i) of paragraph (1)(A), and shall determine areas of emphasis within the category of hazards specified in clause (ii) of such paragraph, based on an assessment of the risk and likely consequences of such hazards and on an evaluation of Federal, State, and local needs, and may also take into account the extent to which receiving an award under subsection (a) will develop capacities that can be used for public health emergencies of varying types.

(h) COORDINATION WITH LOCAL MEDICAL RESPONSE SYSTEM.—An eligible entity and local Metropolitan Medical Response Systems shall, to the extent practicable, ensure that activities carried out under an award under subsection (a) are coordinated with activities that are carried out by local Metropolitan Medical Response Systems.

(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 fiscal years 2004 through 2006.

**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 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, taking into account evaluations under section 319B(a), 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, 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.

(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).

(c) AUTHORIZATION OF APPROPRIATIONS.—

(1) FACILITIES; CAPACITIES.—

(A) FACILITIES.—For the purpose of carrying out subsection (a)(2), there are authorized to be appropriated $300,000,000 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.

(B) MISSION; IMPROVING CAPACITIES.—For the purposes of achieving the mission of the Centers for Disease Control and Prevention described in subsection (a)(1), for carrying out subsection (a)(3), for better conducting the capacities described in section 319A, and for supporting public health activities, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2002 through 2006.

(2) NATIONAL COMMUNICATIONS AND SURVEILLANCE NETWORKS.—For the purpose of carrying out subsection (b), there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2002 through 2006.

**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) WORKING GROUP ON BIOTERRORISM AND OTHER PUBLIC HEALTH EMERGENCIES.—

(1) IN GENERAL.—The Secretary, in coordination with the Secretary of Agriculture, the Attorney General, the Director of Central Intelligence, the Secretary of Defense, the Secretary of Energy, the Administrator of the Environmental Protection Agency, the Director of the Federal Emergency Management Agency, the Secretary of Homeland Security, the Secretary of Labor, the Secretary of Veterans Affairs, and with other similar Federal officials as determined appropriate, shall establish a working group on the prevention, preparedness, and response to bioterrorism and other public health emergencies. Such joint working group, or subcommittees thereof, shall meet periodically for the purpose of consultation on, assisting in, and making recommendations on—

(A) responding to a bioterrorist attack, including the provision of appropriate safety and health training and protective measures for medical, emergency service, and other personnel responding to such attacks;

(B) prioritizing countermeasures required to treat, prevent, or identify exposure to a biological agent or toxin pursuant to section 351A;

(C) facilitation of the awarding of grants, contracts, or cooperative agreements for the development, manufacture, distribution, supply-chain management, and purchase of priority countermeasures;

(D) research on pathogens likely to be used in a biological threat or attack on the civilian population;

(E) development of shared standards for equipment to detect and to protect against biological agents and toxins;

(F) assessment of the priorities for and enhancement of the preparedness of public health institutions, providers of medical care, and other emergency service personnel (including firefighters) to detect, diagnose, and respond (including mental health response) to a biological threat or attack;

(G) in the recognition that medical and public health professionals are likely to provide much of the first response to such an attack, development and enhancement of the quality of joint planning and training programs that address the public health and medical consequences of a biological threat or attack on the civilian population between—

(i) local firefighters, ambulance personnel, police and public security officers, or other emergency response personnel (including private response contractors); and

(ii) hospitals, primary care facilities, and public health agencies;

(H) development of strategies for Federal, State, and local agencies to communicate information to the public regarding biological threats or attacks;

(I) ensuring that the activities under this subsection address the health security needs of children and other vulnerable populations;

(J) strategies for decontaminating facilities contaminated as a result of a biological attack, including appropriate protections for the safety of workers conducting such activities;

(K) subject to compliance with other provisions of Federal law, clarifying the responsibilities among Federal officials for the investigation of suspicious outbreaks of disease and other potential public health emergencies, and for related revisions of the interagency plan known as the Federal response plan; and

(L) in consultation with the National Highway Traffic Safety Administration and the U.S. Fire Administration, ways to enhance coordination among Federal agencies involved with State, local, and community based emergency medical services, including issuing a report that—

(i) identifies needs of community-based emergency medical services; and

(ii) identifies ways to streamline and enhance the process through which Federal agencies support community-based emergency medical services.

(2) CONSULTATION WITH EXPERTS.—In carrying out subparagraphs (B) and (C) of paragraph (1), the working group under such paragraph shall consult with the pharmaceutical, biotechnology, and medical device industries, and other appropriate experts.

(3) USE OF SUBCOMMITTEES REGARDING CONSULTATION REQUIREMENTS.—With respect to a requirement under law that the working group under paragraph (1) be consulted on a matter, the working group may designate an appropriate subcommittee of the working group to engage in the consultation.

(4) DISCRETION IN EXERCISE OF DUTIES.—Determinations made by the working group under paragraph (1) with respect to carrying out duties under such paragraph are matters committed to agency discretion for purposes of section 701(a) of title 5, Unites States Code.

(5) RULE OF CONSTRUCTION.—This subsection may not be construed as establishing new regulatory authority for any of the officials specified in paragraph (1), or as having any legal effect on any other provision of law, including the responsibilities and authorities of the Environmental Protection Agency.

(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)[1].

[1] 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).

(2) NATIONAL ADVISORY COMMITTEE ON CHILDREN AND TERRORISM.—

(A) IN GENERAL.—For purposes of paragraph (1), the Secretary shall establish an advisory committee to be known as the National Advisory Committee on Children and Terrorism (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 bioterrorism as it relates to children;

(ii) needed changes to the health care and emergency medical service systems and emergency medical services protocols to meet the special needs of children; 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 children.

(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 children, and child health experts on infectious disease, environmental health, toxicology, and other relevant professional disciplines.

(D) TERMINATION.—The Advisory Committee terminates one year 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 the working group under subsection (a) and report on appropriate ways to communicate public health information regarding bioterrorism and other public health emergencies to the public.

(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) STRATEGY FOR COMMUNICATION OF INFORMATION REGARDING BIOTERRORISM AND OTHER PUBLIC HEALTH EMERGENCIES.—In coordination with working group under subsection (a), the Secretary shall develop a strategy for effectively communicating information regarding bioterrorism and other public health emergencies, and shall develop means by which to communicate such information. The Secretary may carry out the preceding sentence directly or through grants, contracts, or cooperative agreements.

(d) RECOMMENDATION OF CONGRESS REGARDING OFFICIAL FEDERAL INTERNET SITE ON BIOTERRORISM.—It is the recommendation of Congress that there should be established an official Federal Internet site on bioterrorism, either directly or through provision of a grant to an entity that has expertise in bioterrorism and the development of websites, that should include information relevant to diverse populations (including messages directed at the general public and such relevant groups as medical personnel, public safety workers, and agricultural workers) and links to appropriate State and local government sites.

(e) GRANTS.—

(1) IN GENERAL.—The Secretary, in coordination with the working group established under subsection (b)[1], shall, on a competitive basis and following scientific or technical review, award grants to or enter into cooperative agreements with eligible entities to enable such entities to increase their capacity to detect, diagnose, and respond to acts of bioterrorism upon the civilian population.

(2) ELIGIBILITY.—To be an eligible entity under this subsection, such entity must be a State, political subdivision of a State, a consortium of two or more States or political subdivisions of States, or a hospital, clinic, or primary care facility[2].

(3) USE OF FUNDS.—An entity that receives a grant under this subsection shall use such funds for activities that are consistent with the priorities identified by the working group under subsection (b)[3], including—

(A) training health care professionals and public health personnel to enhance the ability of such personnel to recognize the symptoms and epidemiological characteristics of exposure to a potential bioweapon;

(B) addressing rapid and accurate identification of potential bioweapons;

(C) coordinating medical care for individuals exposed to bioweapons; and

(D) facilitating and coordinating rapid communication of data generated from a bioterrorist attack between na-

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[1] Probably should be "subsection (a)". See footnote for subsection (b)(1).

[2] The probable intent of the Congress is that "or" should be struck after "clinic," and that the following language should be inserted before the period: ", professional organization or society, school or program that trains medical laboratory personnel, private accrediting organization, or other nonprofit private institution or entity meeting criteria established by the Secretary". See section 111(3) of Public Law 107–188 (116 Stat. 611), which provided for an amendment to "section 391F(e)(2), as redesignated by section 104(a)(2)". Section 104(a)(2) made amendments to section 319F, and this Act does not contain a section 391F.

[3] Probably should be "subsection (a)". See footnote for subsection (b)(1).

tional, State, and local health agencies, and health care providers.

(4) COORDINATION.—The Secretary, in awarding grants under this subsection, shall—

(A) notify the Director of the Office of Justice Programs, and the Director of the National Domestic Preparedness Office annually as to the amount and status of grants awarded under this subsection; and

(B) coordinate grants awarded under this subsection with grants awarded by the Office of Emergency Preparedness and the Centers for Disease Control and Prevention for the purpose of improving the capacity of health care providers and public health agencies to respond to bioterrorist attacks on the civilian population.

(5) ACTIVITIES.—An entity that receives a grant under this subsection shall, to the greatest extent practicable, coordinate activities carried out with such funds with the activities of a local Metropolitan Medical Response System.

(f) FEDERAL ASSISTANCE.—The Secretary shall ensure that the Department of Health and Human Services is able to provide such assistance as may be needed to State and local health agencies to enable such agencies to respond effectively to bioterrorist attacks.

(g) EDUCATION; TRAINING REGARDING PEDIATRIC ISSUES.—

(1) MATERIALS; CORE CURRICULUM.—The Secretary, in collaboration with members of the working group described in subsection (b)[1], and professional organizations and societies, shall—

(A) develop materials for teaching the elements of a core curriculum for the recognition and identification of potential bioweapons and other agents that may create a public health emergency, and for the care of victims of such emergencies, recognizing the special needs of children and other vulnerable populations, to public health officials, medical professionals, emergency physicians and other emergency department staff, laboratory personnel, and other personnel working in health care facilities (including poison control centers);

(B) develop a core curriculum and materials for community-wide planning by State and local governments, hospitals and other health care facilities, emergency response units, and appropriate public and private sector entities to respond to a bioterrorist attack or other public health emergency;

(C) develop materials for proficiency testing of laboratory and other public health personnel for the recognition and identification of potential bioweapons and other agents that may create a public health emergency; and

(D) provide for dissemination and teaching of the materials described in subparagraphs (A) through (C) by appropriate means, which may include telemedicine, long-distance learning, or other such means.

[1] Probably should be "subsection (a)". See footnote for subsection (b)(1).

(2) CERTAIN ENTITIES.—The entities through which education and training activities described in paragraph (1) may be carried out include Public Health Preparedness Centers, the Public Health Service's Noble Training Center, the Emerging Infections Program, the Epidemic Intelligence Service, the Public Health Leadership Institute, multi-State, multi-institutional consortia, other appropriate educational entities, professional organizations and societies, private accrediting organizations, and other nonprofit institutions or entities meeting criteria established by the Secretary.

(3) GRANTS AND CONTRACTS.—In carrying out paragraph (1), the Secretary may carry out activities directly and through the award of grants and contracts, and may enter into interagency cooperative agreements with other Federal agencies.

(4) HEALTH-RELATED ASSISTANCE FOR EMERGENCY RESPONSE PERSONNEL TRAINING.—The Secretary, in consultation with the Attorney General and the Director of the Federal Emergency Management Agency, may provide technical assistance with respect to health-related aspects of emergency response personnel training carried out by the Department of Justice and the Federal Emergency Management Agency.

(h) 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 coop-

erative 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).

(i) GENERAL ACCOUNTING OFFICE REPORT[1].—Not later than 180 days after the date of the enactment of this section, the Comptroller General 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—

(1) Federal activities primarily related to research on, preparedness for, and the management of the public health and medical consequences of a bioterrorist attack against the civilian population;

(2) the coordination of the activities described in paragraph (1);

(3) the amount of Federal funds authorized or appropriated for the activities described in paragraph (1); and

(4) the effectiveness of such efforts in preparing national, State, and local authorities to address the public health and medical consequences of a potential bioterrorist attack against the civilian population.

(j) 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.

**SEC. 319F–1. [247d–6a] AUTHORITY FOR USE OF CERTAIN PROCEDURES REGARDING QUALIFIED COUNTERMEASURE RESEARCH AND DEVELOPMENT ACTIVITIES.[2]**

(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.

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[1] Now the Government Accountability Office. See section 8 of Public Law 108–271 (118 Stat. 814).

[2] 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.

(2) QUALIFIED COUNTERMEASURE.—For purposes of this section, 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) to—

(A) treat, identify, or prevent harm from any biological, chemical, radiological, or nuclear agent that may cause a public health emergency affecting national security; or

(B) treat, identify, or prevent 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 subparagraph (A).

(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 gov-

erning 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 governing 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.[1]**

(a) STRATEGIC NATIONAL STOCKPILE.—

(1) IN GENERAL.—The Secretary, in coordination with the Secretary of Homeland Security (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 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.

(2) PROCEDURES.—The Secretary, in managing the stockpile under paragraph (1), shall—

[1] 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.

(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;

(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 BIOMEDICAL 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 under paragraph (10).

(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 treat, identify, or prevent harm from any biological, chemical, radiological, or nuclear agent identified as a material threat under paragraph (2)(A)(ii), or to treat, identify, or prevent 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 eight 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 designated congressional committees (as defined in paragraph (10)) 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 emerg-

ing threats of chemical, biological, radiological, and nuclear agents.

(3) ASSESSMENT OF AVAILABILITY AND APPROPRIATENESS OF COUNTERMEASURES.—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).

(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 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 under paragraph (10) 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 under paragraph (10) (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 needs of the stockpile.

(ii) The feasibility of production and delivery within eight 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 appropriate 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 under paragraph (10) be made available for the procurement of such countermeasure.

(B) PRESIDENTIAL APPROVAL.—The special reserve fund under paragraph (10) 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 DESIGNATED CONGRESSIONAL COMMITTEES.—The Secretary and the Homeland Security Secretary shall notify the designated 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 under paragraph (10) 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 counter-

measure 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 under paragraph (10) 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; COSTS.—

(i) INTERAGENCY AGREEMENT.—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 under paragraph (10) shall be available for payments made by the Secretary to a vendor for such procurement.

(ii) OTHER COSTS.—The actual costs to the Secretary under this section, other than the costs described in clause (i), shall be paid from the appropriation provided for under subsection (f)(1).

(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, 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 has been made 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 is necessary to ensure success of a project, the Secretary may pay an amount, not to exceed 10 percent of the contract amount, in advance of delivery. 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. Nothing in this subclause may be construed as affecting rights of vendors under provisions of law or regulation (including the Federal Acquisition Regulation) relating to 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 eight 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 under paragraph (10) 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.

(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 procurement 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.

(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.

(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.

(9) RESTRICTIONS ON USE OF FUNDS.—Amounts in the special reserve fund under paragraph (10) shall not be used to pay—

(A) costs for the purchase of vaccines under procurement contracts entered into before the date of the enactment of the Project BioShield Act of 2004; or

(B) costs other than payments made by the Secretary to a vendor for a procurement of a security countermeasure under paragraph (7).

(10) DEFINITIONS.—

(A) SPECIAL RESERVE FUND.—For purposes of this subsection, the term "special reserve fund" has the meaning given such term in section 510 of the Homeland Security Act of 2002 [1].

(B) DESIGNATED CONGRESSIONAL COMMITTEES.—For purposes of this section, the term "designated congressional committees" means the following committees of the Congress:

(i) In the House of Representatives: the Committee on Energy and Commerce, the Committee on Appropriations, the Committee on Government Reform, and the Select Committee on Homeland Security (or any successor to the Select Committee).

(ii) In the Senate: the appropriate committees.

(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 $640,000,000 for fiscal year 2002, and such sums as may be necessary for each of fiscal years 2003 through 2006. Such authorization is in addition to amounts in the special reserve fund referred to in subsection (c)(10)(A).

(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.

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[1] Subsections (a) through (c) of such section provide as follows:

(a) AUTHORIZATION OF APPROPRIATIONS.—For the procurement of security countermeasures under section 319F–2(c) of the Public Health Service Act (referred to in this section as the "security countermeasures program"), there is authorized to be appropriated up to $5,593,000,000 for the fiscal years 2004 through 2013. Of the amounts appropriated under the preceding sentence, not to exceed $3,418,000,000 may be obligated during the fiscal years 2004 through 2008, of which not to exceed $890,000,000 may be obligated during fiscal year 2004.

(b) SPECIAL RESERVE FUND.—For purposes of the security countermeasures program, the term "special reserve fund" means the "Biodefense Countermeasures" appropriations account or any other appropriation made under subsection (a).

(c) AVAILABILITY.—Amounts appropriated under subsection (a) become available for a procurement under the security countermeasures program only upon the approval by the President of such availability for the procurement in accordance with paragraph (6)(B) of such program.

**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[1].—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

[1] Now the Government Accountability Office. See section 8 of Public Law 108–271 (118 Stat. 814).

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 subsection (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.—The Secretary shall, directly or through an award of a grant, contract, or cooperative agreement, establish and maintain a system for the advance registration of health professionals for the purpose of verifying the credentials, licenses, accreditations, and hospital privileges of such professionals when, during public health emergencies, the professionals volunteer to provide health services (referred to in this section as the "verification system"). In carrying out the preceding sentence, the Secretary shall provide for an electronic database for the verification system.

(b) CERTAIN CRITERIA.—The Secretary shall establish provisions regarding the promptness and efficiency of the system in collecting, storing, updating, and disseminating information on the credentials, licenses, accreditations, and hospital privileges of volunteers described in subsection (a).

(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 system developed under subsection (a).

(d) COORDINATION AMONG STATES.—The Secretary may encourage each State to provide legal authority during a public health emergency for health professionals authorized in another State to provide certain health services to provide such health services in the State.

(e) 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.

(f) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $2,000,000 for fiscal year 2002, and such sums as may be necessary for each of the fiscal years 2003 through 2006.

**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.

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. [1]

(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.

COORDINATED PROGRAM TO IMPROVE PEDIATRIC ORAL HEALTH

SEC. 320A. [2] [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 na-

[1] Title II of Public Law 105–78. See 111 Stat. 1477, 1489.

[2] 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.

tional 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 hospitals 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 [1]

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), [2] 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, surgical, and hospital services and supplies for persons entitled to treatment under the United States Employees' Compensation Act [3] 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), [4] 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.

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[1] 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.

[2] Now codified to section 4005 of title 18, United States Code.

[3] Codified to chapter 81 of title 5, United States Code.

[4] Codification remains chapter 18 of title 33, United States Code.

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;

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 execu-

tive 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 short-

age 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.

(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 as-

sets 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 migratory 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 ad-

junct 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 comprehensive 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)[1] 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;

[1] Indentation is so in law. See section 101(7)(A)(i)(III) of Public Law 107–251 (116 Stat. 225).

(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

(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 dele-

gated 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 received 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) IN GENERAL.—For the purpose of carrying out this section, in addition to the amounts authorized to be appropriated

under subsection (d), there are authorized to be appropriated $1,340,000,000 for fiscal year 2002 and such sums as may be necessary for each of the fiscal years 2003 through 2006.

(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.

**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 ap-

plication, 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 $40,000,000 for fiscal year 2002, and such sums as may be necessary for each of fiscal years 2003 through 2006.

**SEC. 330B. [254c–2] SPECIAL DIABETES PROGRAMS FOR TYPE I DIABETES.[1]**

(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 2008.

**SEC. 330C. [254c–3] SPECIAL DIABETES PROGRAMS FOR INDIANS.[1]**

(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.

(2) APPROPRIATIONS.—For the purpose of making grants under this section, there is appropriated, out of any money in the Treasury not otherwise appropriated—

[1] 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.

(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 2008.

**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 dis-

ease 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 in-

volved 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 [1].

(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 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

[1] Public Law 106–310, enacted October 17, 2000.

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 [1], 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 States in order that the full national diversity of interests among adoption organizations is represented in the planning and development of the campaign.

[1] Public Law 106–310, enacted October 17, 2000.

(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.

(3) ADDITIONAL GRANTS.—Effective upon increased funding beyond fiscal year 1999 for such Initiative, additional grants may be made to States to assist communities with technical assistance, replication of successful projects, and State policy formation to reduce infant and maternal mortality and morbidity.

(b) REQUIREMENTS FOR MAKING GRANTS.—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).

(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) ADDITIONAL SERVICES FOR AT-RISK PREGNANT WOMEN AND INFANTS.—

(1) IN GENERAL.—The Secretary may make grants to conduct and support research and to provide additional health care services for pregnant women and infants, including grants to increase access to prenatal care, genetic counseling, ultrasound services, and fetal or other surgery.

(2) ELIGIBLE PROJECT AREA.—The Secretary may make a grant under paragraph (1) only if the geographic area in which services under the grant will be provided is a geographic area in which a project under subsection (a) is being carried out, and if the Secretary determines that the grant will add to or expand the level of health services available in such area to pregnant women and infants.

(3) EVALUATION BY GENERAL ACCOUNTING OFFICE [1].—

(A) IN GENERAL.—During fiscal year 2004, the Comptroller General of the United States shall conduct an evaluation of activities under grants under paragraph (1) in order to determine whether the activities have been effective in serving the needs of pregnant women with respect to services described in such paragraph. The evaluation shall include an analysis of whether such activities 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. Not later than January 10, 2004, the Comptroller General shall submit to the Committee on Commerce in the House of Representatives, and to the Committee on Health, Education, Labor, and Pensions in the Senate, a report describing the findings of the evaluation.

(B) RELATION TO GRANTS REGARDING ADDITIONAL SERVICES FOR AT-RISK PREGNANT WOMEN AND INFANTS.—Before the date on which the evaluation under subparagraph (A) is submitted in accordance with such subparagraph—

(i) the Secretary shall ensure that there are not more than five grantees under paragraph (1); and

(ii) an entity is not eligible to receive grants under such paragraph unless the entity has substantial experience in providing the health services described in such paragraph.

(f) FUNDING.—

(1) GENERAL PROGRAM.—

(A) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section (other than subsection (e)), there are authorized to be appropriated such sums as may

[1] Now the Government Accountability Office. See section 8 of Public Law 108–271 (118 Stat. 814).

be necessary for each of the fiscal years 2001 through 2005.

(B) ALLOCATIONS.—

(i) PROGRAM ADMINISTRATION.—Of the amounts appropriated under subparagraph (A) 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.

(ii) EVALUATION.—Of the amounts appropriated under subparagraph (A) 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.

(2) ADDITIONAL SERVICES FOR AT-RISK PREGNANT WOMEN AND INFANTS.—

(A) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out subsection (e), there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005.

(B) ALLOCATION FOR COMMUNITY-BASED MOBILE HEALTH UNITS.—Of the amounts appropriated under subparagraph (A) for a fiscal year, the Secretary shall make available not less than 10 percent for providing services under subsection (e) (including ultrasound services) through visits by mobile units to communities that are eligible for services under subsection (a).

**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 elec-

tronic 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 Congress 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 paragraph (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 [1] 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:

[1] So in law. Probably should be "health professional shortages". See section 401 of Public Law 101–597 (104 Stat. 3035).

(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 extent 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 subparagraph (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.

(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, carry out demonstration projects in which individuals who have entered into a contract for obligated service under the Loan Repayment Program receive waivers under which the individuals are authorized to satisfy the requirement of obligated service through providing clinical service that is not full-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 less than full time;

(B) the Secretary has determined that assignment of a health professional who would serve less than full 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 less than full-time service to an entity described in subparagraph (A);

(D) the entity and the Corps member agree in writing that the less than full-time service provided by the Corps member will not be less than 16 hours of clinical service per week;

(E) the Corps member agrees in writing that the period of obligated service pursuant to section 338B will be extended so that the aggregate amount of less than full-time service performed will equal the amount of service that would be performed through full-time service under section 338C; and

(F) the Corps member agrees in writing that if the Corps member begins providing less than full-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 a demonstration project described in 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.

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. Not earlier than 6 years after such date of designation, and every 6 years thereafter, each such center or clinic shall demonstrate that the center or clinic meets the applicable requirements of the Federal regulations regarding the definition of a health professional shortage area for purposes of this section. 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 migratory 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 comments 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 Secretary, 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; and

(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.

An application for assignment of a Corps member to a health professional shortage area shall include a demonstration by the appli-

cant 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 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 sec-

tion 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 Associations 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 para-

graph, 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 entity 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) ASSISTANCE IN ESTABLISHING LOCAL PROFESSIONAL RELATIONSHIPS.—The Secretary shall assist Corps members in 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, including such relationships with hospitals, with health professions schools, with area health education centers under section 781, with health education and training centers under such section, and with border health education and training centers under such section. Such assistance shall include assistance in obtaining faculty appointments at health professions schools.

(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)[1], 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—

(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

[1] 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.)

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 [1], 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 [1] 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;

(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;

[1] So in law. Probably should be "health professional shortage areas". See section 401 of Public Law 101–597 (104 Stat. 3035).

(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 [1].

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. Members may not be reappointed to the Council.

(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 traveltime) in which they are so serving compensation at a rate fixed by 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.

[1] 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.

(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 2002 through 2006.

(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 tuition 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 con-

tract 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 academic 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 $35,000 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) 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.

(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 employee 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 purposes of carrying out this subpart, there are authorized to be appropriated

$146,250,000 for fiscal year 2002, and such sums as may be necessary for each of fiscal years 2003 through 2006.

(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.

(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 non-financial 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 several States.

(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 2002 and such sums as may be necessary for each of fiscal years 2003 through 2006.

(2) AVAILABILITY.—Amounts appropriated under paragraph (1) shall remain available until expended.

**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 subsection (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 [1];

(II) under a memorandum of agreement entered into with the State under subsection (h) of such section; [2] 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;

[1] Probably should be "subsection (k)". See the amendment made by section 2 of Public Law 104–299 (110 Stat. 3626).

[2] Probably should be "subsection (m)". See the amendment referred to in footnote 1.

(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.

(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.—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.

## 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

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 application) 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.

## Subpart VII [1]—Drug Pricing Agreements

### LIMITATION ON PRICES OF DRUGS PURCHASED BY COVERED ENTITIES

SEC. 340B. [1] **[**256b**]** (a) REQUIREMENTS FOR AGREEMENT WITH SECRETARY.—

(1) IN GENERAL.—The Secretary shall enter into an agreement with each manufacturer of covered 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 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).

(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—

(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)(4) of such Act.

(ii) DEFINITION.—The term "over the counter drug" means a drug that may be sold without a pre-

[1] So in law. Former subpart VI containing section 340A was repealed by section 4(a)(3) of Public Law 104–299 (110 Stat. 3645).

scription 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 [1].

(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 section 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;

[1] See footnote on preceding page. See also footnote for section 217(a).

(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.

(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 notice and hearing, that a covered entity is in violation of a requirement described in subparagraphs [1] (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

[1] So in law. See section 602(a) of Public Law 102–585 (106 Stat. 4967). Probably should be "subparagraph".

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 Secretary 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.—In this section, the terms "average manufacturer price", "covered outpatient drug", and "manufac-

turer" have the meaning given such terms in section 1927(k) of the Social Security Act.

(c) REFERENCES TO SOCIAL SECURITY ACT.—Any reference in this section to a provision of the Social Security Act shall be deemed to be a reference to the provision as in effect on the date of the enactment of this section.

(d) COMPLIANCE WITH REQUIREMENTS.—A manufacturer is deemed to meet the requirements of subsection (a) if the manufacturer establishes to the satisfaction of the Secretary that the manufacturer would comply (and has offered to comply) with the provisions of this section (as in effect immediately after the enactment of the Veterans Health Care Act of 1992), as applied by the Secretary, and would have entered into an agreement under this section (as such section was in effect at such time), but for a legislative change in this section (or the application of this section) after the date of the enactment of such Act.

## 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 [1], 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).

[1] 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) [1].

(2) Entities receiving assistance under section 318 (relating to sexually transmitted diseases).

(3) Migrant health centers receiving assistance under section 329 [2].

(4) Community health centers receiving assistance under section 330 [2].

(5) Entities receiving assistance under section 330(h) (relating to homeless individuals).

(6) Entities receiving assistance under section 340A [2] (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

[1] 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.

[2] See footnote for section 217(a).

through 2005, 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 paragraph (2), 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.

(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 hos-

pital) 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 described in subparagraph (C)(ii) 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 pa-

tients 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 severely 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 26 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). 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 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.

(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; and

(iii) for each of the fiscal years 2002 through 2005, such sums as may be necessary.

(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)(A)—

(A) for fiscal year 2000, $190,000,000;

(B) for fiscal year 2001, $190,000,000; and

(C) for each of the fiscal years 2002 through 2005, such sums as may be necessary.

(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 pur-

pose 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, $50,000,000 for the 5-fiscal year period beginning with fiscal year 2002.

## PART E—NARCOTIC ADDICTS AND OTHER DRUG ABUSERS [1]

### 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

[1] 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).

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 treatment 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 persons 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 depend-

ence 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) [Repealed.]

(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)[1], 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 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).[1]

(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.

[1] 67 Stat. 77. Codified to section 24–601 et seq., D.C. Code.

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 [1]

### Subpart 1—Biological Products

REGULATION OF BIOLOGICAL PRODUCTS [2]

SEC. 351. [262] (a)(1) No person shall introduce or deliver for introduction into interstate commerce any biological product unless—

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[1] 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".

[2] 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)).".

(A) a biologics license 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—

(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).

(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).[1]

(h)[2] 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, the term "biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, 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.

(j) The Federal Food, Drug, and Cosmetic Act applies to a biological product subject to regulation under this section, except that a product for which a license has been approved under subsection (a) shall not be required to have an approved application under section 505 of such Act.

**SEC. 351A. [262a] ENHANCED CONTROL OF DANGEROUS BIOLOGICAL AGENTS AND TOXINS.[3]**

(a) REGULATORY CONTROL OF CERTAIN BIOLOGICAL AGENTS AND TOXINS.—

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[1] Codification remains chapter 9 of title 21, United States Code (§301 et seq.).

[2] 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.

[3] 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–

(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.

(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

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.

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 deter-

mined 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 reg-

ister 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 Sec-

retary, 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.— [1]

(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),

[1] 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.

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:

(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 applicable 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 per-

forming 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.

(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 de-

scribed 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, [1]

(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,

[1] So in law. Probably should be "the Secretary".

(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 after the laboratory receives notification of the withdrawal of the approval, except that the Secretary may extend such period for a laboratory if it [1] 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) [1] STANDARDS.—

[1] 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 estab-

Continued

(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 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

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lished 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.".

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 examination 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 [1] 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) [2]. 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

[1] So in law. Probably should not be hyphenated. Compare with text of subparagraph (D).
[2] So in law. Probably should be "(d)(1)(E)".

(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 [1] 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.

(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 [2] proficiency testing of such individuals, with such testing to take place, to the extent practicable, under normal working conditions,

[1] So in law. Probably should be "proficiency".
[2] See footnote 1 for paragraph (3)(D).

(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[1] 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.

(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,

[1] So in law. Probably should be "require it to be".

(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 [1]

(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),

(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),

[1] So in law. The sentence lacks a period.

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. 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 shall 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 mammogram 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 [1] (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 [2] 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 different 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

[1] So in law. Probably should be "paragraph". See section 2(1)(A)(ii) of Public Law 108–365 (118 Stat. 1738).

[2] 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).

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 action 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 pro-

mulgate 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 en-

forcing 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, [1].

(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, 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,

[1] The comma is so in law. See the amendment made by section 142(a)(1) of Public Law 107–188 (116 Stat. 626).

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.[1] [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),[2] the Surgeon General shall control, direct, and manage 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

[1] 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".

[2] Now codified to sections 191, 192, 194, and 195 of title 50, United States Code.

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 medical 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 [1]

### 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).

(b)(1) [2] 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) [3] 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 ef-

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[1] 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.

[2] 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).

[3] So in law. Probably should be "paragraph (3)".

fect 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—

(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; [1]

(F) has procedures to obtain payment for non-renal organs provided to transplant centers,

[1] So in law. Subparagraphs (D) and (E) have semicolons at the end of organizational units, rather than commas.

(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[1] 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

(V) from each transplant center in its service area which has arrangements described in paragraph (2)[2](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)[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,[3] 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,[3] 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,

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[1] So in law. Probably should be "histocompatibility".
[2] So in law. Probably should be paragraph (3).
[3] Enacted November 16, 1990. See section 201(d) of Public Law 101–616.

(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

(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 $2,000,000. 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)[1] 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)[1] carry out studies and demonstration projects for the purpose of improving procedures for organ donation procurement and allocation, including but not limited to

[1] Indentation is so in law. See section 2101(a)(3) of Public Law 106–310 (114 Stat. 1156).

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)[1] 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 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, in-

[1] See footnote for subparagraph (M).

cluding 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)[1] to patients, their families, and their physicians about transplantation; and

(ii)[1] 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.[2] a report on the scientific and clinical status

[1] 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).

[2] So in law. There probably should be a comma after "Senate" rather than a period. See section 205 of Public Law 101–616.

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—

(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 transplantation 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 conducted 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—NATIONAL BONE MARROW DONOR REGISTRY

**SEC. 379. [274k] NATIONAL REGISTRY.**

(a) ESTABLISHMENT.—The Secretary shall by contract establish and maintain a National Bone Marrow Donor Registry (referred to in this part as the "Registry") that has the purpose of increasing the number of transplants for recipients suitably matched to biologically unrelated donors of bone marrow, and that meets the requirements of this section. The Registry shall be under the general supervision of the Secretary, and under the direction of a board of directors meeting the following requirements:

(1) Each member of the board shall serve for a term of 2 years, and each such member may serve as many as 3 consecutive 2-year terms, except that such limitations shall not apply to the Chair of the board (or the Chair-elect) or to the member of the board who most recently served as the Chair.

(2) A member of the board 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 board, the board shall be appointed so that each year the terms of approximately one-third of the members of the board expire.

(4) The membership of the board shall include representatives of marrow donor centers and marrow transplant centers; recipients of a bone marrow transplant; persons who require or have required such a transplant; family members of such a recipient or family members of a patient who has requested the assistance of the Registry in searching for an unrelated donor of bone marrow; persons with expertise in the social sciences; and members of the general public; and in addition nonvoting representatives from the Naval Medical Research and Development Command and from the Division of Organ Transplantation of the Health Resources and Services Administration.

(b) FUNCTIONS [1].—The Registry shall—

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[1] 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).

(1) establish a system for finding marrow donors suitably matched to unrelated recipients for bone marrow transplantation;

(2) carry out a program for the recruitment of bone marrow donors in accordance with subsection (c), including with respect to increasing the representation of racial and ethnic minority groups (including persons of mixed ancestry) in the enrollment of the Registry;

(3) carry out informational and educational activities in accordance with subsection (c);

(4) annually update information to account for changes in the status of individuals as potential donors of bone marrow;

(5) provide for a system of patient advocacy through the office established under subsection (d);

(6) provide case management services for any potential donor of bone marrow to whom the Registry has provided a notice that the potential donor may be suitably matched to a particular patient (which services shall be provided through a mechanism other than the system of patient advocacy under subsection (d)), and conduct surveys of donors and potential donors to determine the extent of satisfaction with such services and to identify ways in which the services can be improved;

(7) with respect to searches for unrelated donors of bone marrow that are conducted through the system under paragraph (1), collect and analyze and publish data 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; and comparisons of transplant centers regarding search and other costs that prior to transplantation are charged to patients by transplant centers; and

(8) support studies and demonstration projects for the purpose of increasing the number of individuals, especially minorities, who are willing to be marrow donors.

(c) RECRUITMENT; PRIORITIES; INFORMATION AND EDUCATION.—

(1) RECRUITMENT; PRIORITIES.—The Registry shall carry out a program for the recruitment of bone marrow donors. Such program shall identify populations that are underrepresented among potential donors enrolled with the Registry. In the case of populations that are identified under the preceding sentence:

(A) The Registry 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 Registry shall consider racial and ethnic minority groups (including persons of mixed ancestry) to be

"(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.".

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.—In carrying out the program under paragraph (1), the Registry shall carry out informational and educational activities for purposes of recruiting individuals to serve as donors of bone marrow, and shall test and enroll with the Registry potential 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 donors, including providing updates.

(iii) Training individuals in requesting individuals to serve as potential donors.

(B) PRIORITIES.—In carrying out informational and educational activities under subparagraph (A), the Registry 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 program under paragraph (1) shall provide information to physicians, other health care professionals, and the public regarding the availability, as a potential treatment option, of receiving a transplant of bone marrow from an unrelated donor.

(d) PATIENT ADVOCACY; CASE MANAGEMENT.—

(1) IN GENERAL.—The Registry shall establish and maintain 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 operate a system for patient advocacy, which shall be separate from mechanisms for donor advocacy, and which shall serve patients for whom the Registry is conducting, or has been requested to conduct, a search for an unrelated donor of bone marrow.

(C) 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 subsection (b)(1) to conduct an ongoing search for a donor.

(D) In carrying out subparagraph (C), the Office shall monitor the system under subsection (b)(1) 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 donors who are suitability 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.

(E) In carrying out subparagraph (C), the Office shall monitor the system under subsection (b)(1) to determine whether the Registry, donor centers, transplant centers, and other entities participating in the Registry program are complying with standards issued under subsection (e)(4) for the system for patient advocacy under this subsection.

(F) The Office shall ensure that the following data are made available to patients:

(i) The resources available through the Registry.

(ii) A comparison of transplant centers regarding search and other costs that prior to transplantation are charged to patients by transplant centers.

(iii) A list of donor registries, transplant centers, and other entities that meet the applicable standards, criteria, and procedures under subsection (e).

(iv) The posttransplant outcomes for individual transplant centers.

(v) Such other information as the Registry 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.

(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 may, on behalf of patients who have completed the search for an unrelated donor, provide information and education on the process of receiving a transplant of bone marrow, including the posttransplant process.

(e) CRITERIA, STANDARDS, AND PROCEDURES.—Not later than 180 days after the date of enactment of this part, the Secretary shall establish and enforce, for entities participating in the pro-

gram, including the Registry, 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 (d), 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 of records relating to the identity, address, HLA type, and managing marrow donor center for marrow donors and potential marrow donors; 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 Registry.

(f) COMMENT PROCEDURES.—The Secretary shall establish and provide information to the public on procedures, which may include establishment of a policy advisory committee, under which the Secretary shall receive and consider comments from interested persons relating to the manner in which the Registry is carrying out the duties of the Registry under subsection (b) and complying with the criteria, standards, and procedures described in subsection (e).

(g) CONSULTATION.—The Secretary shall consult with the board of directors of the Registry and the bone marrow donor program of the Department of the Navy in developing policies affecting the Registry.

(h) 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.

(i) ELIGIBILITY.—Entities eligible to receive a contract under this section shall include private nonprofit entities.

(j) 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.

(k) PENALTIES FOR DISCLOSURE.—Any person who discloses the content of any record referred to in subsection (e)(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 (e)(5)(B), shall be imprisoned for not more than 2 years or fined in accordance with title 18, United States Code, or both.

(l) ANNUAL REPORT REGARDING PRETRANSPLANT COSTS.—The Registry shall annually submit to the Secretary the data collected under subsection (b)(7) on comparisons of transplant centers regarding search and other costs that prior to transplantation are charged to patients by transplant centers. The data shall be submitted to the Secretary through inclusion in the annual report required in section 379A(c).

**SEC. 379A. [274l] BONE MARROW SCIENTIFIC REGISTRY.**

(a) ESTABLISHMENT OF RECIPIENT REGISTRY.—The Secretary, acting through the Registry under section 379 (in this section referred to as the "Registry"), shall establish and maintain a scientific registry of information relating to patients who have been recipients of a transplant of bone marrow from a biologically unrelated donor.

(b) INFORMATION.—The scientific registry under subsection (a) shall include information with respect to patients described in subsection (a), transplant procedures, and such other information as the Secretary determines to be appropriate to conduct an ongoing evaluation of the scientific and clinical status of transplantation involving recipients of bone marrow from biologically unrelated donors.

(c) ANNUAL REPORT ON PATIENT OUTCOMES.—The Registry shall annually submit to the Secretary a report concerning patient outcomes with respect to each transplant center. Each such report shall use data collected and maintained by the scientific registry under subsection (a). Each such report shall in addition include the data required in section 379(l) (relating to pretransplant costs).

**SEC. 379B. [274m] AUTHORIZATION OF APPROPRIATIONS.**

For the purpose of carrying out this part, there are authorized to be appropriated $18,000,000 for fiscal year 1999, and such sums as may be necessary for each of the fiscal years 2000 through 2003.

## 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 Secretary 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.

PREVENTION OF TRAUMATIC BRAIN INJURY

SEC. 393A. [280b–1b] (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 trauma centers; 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.

**SEC. 393B. [280b–1c] 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 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 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 $80,000,000 for each of fiscal years 2001 through 2005.

(2) NATIONAL RESOURCE CENTER ALLOTMENT.—Of the total amount made available under this subsection in each fiscal year, not more than the greater of $1,000,000 or 2 percent of such amount shall be available for allotment under subsection (b).

(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.

NATIONAL PROGRAM FOR TRAUMATIC BRAIN INJURY REGISTRIES

SEC. 393B.[1] **[**280b–1d**]** (a)[2] 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 operate the State's traumatic brain injury registry, and to academic institutions to conduct applied research that will support the development of such registries, to collect 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

[1] So in law. There are two sections 393B. Section 1301(b) of Public Law 106–310 (114 Stat. 1137) inserted section 393B above. Subsequently, section 1401(a) of Public Law 106–386 (114 Stat. 1512), which relates to the use of allotments for rape prevention education, inserted a section 393B after section 393A.

[2] So in law. There is no subsection (b). See section 1301(b) of Public Law 106–310 (114 Stat. 1137).

(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.

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 [1] 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.. [1]

## 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 [2] skilled nursing care services, homemaker or home health aide services, or per-

[1] 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.

[2] 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)).

sonal 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

(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 minority 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[1]**

(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;

(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—

[1] So in law. The section heading lacks a period. See section 301(b)(1) of Public Law 105–392 (112 Stat. 3586).

(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 so-

cial 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, developmental 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.

## [PART L [1]—]

**SEC. 399A. [280d] GRANTS FOR SERVICES FOR CHILDREN OF SUBSTANCE ABUSERS.[1]**

(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

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[1] The content of section 399A above, and the placement of the section in this Act, probably do not reflect the intent of the Congress. Section 399A formerly was section 399D. Section 3106 of Public Law 106–310 (114 Stat. 1175) attempts to make various amendments to section 399D, but the amendments cannot be executed because section 399D was redesignated as section 399A by section 502(1) of such Public Law (114 Stat. 1115). (Section 399D now relates to technical assistance in operations of Statewide cancer registries.)

Further, section 3106(m) of the Public Law (114 Stat. 1179) attempts to transfer section 399D to title V of this Act as a section 519, but this transfer has not been executed because it applied to section 399D "as amended by this section" (section 3106), and no amendments described in section 3106 have been made to section 399D.

As a conforming amendment, section 3106(n) of the Public Law provided that title III of this Act "is amended by striking the heading for part L". This amendment has been executed, but for the convenience of the reader, a designation for a part L is shown above in brackets to indicate the probable intent of the Congress that section 399A is not included in part K of title III.

For the convenience of the reader, an italicized note follows section 399A above showing the section as it would appear if the amendments described in section 3106 of the Public Law were executed to section 399A.

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 disabilities service providers, and family resource and support programs.

(5) The term "substance abuse" means the abuse of alcohol or other drugs.

(p) FUNDING.—

(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appro-

priated $50,000,000 for fiscal year 1993, and such sums as may be necessary for fiscal year 1994.

(2) CONTINGENT AUTHORITY REGARDING TRAINING OF CERTAIN INDIVIDUALS.—Of the amounts appropriated under paragraph (1) for a fiscal year in excess of $25,000,000, the Secretary may make available not more than 15 percent for the training of health care professionals and other personnel (including child welfare providers) who provide services to children and families of substance abusers.

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**NOTE:** *For the convenience of the reader, the following indicates the probable intent of the Congress by showing section 399A as the section would appear if the amendments described in section 3106 of Public Law 106–310 (114 Stat. 1175) were executed to section 399A, rather than to section 399D as instructed by such section 3106, including the amendment that redesignates the section as section 519 (toward the purpose of transferring the section to title V of this Act). See footnote on page 619.*

***SEC. 519. [280d] GRANTS FOR SERVICES FOR CHILDREN OF SUBSTANCE ABUSERS.***

*(a) ESTABLISHMENT.—*

*(1) IN GENERAL.—The Secretary, acting through the Administrator of the Substance Abuse and Mental Health 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;*

*(C) to identify such children and such families through youth service agencies, family social services, child care providers, Head Start, schools and after-school programs, early childhood development programs, community-based family resource and support centers, the criminal justice system, health, substance abuse and mental health providers through screenings conducted during regular childhood examinations and other examinations, self and family member referrals, substance abuse treatment services, and other providers of services to children and families; and*

*(D) to provide education and training to health, substance abuse and mental health professionals, and other providers of services to children and families through youth service agencies, family social services, child care, Head Start, schools and after-school programs, early childhood development programs, community-based family resource and support centers, the criminal justice system, and other providers of services to children and families.*

*(2) ADMINISTRATIVE CONSULTATIONS.—The Administrator of the Administration for Children, Youth, and Families and the Administrator of the Health Resources and Services Admin-*

*istration 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)(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; and*

*(ii) the entity will identify children who may be eligible for medical assistance under a State program under title XIX or XXI of the Social Security Act.*

*(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, alcohol and drug, 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) Developmentally and age-appropriate drug and alcohol early intervention, treatment and prevention 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 H of the Individuals with Disabilities Education Act.*

*Services shall be provided under paragraphs (2) through (8) by a public health nurse, social worker, or similar professional, or by a trained worker from the community who is supervised by a professional, or by an entity, where the professional or entity provides assurances that the professional or entity is licensed or certified by the State if required and is complying with applicable licensure or certification requirements.*

*(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, or by an entity, where the professional or entity provides assurances that the professional or entity is licensed or certified by the State if required and is complying with applicable licensure or certification requirements:*

*(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).*

*(D) Aggressive outreach to family members with substance abuse problems.*

*(E) Inclusion of consumer in the development, implementation, and monitoring of Family Services Plan.*

*(2) In the case of substance abusers:*

*(A) Alcohol and drug treatment services, including screening and assessment, diagnosis, detoxification, individual, group and family counseling, relapse prevention, pharmacotherapy treatment, after-care services, and case management.*

*(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 and counseling on the human immunodeficiency virus and acquired immune deficiency syndrome.*

*(D) Where appropriate, counseling regarding family violence.*

*(E) Career planning and 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 which include child abuse and neglect prevention techniques.*

*(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) TRAINING FOR PROVIDERS OF SERVICES TO CHILDREN AND FAMILIES.—The Secretary may make a grant under subsection (a) for the training of health, substance abuse and mental health professionals and other providers of services to children and families through youth service agencies, family social services, child care providers, Head Start, schools and after-school programs, early childhood development programs, community-based family resource centers, the criminal justice system, and other providers of services to children and families. Such training shall be to assist professionals in recognizing the drug and alcohol problems of their clients and to enhance their skills in identifying and understanding the nature of substance abuse, and obtaining substance abuse early intervention, prevention and treatment resources.*

*(e) ELIGIBLE ENTITIES.—The Secretary shall distribute the grants through the following types of entities:*

*(1) Alcohol and drug early intervention, prevention or 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; or*

*(B) an affiliation or contractual relationship with one or more substance abuse treatment programs or pediatric health or mental health providers and family mental health providers.*

*(3) Consortia of public or nonprofit private entities that include at least one substance abuse treatment program.*

*(4) Indian tribes.*

*(f) 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.*

*(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, including maternal and child health [1] mental health, child welfare, education, juvenile justice, developmental disabilities, and substance abuse 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, the State agency responsible for administering alcohol and drug programs, the State lead agency, and the State Interagency Coordinating Council under part H of the Individuals with Disabilities Education Act; and;* [2]

*(3) 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*

[1] The lack of a comma would be so in law. See section 3106(e)(1)(A) of Public Law 106–310 (114 Stat. 1177).

[2] The superfluous semicolon would be so in law. See section 3106(e)(1)(C) of Public Law 106–310 (114 Stat. 1177).

*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; and*

*(C) the number of case workers or other professionals trained to identify and address substance abuse issues.*

*(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) 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; and*

*(4) in improving parental and family functioning, including increased participation in work or employment-related activities and decreased participation in welfare programs.*

*(l) 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; and*

*(3) information concerning—*

*(A) the number and characteristics of families, parents, and children served; and*

*(B) the number of children served who remained with their parents during or after the period in which entities provided services under this section.* [1]

*analyzed by the type of entity described in subsection (d)* [2] *that provided services;* [3]

*(m) 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. The periodic report shall include a quantitative estimate of the prevalence of alcohol and drug problems in families involved in the child welfare system, the barriers to treatment and prevention services facing these families, and policy recommendations for removing the identified barriers, including training for child welfare workers.*

*(n) 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 drugs.*

*(3) The term "Indian tribe" means any tribe, band, nation, or other organized group or community of Indians, including*

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[1] The period at the end of subparagraph (B), and the semicolon at the end of paragraph (3), would be so in law. See section 3106(h) of Public Law 106–310 (114 Stat. 1178). The period probably should be a semicolon, and the semicolon probably should be a period.

[2] The reference to subsection (d) probably should be a reference to subsection (e). Section 3106(l) of Public Law 106–310 (114 Stat. 1178) would redesignate subsection (d) as subsection (e) and make conforming changes in cross-references. One of the conforming changes would be to subsection (m), and would strike "(d)" and insert "(e)". The reference to subsection (d) appears in subsection (l), however, not subsection (m).

[3] See footnote for subsection (l)(3)(B).

*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 disabilities service providers, and family resource and support programs.*

*(5) The term "substance abuse" means the abuse of alcohol or other drugs.*

*(o) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $50,000,000 for fiscal year 2001, and such sums as may be necessary for each of fiscal years 2002 and 2003.*

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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, hos-

pitals, 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.

(e) REPORT.—Not later than September 30, 1999, the Secretary shall complete the study required in subsection (a) 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 describing the findings and recommendations made as a result of the study.

**SEC. 399F. [280e–4] AUTHORIZATION OF APPROPRIATIONS.**

(a) REGISTRIES.—For the purpose of carrying out this part, 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[1] 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] 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".)

(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 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 mem-

bers 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, donation, 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 for not more than 2 years.

(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.

(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 for public inspection, and shall upon request provide a copy of the report to any individual for a charge not exceeding the cost of providing the copy.

(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 $500,000 for each fiscal year.

(B) For the purpose of grants under paragraph (1), the Secretary may for each fiscal year make available not more than $500,000 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.

(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 described 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 [1].

(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

(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

[1] Enacted October 27, 1992.

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 [1], 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, and contains such other agreements and such assurances and information as the Secretary determines to be necessary to carry out this paragraph.

[1] Enacted October 27, 1992.

# 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 test-

ing, 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)[1] 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—

(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.);

[1] 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).

(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.—[1]

(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

(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.

[1] 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.".

(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.

(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) 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 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 and intervention programs and systems for the following purposes:

(1) To develop and monitor the efficacy of state-wide newborn and infant hearing screening, evaluation and intervention programs and systems. Early intervention includes referral to 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.

(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.

(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, 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 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 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, communication options and are given the opportunity to consider the full range of educational and program placements and options for their child.

(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, after rescreening, 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 Administration such sums as may be necessary for fiscal year 2002.

(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 year 2002.

(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 year 2002.

**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.

## 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 man-

ner, 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.

# TITLE IV—NATIONAL RESEARCH INSTITUTES

## PART A—NATIONAL INSTITUTES OF HEALTH

### ORGANIZATION OF THE NATIONAL INSTITUTES OF HEALTH

SEC. 401. [281] (a) The National Institutes of Health is an agency of the Service. [1]

(b)(1) The following national research institutes are agencies of the National Institutes of Health:

(A) The National Cancer Institute.

(B) The National Heart, Lung, and Blood Institute.

(C) The National Institute of Diabetes and Digestive and Kidney Diseases.

(D) The National Institute of Arthritis and Musculoskeletal and Skin Diseases.

(E) The National Institute on Aging.

(F) The National Institute of Allergy and Infectious Diseases.

(G) The National Institute of Child Health and Human Development.

(H) The National Institute of Dental and Craniofacial Research. [2]

(I) The National Eye Institute.

(J) The National Institute of Neurological Disorders and Stroke.

(K) The National Institute of General Medical Sciences.

(L) The National Institute of Environmental Health Sciences.

(M) The National Institute on Deafness and Other Communication Disorders.

(N) The National Institute on Alcohol Abuse and Alcoholism.

(O) The National Institute on Drug Abuse.

(P) The National Institute of Mental Health.

(Q) The National Institute of Nursing Research.

(R) The National Institute of Biomedical Imaging and Bioengineering.

(2) The following entities are agencies of the National Institutes of Health:

(A) The National Library of Medicine.

(B) The National Center for Research Resources.

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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).

(C) The John E. Fogarty International Center for Advanced Study in the Health Sciences.

(D) The National Center for Human Genome Research.

(E) The Office of Dietary Supplements.

(F) The National Center for Complementary and Alternative Medicine.

(G) The National Center on Minority Health and Health Disparities.

(c)(1) 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 respect to any particular disease or groups of diseases or any other aspect of human health if—

(A) the Secretary determines that an additional institute is necessary to carry out such activities; and

(B) 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 Labor and Human Resources of the Senate written notice of the determination made under subparagraph (A) with respect to the institute.

(2) 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 Labor and Human Resources of the Senate written notice of the reorganization or abolition.

(d) For purposes of this title, the term "national research institute" means a national research institute listed in subsection (b) or established under subsection (c). 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 the National Institutes of Health (hereafter in this title referred to as the "Director of NIH") who shall be appointed by the President by and with the advice and consent of the Senate. The Director 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 be 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 and administrative entities within the National Institutes of Health;

(3) shall assure that research at or supported by the National Institutes of Health is subject to review in accordance with section 492;

(4) 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;

(5) may secure resources for research conducted by or through the National Institutes of Health;

(6) 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;

(7) may secure for the National Institutes of Health consultation services and advice of persons from the United States or abroad;

(8) 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;

(9) may, for purposes of study, admit and treat at facilities of the National Institutes of Health individuals not otherwise eligible for such treatment;

(10) may accept voluntary and uncompensated services;

(11) may perform such other administrative functions as the Secretary determines are needed to effectively carry out this title;

(12) after consultation with the Director of the Office of Research on Women's Health, shall ensure that resources of the National Institutes of Health are sufficiently allocated for projects of research on women's health that are identified under section 486(b);

(13) may conduct and support research training—

(A) for which fellowship support is not provided under section 487; and

(B) which does not consist of residency training of physicians or other health professionals; and

(14) 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.

The Federal Advisory Committee Act shall not apply to the duration of a peer review group appointed under paragraph (6). 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 func-

tional literacy, as defined in the National Literacy Act of 1991 (Public Law 102–73) [1].

(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.

(g)(1)(A) In the case of entities described in subparagraph (B), the Director of NIH, acting through the Director of the National Center for Research Resources, 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.

(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 back-

[1] So in law. That Act was repealed by section 251(a)(2) of Public Law 105–220 (112 Stat. 1079).

grounds (including racial and ethnic minorities) in the fields of biomedical and behavioral research.

(i)(1) There is established a fund, consisting of amounts appropriated under paragraph (3) and made available for the fund, for use by the Director of NIH to carry out the activities authorized in this Act for the National Institutes of Health. The purposes for which such fund may be expended include—

(A) providing for research on matters that have not received significant funding relative to other matters, responding to new issues and scientific emergencies, and acting on research opportunities of high priority;

(B) supporting research that is not exclusively within the authority of any single agency of such Institutes; and

(C) purchasing or renting equipment and quarters for activities of such Institutes.

(2) Not later than February 10 of each fiscal year, 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 undertaken and expenditures made under this section during the preceding fiscal year. The report may contain such comments of the Secretary regarding this section as the Secretary determines to be appropriate.

(3) For the purpose of carrying out this subsection, there are authorized to be appropriated $25,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.

(j)(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.[1] 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.

(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) For the purpose of carrying out this subsection, there are authorized to be appropriated such sums as may be necessary. Fees collected under section 736 of the Federal Food, Drug, and Cosmetic Act shall not be used in carrying out this subsection.

(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.

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[1] 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.".

(l) The Director of NIH shall carry out the program established in part F of title XII (relating to interagency research on trauma).

REPORT OF DIRECTOR OF NIH

SEC. 403. [283] The Secretary shall transmit to the President and to the Congress a biennial report which shall be prepared by the Director of NIH and which shall consist of—

(1) a description of the activities carried out by and through the National Institutes of Health and the policies respecting the programs of the National Institutes of Health and such recommendations respecting such policies as the Secretary considers appropriate;

(2) a description of the activities undertaken to improve grants and contracting accountability and technical and scientific peer review procedures of the National Institutes of Health and the national research institutes;

(3) the reports made by the Associate Director for Prevention under section 402(f) during the period for which the biennial report is prepared;

(4) a description of the health related behavioral research that has been supported by the National Institutes of Health in the preceding 2-year period, and a description of any plans for future activity in such area; and

(5) the biennial reports of the Directors of each of the national research institutes, the Director of the Division of Research Resources, [1] and the Director of the National Center for Nursing Research. [2]

The first report under this section shall be submitted not later than July 1, 1986, and shall relate to the fiscal year ending September 30, 1985. The next report shall be submitted not later than December 30, 1988, and shall relate to the two-fiscal-year period ending on the preceding September 30. Each subsequent report shall be submitted not later than 90 days after the end of the two-fiscal-year period for which the report is to be submitted.

DES

SEC. 403A. [283a] (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, including the importance of identifying and treating individuals who have been exposed to the drug.

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[1] Now the National Center for Research Resources. See section 1501 of Public Law 103–43 (107 Stat. 172).

[2] Now the National Institute of Nursing Research. See section 1511 of Public Law 103–43 (107 Stat. 178).

(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.

(e) In addition to any other authorization of appropriations available for the purpose of carrying out this section, there are authorized to be appropriated for such purpose such sums as may be necessary for each of the fiscal years 1993 through 2003.

OFFICE OF BEHAVIORAL AND SOCIAL SCIENCES RESEARCH

SEC. 404A.[1] [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.

[1] 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 National Institute for 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 [1], 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.

(c) AUTHORIZATION OF APPROPRIATIONS.—In addition to any other amounts authorized to be appropriated for activities of the type described in this section, there are authorized to be appropriated to carry out this section $20,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.

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.

[1] Section 2104 was repealed by section 601(a)(1)(H) of Public Law 105–362 (112 Stat. 3285).

(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.

(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 and the Director of the Center for Research Resources (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 National Institute of Child Health and Human Development, 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.

(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; REPORTS.—The Director of NIH—

(A) shall, as appropriate, provide for the coordination of information among centers under paragraph (1) and ensure regular communication between such centers; and

(B) shall require the periodic preparation of reports on the activities of the centers and the submission of the reports to the Director.

(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 accordance 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) REPORTS TO CONGRESS.—The Coordinating Committee shall biennially 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 research, education, and other activities on muscular dystrophy being conducted or supported through the Department of Health and Human Services. Each such report shall include the following:

(1) The plan under subsection (e)(1) (or revisions to the plan, as the case may be).

(2) Provisions specifying the amounts expended by the Department of Health and Human Services with respect to various forms of muscular dystrophy, including Duchenne, myotonic, FSHD and other forms of muscular dystrophy.

(3) Provisions identifying particular projects or types of projects that should in the future be considered by the national

research institutes or other entities in the field of research on all muscular dystrophies.

(g) 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.

(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 2002 through 2006. The authorization of appropriations established in the preceding sentence is in addition to any other authorization of appropriations that is available for conducting or supporting through the National Institutes of Health research and other activities with respect to muscular dystrophy.

OFFICE OF RARE DISEASES

SEC. 404F. [283h] (a) ESTABLISHMENT.—There is established within the Office of the Director of NIH 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 NIH.

(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 404G.

(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.

(F) The Director shall biennially prepare a report that describes the research and education activities on rare diseases being conducted or supported through the national research institutes and centers, and that identifies par-

ticular projects or types of projects that should in the future be conducted or supported by the national research institutes and centers or other entities in the field of research on rare diseases.

(G) The Director shall prepare the NIH Director's annual report to Congress on rare disease research conducted by or supported through the national research institutes and centers.

(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.

(d) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as already have been appropriated for fiscal year 2002, and $4,000,000 for each of the fiscal years 2003 through 2006.

RARE DISEASE REGIONAL CENTERS OF EXCELLENCE

SEC. 404G. [283i] (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.

(e) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as already have been appropriated for fiscal year 2002, and $20,000,000 for each of the fiscal years 2003 through 2006.

## 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 activities 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 multidisciplinary 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)(6); 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.

BIENNIAL REPORT

SEC. 407. [284b] The Director of each national research 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 each national research institute may prepare such additional reports as the Director determines appropriate. The Director of each national research institute shall provide the advisory council for the institute an opportunity for the submission of the written comments referred to in section 406(g).

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,[1] the John E. Fogarty International Center for Advanced Study in the Health

[1] See footnote 2 for section 403(5).

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 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, [1] 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 pro-

[1] See footnote for section 401(b)(1)(H).

vide 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.

(d) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $40,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 through 2003.

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 under subsection (e)).

(b) INTER-INSTITUTE COORDINATION.—

(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.

(e) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section and section 301 and title IV of the Public Health Service Act with respect to research focused on Parkinson's disease, there are authorized to be appropriated up to $100,000,000 for fiscal year 1998, and such sums as may be necessary for each of the fiscal years 1999 and 2000.

EXPANSION, INTENSIFICATION, AND COORDINATION OF ACTIVITIES OF NATIONAL INSTITUTES OF HEALTH WITH RESPECT TO RESEARCH ON AUTISM [1]

SEC. 409C. [284g] (a) IN GENERAL.—

[1] 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

Continued

(1) EXPANSION OF ACTIVITIES.—The Director of NIH (in this section referred to as the "Director") shall expand, intensify, and coordinate the activities of the National Institutes of Health with respect to research on autism.

(2) 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.

(2) RESEARCH.—Each center under paragraph (1) shall conduct basic and clinical research into autism. Such research should include investigations into the cause, diagnosis, early detection, prevention, control, and treatment of autism. 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) COORDINATION OF CENTERS; REPORTS.—The Director shall, as appropriate, provide for the coordination of information among centers under paragraph (1) and ensure regular communication between such centers, and may require the periodic preparation of reports on the activities of the centers and the submission of the reports to the Director.

(5) 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.

(6) NUMBER OF CENTERS; DURATION OF SUPPORT.—

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annual reports to the Congress on the implementation of such title I and the amendments made by the title.

(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 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 and through which the Director can receive comments from the public regarding such programs and activities.

(e) FUNDING.—There are authorized to be appropriated such sums as may be necessary to carry out this section. Amounts appropriated under this subsection are in addition to any other amounts appropriated for such purpose.

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 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) AUTHORIZATION.—For the purpose of carrying out this section, 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) 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).

(d) REPORTS TO CONGRESS.—The Coordinating Committee under subsection (b)(1) shall biennially submit to the Committee on Commerce of the House of Representatives, and the Committee on Health, Education, Labor and Pensions of the Senate, a report that describes the research, education, and other activities on autoimmune diseases being conducted or supported through the na-

tional research institutes, and that in addition includes the following:

(1) The plan under subsection (c)(1) (or revisions to the plan, as the case may be).

(2) Provisions specifying the amounts expended by the National Institutes of Health with respect to each of the autoimmune diseases included in the plan.

(3) Provisions identifying particular projects or types of projects that should in the future be considered by the national research institutes or other entities in the field of research on autoimmune diseases.

(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. The authorization of appropriations established in the preceding sentence is in addition to any other authorization of appropriations that is available for conducting or supporting through the National Institutes of Health research and other activities with respect to autoimmune diseases.

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.

(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary to carry out this section for each of the fiscal years 2001 through 2005. Amounts appropriated under this subsection shall be in addition to any other amounts appropriated for such purpose.

**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 com-

munity, 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.

(3) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this subsection, there are authorized to be appropriated such sums as may be necessary for each fiscal year.

(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.

(3) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this subsection, there are authorized to be appropriated such sums as may be necessary for each fiscal year.

(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 individ-

uals 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.

(5) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this subsection, there are authorized to be appropriated such sums as may be necessary for each fiscal year.

(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.

(4) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this subsection, there are authorized to be appropriated such sums as may be necessary for each fiscal year.

**SEC. 409I. [284m] PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.[1]**

(a) LIST OF DRUGS FOR WHICH PEDIATRIC STUDIES ARE NEEDED.—

(1) IN GENERAL.—Not later than one year after the date of enactment of this section, 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, prioritize, and publish an annual list of approved drugs for which—

(A)(i) there is an approved application under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j));

(ii) there is a submitted application that could be approved under the criteria of section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j));

(iii) there is no patent protection or market exclusivity protection under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.); or

(iv) there is a referral for inclusion on the list under section 505A(d)(4)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(d)(4)(C)); and

(B) in the case of a drug referred to in clause (i), (ii), or (iii) of subparagraph (A), additional studies are needed to assess the safety and effectiveness of the use of the drug in the pediatric population.

(2) CONSIDERATION OF AVAILABLE INFORMATION.—In developing and prioritizing the list under paragraph (1), the Secretary shall consider, for each drug on the list—

(A) the availability of information concerning the safe and effective use of the drug in the pediatric population;

(B) whether additional information is needed;

(C) whether new pediatric studies concerning the drug may produce health benefits in the pediatric population; and

(D) whether reformulation of the drug is necessary.

(b) CONTRACTS FOR PEDIATRIC STUDIES.—The Secretary shall award contracts to entities that have the expertise to conduct pediatric clinical trials (including qualified universities, hospitals, laboratories, contract research organizations, federally funded programs such as pediatric pharmacology research units, other public or private institutions, or individuals) to enable the entities to conduct pediatric studies concerning one or more drugs identified in the list described in subsection (a).

(c) PROCESS FOR CONTRACTS AND LABELING CHANGES.—

(1) WRITTEN REQUEST TO HOLDERS OF APPROVED APPLICATIONS FOR DRUGS LACKING EXCLUSIVITY.—The Commissioner of Food and Drugs, in consultation with the Director of the National Institutes of Health, may issue a written request (which shall include a timeframe for negotiations for an agreement) for pediatric studies concerning a drug identified in the list de-

[1] 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.

scribed in subsection (a)(1)(A) (except clause (iv)) to all holders of an approved application for the drug under section 505 of the Federal Food, Drug, and Cosmetic Act. Such a written request shall be made in a manner equivalent to the manner in which a written request is made under subsection (a) or (b) of section 505A of the Federal Food, Drug, and Cosmetic Act, including with respect to information provided on the pediatric studies to be conducted pursuant to the request.

(2) REQUESTS FOR CONTRACT PROPOSALS.—If the Commissioner of Food and Drugs does not receive a response to a written request issued under paragraph (1) within 30 days of the date on which a request was issued, or if a referral described in subsection (a)(1)(A)(iv) is made, 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 contract proposals to conduct the pediatric studies described in the written request.

(3) DISQUALIFICATION.—A holder that receives a first right of refusal shall not be entitled to respond to a request for contract proposals under paragraph (2).

(4) GUIDANCE.—Not later than 270 days after the date of enactment of this section, the Commissioner of Food and Drugs shall promulgate guidance to establish the process for the submission of responses to written requests under paragraph (1).

(5) CONTRACTS.—A contract under this section may be awarded only if a proposal for the contract 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 a contract awarded 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.

(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)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(d)(4)(D)) 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 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 may deem the drug to be misbranded under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(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.

(12) RECOMMENDATION FOR FORMULATION CHANGES.—If a pediatric study completed under public contract indicates that

a formulation change is necessary and the Secretary agrees, the Secretary shall send a nonbinding letter of recommendation regarding that change to each holder of an approved application.

(d) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—There are authorized to be appropriated to carry out this section—

(A) $200,000,000 for fiscal year 2002; and

(B) such sums as are necessary for each of the five succeeding fiscal years.

(2) AVAILABILITY.—Any amount appropriated under paragraph (1) shall remain available to carry out this section until expended.

## 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 exchange 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 [1] 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.

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 di-

[1] Now Ruth L. Kirschstein National Research Service Awards. See section 487.

rectly 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)[1]. 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;

[1] So in law. See section 401 of Public Law 103–43 (107 Stat. 153). Probably should be section "413(b)(9)".

(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 respect 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 re-

search 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)[1]. 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.

AUTHORIZATION OF APPROPRIATIONS

SEC. 417B. [285a–8] (a) ACTIVITIES GENERALLY.—For the purpose of carrying out this subpart, there are authorized to be appro-

[1] So in law. See section 402 of Public Law 103–43 (107 Stat. 155). Probably should be "section 413(b)(9)".

priated $2,728,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.

(b) BREAST CANCER AND GYNECOLOGICAL CANCERS.—

(1) BREAST CANCER.—

(A) For the purpose of carrying out subparagraph (A) of section 417(c)(1), there are authorized to be appropriated $225,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 through 2003. Such authorizations of appropriations are in addition to the authorizations of appropriations established in subsection (a) with respect to such purpose.

(B) For the purpose of carrying out subparagraphs (B) through (E) of section 417(c)(1), there are authorized to be appropriated $100,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 through 2003. Such authorizations of appropriations are in addition to the authorizations of appropriations established in subsection (a) with respect to such purpose.

(2) OTHER CANCERS.—For the purpose of carrying out subsection (d) of section 417, there are authorized to be appropriated $75,000,000 for fiscal year 1994, and such sums as are necessary for each of the fiscal years 1995 through 2003. Such authorizations of appropriations are in addition to the authorizations of appropriations established in subsection (a) with respect to such purpose.

(c) PROSTATE CANCER.—For the purpose of carrying out section 417A, there are authorized to be appropriated $72,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 through 2004. Such authorizations of appropriations are in addition to the authorizations of appropriations established in subsection (a) with respect to such purpose.

(d) ALLOCATION REGARDING CANCER CONTROL.—

(1) IN GENERAL.—Of the amounts appropriated for the National Cancer Institute for a fiscal year, the Director of the Institute shall make available not less than the applicable percentage specified in paragraph (2) for carrying out the cancer control activities authorized in section 412 and for which budget estimates are made under section 413(b)(9) for the fiscal year.

(2) APPLICABLE PERCENTAGE.—The percentage referred to in paragraph (1) is—

(A) 7 percent, in the case of fiscal year 1994;

(B) 9 percent, in the case of fiscal year 1995; and

(C) 10 percent, in the case of fiscal year 1996 and each subsequent fiscal year.

**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;

(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).

(f) REPORT TO CONGRESS.—Beginning on October 1 of the year following the date on which amounts are first appropriated to carry out this section and annually on each October 1 thereafter, the Secretary shall submit a report to the Committee on the Judiciary and the Committee on Health, Education, Labor, and Pensions of the Senate and to the Committee on the Judiciary and the Committee on Commerce of the House of Representatives. Each report shall summarize the expenditures and programs funded under this section as the Secretary determines to be appropriate.

(g) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated for the purpose of carrying out this section $20,000,000 for fiscal year 1999 and such sums as may be necessary for each of the fiscal years 2000 through 2009.

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***SEC. 417D. [285a–10] RESEARCH, INFORMATION, AND EDUCATION WITH RESPECT TO BLOOD CANCER.*** [1]

*(a) JOE MOAKLEY RESEARCH EXCELLENCE PROGRAM.—*

[1] Section 417D 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.

*(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.*

*(3) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this subsection, there is authorized to be appropriated such sums as may be necessary for fiscal year 2002 and each subsequent fiscal year. Such authorizations of appropriations are in addition to other authorizations of appropriations that are available for such purpose.*

*(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.*

*(3) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this subsection, there is authorized to be appropriated such sums as may be necessary for fiscal year 2002 and each subsequent fiscal year. Such authorizations of appropriations are in addition to other authorizations of appropriations that are available for such purpose.*

## 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 refine-

ment, 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 diagnostic, 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 education 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, pre-

vention, 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 [1] 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 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 re-

[1] Now Ruth L. Kirschstein National Research Service Awards. See section 487.

search, 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)[1].

(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 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 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[2] 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

[1] So in law. See section 503 of Public Law 103–43 (107 Stat. 159). Probably should be "subsection (d)".

[2] So in law. See section 503 of Public Law 103–43 (107 Stat. 159). Probably should be capitalized.

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 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 appli-

cations 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.

(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 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.

COORDINATION OF FEDERAL ASTHMA ACTIVITIES

SEC. 424B[1] [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;

(2) develop, in consultation with appropriate Federal agencies and professional and voluntary health organizations, a Federal plan for responding to asthma; and

(3) not later than 12 months after the date of the enactment of the Children's Health Act of 2000, submit recommendations to the appropriate committees of the Congress on ways to strengthen and improve the coordination of asthma-related activities of the Federal Government.

(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).

(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.

AUTHORIZATION OF APPROPRIATIONS

SEC. 425. [285b–8] For the purpose of carrying out this subpart, there are authorized to be appropriated $1,500,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.

[1] So in law. The section designation lacks a period. See section 521 of Public Law 106–310 (114 Stat. 1116).

## 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 [1] 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-

[1] 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.

(c) Each Committee shall prepare an annual report for—

(1) the Secretary;

(2) the Director of NIH; and

(3) the Advisory Board established under section 430 for the diseases for which the Committee was established,

detailing the work of the Committee in carrying out paragraphs (1) and (2) of subsection (a) in the fiscal year for which the report was prepared. Such report shall be submitted not later than 120 days after the end of each fiscal year.

(d) In each annual report prepared by the Diabetes Mellitus Interagency Coordinating Committee pursuant to subsection (c), the Committee shall include an assessment of the Federal activities and programs related to pancreatic islet cell transplantation. Such assessment shall, at a minimum, address the following:

(1) The adequacy of Federal funding for taking advantage of scientific opportunities relating to pancreatic islet cell transplantation.

(2) Current policies and regulations affecting the supply of pancreata for islet cell transplantation.

(3) The effect of xenotransplantation on advancing pancreatic islet cell transplantation.

(4) The effect of United Network for Organ Sharing policies regarding pancreas retrieval and islet cell transplantation.

(5) The existing mechanisms to collect and coordinate outcomes data from existing islet cell transplantation trials.

(6) Implementation of multiagency clinical investigations of pancreatic islet cell transplantation.

(7) Recommendations for such legislation and administrative actions as the Committee considers appropriate to increase the supply of pancreata available for islet cell transplantation.

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 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 ap-

pointment 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 ap-

pointed 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;

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 capabili-

ties. 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.

(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.

## 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[1] 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.

[1] Now Ruth L. Kirschstein National Research Service Awards. See section 487.

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 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,

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 Di-

rector 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.

(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 2003.

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 con-

sultants, 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 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 Advisory Board shall prepare an annual report for the Secretary which—

(1) describes the Advisory Board's activities in the fiscal year for which the report is made;

(2) describes and evaluates the progress made in such fiscal year in research, treatment, education, and training with respect to arthritis, musculoskeletal diseases, and skin diseases;

(3) summarizes and analyzes expenditures made by the Federal Government for activities respecting such diseases in such fiscal year for which the report is made;

(4) contains the Advisory Board's recommendations (if any) for changes in the plan prepared under section 436(a); and

(5) contains recommendations for expanding the Institute's funding of research directly applicable to the cause, diagnosis, early detection, prevention, control, and treatment of, and rehabilitation of children with arthritis and musculoskeletal diseases.

(k) 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.

(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 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 strength-

ening, 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 [1] 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 research 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

[1] Now Ruth L. Kirschstein National Research Service Awards. See section 487.

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.[1] [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 appropriate 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—

[1] 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.)

(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[1] 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.

(e) For purposes of this section, the term "Council on Alzheimer's Disease" means the council established in section 911(a)[2] 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 re-

[1] So in law. See section 9 of Public Law 102–507 (106 Stat. 3287). Probably should be "The".
[2] Section 911 was repealed by section 601(a)(2)(E) of Public Law 105–362 (112 Stat. 3286).

ferred 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). [1]

(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 understandable 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.

[1] So in law. Section 445E does not contain a subsection (a)(3). Section 445F(b)(2) provides for a toll-free telephone line.

(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] (a) 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 post-menopause, and into the diagnosis, disorders, and complications related to aging and loss of ovarian hormones in women.

(b) 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.

**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.

(d) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $2,250,000 for fiscal year 2001, and such sums as may be necessary for each of fiscal years 2002 through 2005.

AUTHORIZATION OF APPROPRIATIONS

SEC. 445J. [285e–11] For the purpose of carrying out this subpart, there are authorized to be appropriated $500,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.

## 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] (a) 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.

(b) For the purpose of carrying out subsection (a), there are authorized to be appropriated $50,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995

through 1998. Such authorization is in addition to any other authorization of appropriations that is available for such purpose.

**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.

(d) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $2,250,000 for fiscal year 2001, and such sums as may be necessary for each of fiscal years 2002 through 2005.

## Subpart 7—National Institute of Child Health and Human Development [1]

### PURPOSE OF THE INSTITUTE

SEC. 448. [285g] The general purpose of the National Institute of Child Health and Human Development (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, mental retardation, 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.

[1] 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.

MENTAL RETARDATION RESEARCH

SEC. 450. [285g–2] The Director of the Institute shall conduct and support research and related activities into the causes, prevention, and treatment of mental retardation.

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")[1]. 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)(6); and

(ii) appoint the members of peer review groups established under subparagraph (A); and

[1] 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.

(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).

(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, [1] 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

[1] 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.

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.

(f)(1) Not later than 90 days after the date of the enactment of the National Institutes of Health Revitalization Amendments of 1990,[1] 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

[1] See footnote for subsection (d)(3)(A).

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 respect 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.

(g) For the purpose of carrying out this section, 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 and 1996.

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 improv-

ing 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.

(7) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this subsection, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005.

INVESTMENT IN TOMORROW'S PEDIATRIC RESEARCHERS

SEC. 452G.[1] [285g–10] (a) ENHANCED SUPPORT.—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

[1]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.)

(2) an increase in the number of career development awards for health professionals who intend to build careers in pediatric basic and clinical research.

(b) AUTHORIZATION.—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 2001 through 2005.

## Subpart 8—National Institute of Dental Research [1]

### PURPOSE OF THE INSTITUTE

SEC. 453. [285h] The general purpose of the National Institute of Dental Research [1] 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.

## 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.

[1] See footnote for section 401(b)(1)(H).

(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

### PURPOSE OF THE INSTITUTE

SEC. 461. [285k] 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.

## 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[1] 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 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

[1] So in law. See section 2(4) of Public Law 100–553 (102 Stat. 2769). Probably should be "Director of".

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 advisory 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 Ad-

visory 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.

(j) The Advisory Board shall prepare an annual report for the Secretary which—

(1) describes the Advisory Board's activities in the fiscal year for which the report is made;

(2) describes and evaluates the progress made in such fiscal year in research, treatment, education, and training with respect to the deafness and other communication disorders;

(3) summarizes and analyzes expenditures made by the Federal Government for activities respecting such disorders in such fiscal year; and

(4) contains the Advisory Board's recommendations (if any) for changes in the plan prepared under section 464A(a).

(k) 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").

(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.

(e) Not later than 120 days after the end of each fiscal year, the Coordinating Committee shall prepare and transmit to the Secretary, the Director of NIH, the Director of the Institute, and the advisory council for the Institute a report detailing the activities of the Committee in such fiscal year in carrying out subsection (b).

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; [1] 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.

(d) FUNDING.—

(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this subpart, there are authorized to be appropriated $300,000,000 for fiscal year 1993, and such sums as may be necessary for fiscal year 1994.

(2) ALLOCATION FOR HEALTH SERVICES RESEARCH.—Of the amounts appropriated under paragraph (1) for a fiscal year, the Director shall obligate not less than 15 percent to carry out health services research relating to alcohol abuse and alcoholism.

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

[1] Now codified to section 3324 of title 31, United States Code.

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;

(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. [1]

(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). [2] 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.

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[1] 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.)

[2] 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".

## 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).

(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.

(d) FUNDING.—

(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this subpart, other than section 464P, there are authorized to be appropriated $440,000,000 for fiscal year 1993, and such sums as may be necessary for fiscal year 1994.

(2) ALLOCATION FOR HEALTH SERVICES RESEARCH.—Of the amounts appropriated under paragraph (1) for a fiscal year, the Director shall obligate not less than 15 percent to carry out health services research relating to drug abuse.

### 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. [1]

(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). [2]

(c) DRUG ABUSE AND ADDITION [3] 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—

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[1] So in law. See section 123(b) of Public Law 102–321 (106 Stat. 361). The period probably should be "; and".

[2] See footnote for section 464J(b).

[3] Probably should be "ADDICTION". See section 2203 of Public Law 107–273 (116 Stat. 1794).

(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.

(4) AUTHORIZATION OF APPROPRIATIONS.—

(A) IN GENERAL.—There are authorized to be appropriated to carry out this subsection such sums as may be necessary for each fiscal year.

(B) SUPPLEMENT NOT SUPPLANT.—Amounts appropriated pursuant to the authorization of appropriations in subparagraph (A) for a fiscal year shall supplement and not supplant any other amounts appropriated in such fiscal year for research on drug abuse and addiction.

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.

(e) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $85,000,000 for fiscal year 1993, and $95,000,000 for fiscal year 1994.

## 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.

(f) FUNDING.—

(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this subpart, there are authorized to be appropriated $675,000,000 for fiscal year 1993, and such sums as may be necessary for fiscal year 1994.

(2) ALLOCATION FOR HEALTH SERVICES RESEARCH.—Of the amounts appropriated under paragraph (1) for a fiscal year, the Director shall obligate not less than 15 percent to carry out health services research relating to mental health.

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.

(e) REPORT TO CONGRESS.—Not later than February 1, 1993, and each fiscal year thereafter, the Director shall submit to the Subcommittee on Health and the Environment of 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 of the Office during the preceding fiscal year, including a summary of the activities of demonstration projects and a summary of evaluations of the projects.

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,[1] 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—

(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 Af-

[1] 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).)

fairs, 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 Foundation, and the Director of the National Institute of Standards and Technology (or the designees of such officers).

(d)(1) Subject to paragraph (2), for the purpose of carrying out this section:

(A) For fiscal year 2001, there is authorized to be appropriated an amount equal to the amount obligated by the National Institutes of Health during fiscal year 2000 for biomedical imaging and bioengineering, except that such amount shall be adjusted to offset any inflation occurring after October 1, 1999.

(B) For each of the fiscal years 2002 and 2003, there is authorized to be appropriated an amount equal to the amount appropriated under subparagraph (A) for fiscal year 2001, except that such amount shall be adjusted for the fiscal year involved to offset any inflation occurring after October 1, 2000.

(2) The authorization of appropriations for a fiscal year under paragraph (1) is hereby reduced by the amount of any appropriation made for such year for the conduct or support by any other national research institute of any program with respect to biomedical imaging and bioengineering.

## 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 connection 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] There are authorized to be appropriated amounts sufficient for the erection and equipment of suitable and adequate buildings and facilities for use of the Library. 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 such buildings and facilities and to erect thereon, furnish, and equip such buildings and facilities. The amounts authorized to be appropriated by this section include 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.

AUTHORIZATION OF APPROPRIATIONS

SEC. 468. [286a–2] (a) For the purpose of carrying out this part, there are authorized to be appropriated $150,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.

(b) Amounts appropriated under subsection (a) and made available for grants or contracts under any of sections 472 through 476 shall remain available until the end of the fiscal year following the fiscal year for which the amounts were appropriated.

## 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, ex-

cept 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 Research Resources

#### GENERAL PURPOSE

SEC. 479. [287] The general purpose of the National Center for Research Resources (in this subpart referred to as the "Center") is to strengthen and enhance the research environments of entities engaged in health-related research by developing and supporting essential research resources.

#### ADVISORY COUNCIL

SEC. 480. [287a] (a)(1) The Secretary shall appoint an advisory council for the Center which shall advise, assist, consult with, and make recommendations to the Secretary and the Director of the Center on matters related to the activities carried out by and through the Center and the policies respecting such activities.

(2) The advisory council for the Center may recommend to the Secretary acceptance, in accordance with section 231, of conditional gifts for study, investigations, and research and for the acquisition of grounds or construction, equipping, or maintenance of facilities for the Center.

(3) The advisory council for the Center—

(A)(i) may make recommendations to the Director of the Center respecting research conducted at the Center,

(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 Center;

(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 Center is concerned and with the approval of the Director of the Center 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—

(A) the Secretary, the Director of NIH, the Director of the Center, 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 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 Center.

(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 mem-

bers, 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 Center 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 Center, 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 Center.

(f) The Director of the Center shall designate a member of the staff of the Center to serve as the executive secretary of the advisory council. The Director of the Center 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 Center 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 481, (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 Center in meeting its objectives, and (3) recommendations respecting the future directions and program and policy emphasis of the Center. The advisory council may prepare such additional reports as it may determine appropriate.

(h) This section does not terminate the membership of the advisory council for the Center which was in existence on the date of enactment of the Health Research Extension Act of 1985. After such date—

(1) the Secretary shall make appointments to such advisory council in such a manner as to bring about as soon as practicable the composition for such council prescribed by this section;

(2) the advisory council shall organize itself in accordance with this section and exercise the functions prescribed by this section; and

(3) the Director of the Center shall perform for such advisory council the functions prescribed by this section.

BIENNIAL REPORT

SEC. 481. [287a–1] The Director of the Center, after consultation with the advisory council for the Center, 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 Center and program policies of the Director of the Center in the fiscal years respecting which the report is prepared. The Director of the Center may prepare such additional reports as the Director determines appropriate. The Director of the Center shall provide the advisory council of the Center an opportunity for the submission of the written comments referred to in section 480(g).

**SEC. 481A. [287a–2] BIOMEDICAL AND BEHAVIORAL RESEARCH FACILITIES.**

(a) MODERNIZATION AND CONSTRUCTION OF FACILITIES.—

(1) IN GENERAL.—The Director of NIH, acting through the Director of the Center 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 within the Center 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 the Center 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 the Center and the advisory council established under section 480 (in this section referred to as the "Advisory 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 the Center and the Advisory 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 Advisory 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 the Center and the Advisory 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 the Center; 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 the Center, and such ad-hoc or temporary members as the Director of the Center 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 the Center 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 the Center 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 the Center 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 the Center or the Director of 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 under subsection (i)(1) for a fiscal year up to $50,000,000, the Director of the Center shall make available 25 percent of such amount, and from the amount appropriated under such subsection for a fiscal year that is over $50,000,000, the Director of the Center 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 the Center or the Director of 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 the Center or the Director of the National Institute of Allergy and Infectious Diseases, 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 deter-

mines 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 the Center or the Director of 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 the Center or the Director of 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 the Center, the applicant or 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 the Center or the Director of 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 the Center, after consultation with the Advisory Council, shall issue guidelines with respect to grants under subsection (a).

(h) REPORT TO CONGRESS.—The Director of the Center shall prepare and submit to the appropriate committees of Congress a bi-

ennial report concerning the status of the biomedical and behavioral research facilities and the availability and condition of technologically sophisticated laboratory equipment in the United States. Such reports shall be developed in concert with the report prepared by the National Science Foundation on the needs of research facilities of universities as required under section 108 of the National Science Foundation Authorization Act for Fiscal Year 1986 (42 U.S.C. 1886).

(i) AUTHORIZATION OF APPROPRIATIONS.—

(1) CENTER.—For the purpose of carrying out this section with respect to the Center, there are authorized to be appropriated $250,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 and 2003.

(2) NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES.—For the purpose of carrying out this section with respect to the National Institute of Allergy and Infectious Diseases, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2004 and 2005.

CONSTRUCTION OF REGIONAL CENTERS FOR RESEARCH ON PRIMATES

SEC. 481B. [287a–3] (a) With respect to activities carried out by the National Center for Research Resources to support regional centers for research on primates, the Director of NIH may, for each of the fiscal years 1994 through 1996 [1], reserve from the amounts appropriated under section 481A(h) 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. 481C. [287a–3a] 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

[1] 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. If any chimpanzee is removed from a sanctuary facility for purposes of research authorized under paragraph (3)(A)(ii), the chimpanzee shall be returned immediately upon the completion of that research. All costs associated with the removal of the chimpanzee from the facility, with the care of the chimpanzee during such absence from the facility, and with the return of the chimpanzee to the facility shall be the responsibility of the entity that obtains approval under such paragraph regarding use of the chimpanzee and removes the chimpanzee from the sanctuary facility.

(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 as provided in clause (i) or (ii), as follows:

(i) 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.

(ii) The chimpanzee may be used in research if—

(I) the Secretary finds that there are special circumstances in which there is need for that individual, specific chimpanzee (based on that chimpanzee's prior medical history, prior research protocols, and current status), and there is no chimpanzee with a similar history and current status that is reasonably available among chimpanzees that are not in the sanctuary system;

(II) the Secretary finds that there are technological or medical advancements that were not available at the time the chimpanzee entered the sanctuary system, and that such advancements can and will be used in the research;

(III) the Secretary finds that the research is essential to address an important public health need; and

(IV) the design of the research involves minimal pain and physical harm to the chimpanzee, and otherwise minimizes mental harm, distress, and disturbance to the chimpanzee and the social

group in which the chimpanzee lives (including with respect to removal of the chimpanzee from the sanctuary facility involved).

(B) APPROVAL OF RESEARCH DESIGN.—

(i) EVALUATION BY SANCTUARY BOARD.—With respect to a proposed use in research of a chimpanzee in the sanctuary system under subparagraph (A)(ii), the board of directors of the nonprofit private entity that receives the contract under subsection (e) shall, after consultation with the head of the sanctuary facility in which the chimpanzee has been placed and with the attending veterinarian, evaluate whether the design of the research meets the conditions described in subparagraph (A)(ii)(IV) and shall submit to the Secretary the findings of the evaluation.

(ii) ACCEPTANCE OF BOARD FINDINGS.—The Secretary shall accept the findings submitted to the Secretary under clause (i) by the board of directors referred to in such clause unless the Secretary makes a determination that the findings of the board are arbitrary or capricious.

(iii) PUBLIC PARTICIPATION.—With respect to a proposed use in research of a chimpanzee in the sanctuary system under subparagraph (A)(ii), the proposal shall not be approved until—

(I) the Secretary publishes in the Federal Register the proposed findings of the Secretary under such subparagraph, the findings of the evaluation by the board under clause (i) of this subparagraph, and the proposed evaluation by the Secretary under clause (ii) of this subparagraph; and

(II) the Secretary seeks public comment for a period of not less than 60 days.

(C) 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 subparagraphs (A) and (B) 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 sanc-

tuary 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 National Center for Research Resources.

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. 481C.[1] [287a–2] GENERAL CLINICAL RESEARCH CENTERS.**

(a) GRANTS.—The Director of the National Center for Research Resources 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 gen-

[1] So in law. There are two sections 481C. Section 204(a) of Public Law 106–505 (114 Stat. 2327) amended this subpart by adding at the end the section 481C above that relates to general clinical research centers. Subsequently, section 2 of Public Law 106–551 (114 Stat. 2752) amended this subpart by inserting after section 481B the section 481C that relates to the sanctuary system for surplus chimpanzees.

eral clinical research centers through the increased use of telecommunications and telemedicine initiatives.

(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 fiscal year.

## 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 3—National Center for Human Genome Research

### PURPOSE OF THE CENTER

SEC. 485B. [287c] (a) The general purpose of the National Center for Human Genome Research (in this subpart referred to as the "Center") 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 Center 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 Center 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 Center 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 4—Office of Dietary Supplements

**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—

(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.

(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $5,000,000 for fiscal year 1994 and such sums as may be necessary for each subsequent fiscal year.

## 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 appropriate 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 dis-

cipline 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 appropriately 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.

## Subpart 6—National Center on Minority Health and Health Disparities

**SEC. 485E. [287c–31] PURPOSE OF CENTER.**

(a) IN GENERAL.—The general purpose of the National Center on Minority Health and Health Disparities (in this subpart referred to as the "Center") is the conduct and support of research, training, dissemination of information, and other programs with respect to minority health conditions and other populations with health disparities.

(b) PRIORITIES.—The Director of the Center 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 Center 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 Center 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 Center, and the directors of the other agencies of the National Institutes of Health in collaboration (and in consultation with the advisory council for the Center) 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 Center, 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 Center 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 Center 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 Center may carry out a program to facilitate minority health disparities research and other health disparities research by providing for research endowments at centers of excellence under section 736.

(2) ELIGIBILITY.—The Director of the Center 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 average 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 Center—

(1) shall assist the Director of the National Center for Research Resources in carrying out section 481(c)(3) and in committing resources for construction at Institutions of Emerging Excellence;

(2) shall establish projects to promote cooperation among Federal agencies, State, local, tribal, and regional public health

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 Center 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.

(k) ANNUAL REPORT.—The Director of the Center shall prepare an annual report on the activities carried out or to be carried out by the Center, and shall submit each such report to the Committee on Health, Education, Labor, and Pensions of the Senate, the Committee on Commerce of the House of Representatives, the Secretary, and the Director of NIH. With respect to the fiscal year involved, the report shall—

(1) describe and evaluate the progress made in health disparities research conducted or supported by the national research institutes;

(2) summarize and analyze expenditures made for activities with respect to health disparities research conducted or supported by the National Institutes of Health;

(3) include a separate statement applying the requirements of paragraphs (1) and (2) specifically to minority health disparities research; and

(4) contain such recommendations as the Director considers appropriate.

(l) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this subpart, 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 through 2005. Such authorization of appropriations is in addition to other authorizations of appropriations that are available for the conduct and support of minority health disparities research or other health disparities research by the agencies of the National Institutes of Health.

**SEC. 485F.[287c–32] CENTERS OF EXCELLENCE FOR RESEARCH EDUCATION AND TRAINING.**

(a) IN GENERAL.—The Director of the Center 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 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 Center 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 Center 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 Center 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 Center 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 Center 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.

(h) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of making grants under subsection (a), there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005.

**SEC. 485G. [287c–33] LOAN REPAYMENT PROGRAM FOR MINORITY HEALTH DISPARITIES RESEARCH.**

(a) IN GENERAL.—The Director of the Center 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 Center 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.

(e) FUNDING.—

(1) 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.

(2) AVAILABILITY OF APPROPRIATIONS.—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.

**SEC. 485H. [287c–34] GENERAL PROVISIONS REGARDING THE CENTER.**

(a) ADMINISTRATIVE SUPPORT FOR 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 Center and shall ensure that such support takes maximum advantage of existing administrative structures at the agencies of the National Institutes of Health.

(b) EVALUATION AND REPORT.—

(1) EVALUATION.—Not later than 5 years after the date of the enactment of this subpart, the Secretary shall conduct an evaluation to—

(A) determine the effect of this subpart on the planning and coordination of health disparities research programs at the agencies of the National Institutes of Health;

(B) evaluate the extent to which this subpart has eliminated the duplication of administrative resources among such Institutes, centers and divisions; and

(C) provide, to the extent determined by the Secretary to be appropriate, recommendations concerning future legislative modifications with respect to this subpart, for both minority health disparities research and other health disparities research.

(2) MINORITY HEALTH DISPARITIES RESEARCH.—The evaluation under paragraph (1) shall include a separate statement that applies subparagraphs (A) and (B) of such paragraph to minority health disparities research.

(3) REPORT.—Not later than 1 year after the date on which the evaluation is commenced under paragraph (1), 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 concerning the results of such evaluation.

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.

(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 subsection (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 [1]

SEC. 487. [288] (a)(1) The Secretary shall—

(A) provide Ruth L. Kirschstein National Research Service Awards [2] 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 health problems to which the activities of the National Institutes of Health and Administration [1] are directed;

(ii) training at the National Institutes of Health and at the Administration [1] 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;

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[1] The typeface is so in law. See section 804(b) of Public Law 107–206 (116 Stat. 874).

[2] 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'".

(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, [1] 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 institution 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.

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[1] 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.

(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 receives 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 Sec-

retary 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.

(d) For the purpose of carrying out this section, there are authorized to be appropriated $400,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996. Of the amounts appropriated under this subsection—

(1) not less than 15 percent shall be made available for payments under Ruth L. Kirschstein National Research Service Awards provided by the Secretary under subsection (a)(1)(A);

(2) not less than 50 percent shall be made available for grants under subsection (a)(1)(B) for Ruth L. Kirschstein National Research Service Awards;

(3) 1 percent shall be made available to the Secretary, acting through the Administrator of the Health Resources and Services Administration, for payments under Ruth L. Kirschstein National Research Service Awards which (A) are made to individuals affiliated with entities which have received grants or contracts under section 747, 748, or 749, [1] and (B) are for research in primary medical care; and 1 percent shall be made available for payments under Ruth L. Kirschstein National Research Service Awards made for health services research by the Agency for Health Care Policy and Research under section 304(a); and

(4) not more than 4 percent may be obligated for Ruth L. Kirschstein National Research Service Awards for periods of three months or less.

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.

(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 1994 through 2001.

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 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

[1] Section 102(4) of Public Law 105–392 (112 Stat. 3539) repealed sections 748 through 752.

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 Institutes 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 [1] 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 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.

(c) FUNDING.—

(1) 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.

(2) AVAILABILITY.—Amounts appropriated 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.

PEDIATRIC RESEARCH LOAN REPAYMENT PROGRAM

SEC. 487F. [2] [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] So in law. There is no comma after "338C".

[2] 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.

(1) the Secretary shall enter into contracts with qualified health professionals under which such professionals will agree to conduct pediatric 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.

(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 in-

volves 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)(6) 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.

(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 de-

scribing 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 "minor-

ity 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] (a) 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.

(b) Not later than 90 days after the end of a fiscal year, the Secretary shall report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate on actions taken under subsection (a) in such fiscal year.

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—

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) CRIMINAL PENALTIES FOR VIOLATIONS.—

(1) IN GENERAL.—Any person who violates subsection (a) or (b) 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.

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

(1) The term "human fetal tissue" has the meaning given such term in section 498A(f)[1].

(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.

## 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

[1] So in law. Probably should be "section 498A(g)". See section 112 of Public Law 103–43 (107 Stat. 131).

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 listed by the Secretary pursuant to section 409I(a)(1)(A) of this Act and referred under section 505A(d)(4)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(d)(4)(C)).

(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).

(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 members of the Board under clause (i)(II), the terms of service of the ex officio members of the Board as members of the Board shall terminate.

(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 mem-

bers 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 Board shall be filled in the manner in which the original position was made and shall not affect the power of the remaining 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 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)(2)(B)(i)(II) [1]) [2] 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

[1] So in law. See section 1701(6) of Public Law 103–43 (107 Stat. 189). Subsection (d)(2)(B) does not contain a clause (i); see section 1701(4)(B)(iii) of such Public Law.

[2] 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).

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 operations, activities, financial condition, and accomplishments of the Foundation.

(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 for public inspection, and shall upon request provide a copy of the report to any individual for a charge not exceeding the cost of providing the copy.

(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 pediatric 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. 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.—

(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this part, there is authorized to be appropriated an aggregate $500,000 for each fiscal year.

(2) LIMITATION REGARDING OTHER FUNDS.—Amounts appropriated under any provision of law other than paragraph (1) may not be expended to establish or operate the Foundation.

# 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 avail-

ability 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 [1] 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

(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

[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).

(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.

(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) 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 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 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 [1] 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 enti-

[1] So in law. See section 101(a) of Public Law 102–321 (106 Stat. 324). Probably should be "Administrator".

ties 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.[1] [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.

[1] 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:".

(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 [1]

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

(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;

[1] 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.".

(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 Council 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.[1]**

(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;

(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

[1] 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".

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 [1]

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 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 tech-

[1] 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.

nical 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 [1] behalf of an eligible woman, 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 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] So in law. See section 108(a) of Public Law 102–321 (106 Stat. 336). Probably should be "to or on".

(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 [1] 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.

(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.

[1] So in law. Probably should be "for". See section 3301(a) of Public Law 106–310 (114 Stat. 1207).

(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.[1] [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

(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

[1] Sections 510 through 512 were repealed by section 3301(c) of Public Law 106–310 (114 Stat. 1209).

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 ap-

plication 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 eval-

uation 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.[1] [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 addiction 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.

[1] 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.

(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 [1] 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,; [2]

(6) in cooperation with the Director of the Centers for Disease Control [3], 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;

(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

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[1] 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".

[2] So in law. See section 113(c)(1) of Public Law 102-321 (106 Stat. 345).

[3] 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".

(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 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 that project provide non-Federal matching funds, as deter-

mined 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 abusers, 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, unem-

ployment, 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 [1] 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;
(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.

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[1] 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".

**SEC. 519A.[1] [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—

(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

[1] 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).

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) 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 enable such entities to develop plans for and to carry out school-based (including institutions of higher education) and community-based programs for the prevention of alcoholic-beverage consumption by individuals who have not attained the legal drinking age.

(b) ELIGIBILITY REQUIREMENTS.—To be eligible to receive an award under subsection (a), an entity shall provide any assurances to the Secretary which the Secretary may require, including that the entity will—

(1) annually report to the Secretary on the effectiveness of the prevention approaches implemented by the entity;

(2) use science based and age appropriate approaches; and

(3) involve local public health officials and community prevention program staff in the planning and implementation of the program.

(c) EVALUATION.—The Secretary shall evaluate each project under subsection (a) and shall disseminate the findings with respect to each such evaluation to appropriate public and private entities.

(d) GEOGRAPHICAL DISTRIBUTION.—The Secretary shall ensure that awards will be distributed equitably among the regions of the country and among urban and rural areas.

(e) DURATION OF AWARD.—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. The preceding sentence may not be construed as establishing a limitation on the number of awards under such subsection that may be made to the recipient.

(f) 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.

**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 National Institute on Child Health and Human Development, the Health Resources and Services Administration, the Agency for Healthcare Research and Qual-

ity, 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; [1]

(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.

[1] So in law. Probably should read "; and". See section 3110 of Public Law 106–310 (114 Stat. 1185).

(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.[1] [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.

(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;

[1] 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.

(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 com-

munities 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 [1];

(10) conduct services-related assessments, including evaluations of the organization and financing of care, self-help and consumer-run programs, mental health economics, mental 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

[1] 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".)

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 special 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. 520C.[1] [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).

[1]Section 520B was repealed by section 3201(b)(2) of Public Law 106–310 (114 Stat. 1190).

(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 enforcement 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 sys-

tems, 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-sponsored 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 men-

tal 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 [1].**

(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;

[1] 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.)

(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, 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; [1]

(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

[1] 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).

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 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 [1] 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

[1] 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).

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;

(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 dona-

tions 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 Sec-

retary 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[1].—In this subsection, the term "emergency services personnel" includes paramedics, firefighters, and emergency medical technicians.

(3) DISTRIBUTION OF AWARDS[1].—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.

[1]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).

(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 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 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.

## 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 [1] 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 sub-

[1] 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.

divisions 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, food stamps, 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 Is-

lands, 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)[1] 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 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;

[1] 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).

(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 [1] 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.

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[1] 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).

(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.

(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 reg-

ulations 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, rehabilitation, 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-Fed-

eral 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; [1]

(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

[1] So in law. See section 119 of Public Law 102–321 (106 Stat. 349). Probably should be a period.

(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.

**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)[1] 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[2]

## PART G[3]—PROJECTS FOR CHILDREN AND VIOLENCE

**SEC. 581.[3] [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—

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[1] Indentation is so in law. See section 2017(2)(C)(ii) of Public Law 103–43 (107 Stat. 218).

[2] 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.

[3] 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.

(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
(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 evaluation, 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 falling 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 [1] 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 [1] (42 U.S.C. 10802(3)).

**SEC. 593. [2] [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,

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[1] Probably should be Protection and Advocacy for Individuals with Mental Illness Act. See section 3206(a) of Public Law 106–310 (114 Stat. 1193).

[2] 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.

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 [1] (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—

(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

[1] See footnote for subsection (a).

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 licensing 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 [1]—SERVICES PROVIDED THROUGH RELIGIOUS ORGANIZATIONS [2]

**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 impairing the religious character of such organizations, and without diminishing the religious freedom of program beneficiaries.

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[1] 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.

[2] 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).

(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.

## 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 allotment 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 allot-

ment 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 approved 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 subparagraphs 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

[1] Subtitle D of title VII of Public Law 100–607 waived the applicability of section 609 regarding a specified medical facility if certain conditions relating to satisfaction of the obligations under section 603(e) were met. (The text of such subtitle D is provided in this compilation under the heading "Waiver Regarding Title VI of Public Health Service Act".) Private Law 99–21 provided such a waiver regarding another specified medical facility.

(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. [1]

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

(iii) in the case of a facility with respect to which such notice is not provided as prescribed by subsection (b), on the date

[1] So in law. The period probably should be a comma.

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 centum 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 inter-

est 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)[1] to make payments of interest on loans to nonprofit private agencies which he has guaranteed under this part;

(ii)[1] to otherwise comply with guarantees under this part of loans to nonprofit private agencies;

(iii)[1] to make payments of interest subsidies with respect to loans to public agencies which he has made, sold, and guaranteed under this part;

(iv)[1] 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)[1] 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 securities 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 sub-

[1] 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).

section. 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 med-

ical 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 the mentally retarded, 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.[1] [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 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 professions personnel operated as an integral part of a hospital, but does not include any hospital furnishing primarily domiciliary care.

[1] Section 644 was repealed by section 3(b) of Public Law 90–174.

(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.

# 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 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

[1] So in law. Probably should include another closing parenthesis.

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 forbearance 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 indebtedness 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 documentation 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 [1] 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-

[1] 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 [1] 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-

[1] 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 through the date on which the loan is repaid in full.

(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 18 percent per year beginning on the date of such noncompliance.

(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;[1] 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.—

(A)(i) Subject to subparagraph (C), each agreement under section 721 with a school of medicine or osteopathic

[1] 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.

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.

**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)[1] IN GENERAL.—With respect to making Federal capital contributions to student loan funds for purposes of subsection (a), there is authorized to be appropriated for such contributions $8,000,000 for each of the fiscal years 1998 through 2002.

(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.

[1] Effective October 1, 2002, this paragraph is repealed by section 132(b) of Public Law 105–392 (112 Stat. 3575).

**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 re-

spect 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.[1] [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 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

[1] Title VII does not have sections 729 through 734. See section 102 of Public Law 102–408 (106 Stat. 1994, 2021).

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 enable 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) [1].

(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

(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

[1] So in law. Probably should read "paragraph (2) or (5)".

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) FUNDING.—

(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of making grants under subsection (a), there are authorized to be appropriated $26,000,000 for fiscal year 1998, and such sums as may be necessary for each of the fiscal years 1999 through 2002.

(2) ALLOCATIONS.—Based on the amount appropriated under paragraph (1) for a fiscal year, one of the following subparagraphs shall apply:

(A) IN GENERAL.—If the amounts appropriated under paragraph (1) 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 paragraph (1) 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 paragraph (1) for a fiscal year are $30,000,000 or more, 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 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).

(3) 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 other grants under this section.

(4) 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 Secretary may not make such a grant to the center for any fiscal year unless the center agrees that the center will, before expending the

grant, expend the Federal amounts obtained from sources other than the grant.

**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 $20,000 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, 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 medicine, 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, $37,000,000 for fiscal year 1998, and such sums as may be necessary for each of the fiscal years 1999 through 2002. 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 $1,100,000 for fiscal year 1998, and such sums as may be necessary for each of the fiscal years 1999 through 2002.

(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 $29,400,000 for fiscal year 1998, and such sums as may be necessary for each of the fiscal years 1999 through 2002. 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) GRANTS FOR HEALTH PROFESSIONS EDUCATION IN HEALTH DISPARITIES AND CULTURAL COMPETENCY.—

(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 purpose of carrying out research and demonstration projects (including research and demonstration projects for continuing health professions education) for training and education of health professionals for the reduction of

disparities in health care outcomes and the provision of culturally competent health care.

(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) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out subsection (a), $3,500,000 for fiscal year 2001, $7,000,000 for fiscal year 2002, $7,000,000 for fiscal year 2003, and $3,500,000 for fiscal year 2004.

## PART C—TRAINING IN FAMILY MEDICINE, GENERAL INTERNAL MEDICINE, GENERAL PEDIATRICS, PHYSICIAN ASSISTANTS, GENERAL DENTISTRY, AND PEDIATRIC DENTISTRY

### SEC. 747. [293k] FAMILY MEDICINE, GENERAL INTERNAL MEDICINE, GENERAL PEDIATRICS, GENERAL DENTISTRY, PEDIATRIC DENTISTRY, AND PHYSICIAN ASSISTANTS.

(a) TRAINING GENERALLY.—The Secretary may make grants to, or enter into contracts with, any public or nonprofit private hospital, school of medicine or osteopathic medicine, or to or with a public or private nonprofit entity (which the Secretary has determined is capable of carrying out such grant or contract)—

(1) to plan, develop, and operate, or participate in, an approved professional training program (including an approved residency or internship program) in the field of family medicine, internal medicine, or pediatrics for medical (M.D. and D.O.) students, interns (including interns in internships in osteopathic medicine), residents, or practicing physicians that emphasizes training for the practice of family medicine, general internal medicine, or general pediatrics (as defined by the Secretary);

(2) to provide financial assistance (in the form of traineeships and fellowships) to medical (M.D. and D.O.) students, interns (including interns in internships in osteopathic medicine), residents, practicing physicians, or other medical personnel, who are in need thereof, who are participants in any such program, and who plan to specialize or work in the practice of family medicine, general internal medicine, or general pediatrics;

(3) to plan, develop, and operate a program for the training of physicians who plan to teach in family medicine (including geriatrics), general internal medicine or general pediatrics training programs;

(4) to provide financial assistance (in the form of traineeships and fellowships) to physicians who are participants in any such program and who plan to teach in a family medicine (including geriatrics), general internal medicine or general pediatrics training program;

(5) to meet the costs of projects to plan, develop, and operate or maintain programs for the training of physician assistants (as defined in section 799B), and for the training of individuals who will teach in programs to provide such training; and

(6) to meet the costs of planning, developing, or operating programs, and to provide financial assistance to residents in such programs, of general dentistry or pediatric dentistry.

For purposes of paragraph (6), entities eligible for such grants or contracts shall include entities that have programs in dental schools, approved residency programs in the general or pediatric practice of dentistry, approved advanced education programs in the general or pediatric practice of dentistry, or approved residency programs in pediatric dentistry.

(b) ACADEMIC ADMINISTRATIVE UNITS.—

(1) IN GENERAL.—The Secretary may make grants to or enter into contracts with schools of medicine or osteopathic medicine to meet the costs of projects to establish, maintain, or improve academic administrative units (which may be departments, divisions, or other units) to provide clinical instruction in family medicine, general internal medicine, or general pediatrics.

(2) PREFERENCE IN MAKING AWARDS.—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 an academic administrative unit for programs in family medicine, general internal medicine, or general pediatrics;

(B) substantially expanding the programs of such a unit; or [1]

(3) PRIORITY IN MAKING AWARDS.—In making awards of grants and contracts under paragraph (1), the Secretary shall give priority to any qualified applicant for such an award that proposes a collaborative project between departments of primary care.

(c) PRIORITY.—

(1) IN GENERAL.—With respect to programs for the training of interns or residents, the Secretary shall give priority in awarding grants under this section to qualified applicants that have a record of training the greatest percentage of providers, or that have demonstrated significant improvements in the percentage of providers, which enter and remain in primary care practice or general or pediatric dentistry.

(2) DISADVANTAGED INDIVIDUALS.—With respect to programs for the training of interns, residents, or physician assist-

[1] So in law. See section 102(3)(C)(ii) of Public Law 105–392 (112 Stat. 3538), which amended subsection (b)(2) as if a subparagraph (C) were being added, but instead added a paragraph (3).

ants, the Secretary shall give priority in awarding grants under this section to qualified applicants that have a record of training individuals who are from disadvantaged backgrounds (including racial and ethnic minorities underrepresented among primary care practice or general or pediatric dentistry).

(3) SPECIAL CONSIDERATION.—In awarding grants under this section the Secretary shall give special consideration to projects which prepare practitioners to care for underserved populations and other high risk groups such as the elderly, individuals with HIV-AIDS, substance abusers, homeless, and victims of domestic violence.

(d) DURATION OF AWARD.—The period during which payments are made to an entity from an award of a grant or contract 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) FUNDING.—

(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there is authorized to be appropriated $78,300,000 for fiscal year 1998, and such sums as may be necessary for each of the fiscal years 1999 through 2002.

(2) ALLOCATION.—

(A) IN GENERAL.—Of the amounts appropriated under paragraph (1) for a fiscal year, the Secretary shall make available—

(i) not less than $49,300,000 for awards of grants and contracts under subsection (a) to programs of family medicine, of which not less than $8,600,000 shall be made available for awards of grants and contracts under subsection (b) for family medicine academic administrative units;

(ii) not less than $17,700,000 for awards of grants and contracts under subsection (a) to programs of general internal medicine and general pediatrics;

(iii) not less than $6,800,000 for awards of grants and contracts under subsection (a) to programs relating to physician assistants; and

(iv) not less than $4,500,000 for awards of grants and contracts under subsection (a) to programs of general or pediatric dentistry.

(B) RATABLE REDUCTION.—If amounts appropriated under paragraph (1) for any fiscal year are less than the amount required to comply with subparagraph (A), the Secretary shall ratably reduce the amount to be made available under each of clauses (i) through (iv) of such subparagraph accordingly.

**SEC. 748. [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[1], 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.

(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; and

(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.

(e) MEETINGS AND DOCUMENTS.—

[1] 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.)

(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 [1] 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.

## 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

[1] So in law. Probably should be "Advisory Committee". See section 102(4) of Public Law 105–392 (112 Stat. 3539).

(6) for other activities that will produce outcomes consistent with the purposes of this part.

**SEC. 751. [294a] AREA HEALTH EDUCATION CENTERS.**

(a) AUTHORITY FOR PROVISION OF FINANCIAL ASSISTANCE.—

(1) ASSISTANCE FOR PLANNING, DEVELOPMENT, AND OPERATION OF PROGRAMS.—

(A) IN GENERAL.—The Secretary shall award grants to and enter into contracts with schools of medicine and osteopathic medicine, and incorporated consortia made up of such schools, or the parent institutions of such schools, for projects for the planning, development and operation of area health education center programs that—

(i) improve the recruitment, distribution, supply, quality and efficiency of personnel providing health services in underserved rural and urban areas and personnel providing health services to populations having demonstrated serious unmet health care needs;

(ii) increase the number of primary care physicians and other primary care providers who provide services in underserved areas through the offering of an educational continuum of health career recruitment through clinical education concerning underserved areas in a comprehensive health workforce strategy;

(iii) carry out recruitment and health career awareness programs to recruit individuals from underserved areas and under-represented populations, including minority and other elementary or secondary students, into the health professions;

(iv) prepare individuals to more effectively provide health services to underserved areas or underserved populations through field placements, preceptorships, the conduct of or support of community-based primary care residency programs, and agreements with community-based organizations such as community health centers, migrant health centers, Indian health centers, public health departments and others;

(v) conduct health professions education and training activities for students of health professions schools and medical residents;

(vi) conduct at least 10 percent of medical student required clinical education at sites remote to the primary teaching facility of the contracting institution; and

(vii) provide information dissemination and educational support to reduce professional isolation, increase retention, enhance the practice environment, and improve health care through the timely dissemination of research findings using relevant resources.

(B) OTHER ELIGIBLE ENTITIES.—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 subparagraph (A) to a school of nursing.

(C) PROJECT TERMS.—

(i) IN GENERAL.—Except as provided in clause (ii), the period during which payments may be made under an award under subparagraph (A) may not exceed—

(I) in the case of a project, 12 years or

(II) in the case of a center within a project, 6 years.

(ii) EXCEPTION.—The periods described in clause (i) shall not apply to projects that have completed the initial period of Federal funding under this section and that desire to compete for model awards under paragraph (2)(A).

(2) ASSISTANCE FOR OPERATION OF MODEL PROGRAMS.—

(A) IN GENERAL.—In the case of any entity described in paragraph (1)(A) that—

(i) has previously received funds under this section;

(ii) is operating an area health education center program; and

(iii) is no longer receiving financial assistance under paragraph (1);

the Secretary may provide financial assistance to such entity to pay the costs of operating and carrying out the requirements of the program as described in paragraph (1).

(B) MATCHING REQUIREMENT.—With respect to the costs of operating a model program under subparagraph (A), an entity, to be eligible for financial assistance under subparagraph (A), shall make available (directly or through contributions from State, county or municipal governments, or the private sector) recurring non-Federal contributions in cash toward such costs in an amount that is equal to not less than 50 percent of such costs.

(C) LIMITATION.—The aggregate amount of awards provided under subparagraph (A) to entities in a State for a fiscal year may not exceed the lesser of—

(i) $2,000,000; or

(ii) an amount equal to the product of $250,000 and the aggregate number of area health education centers operated in the State by such entities.

(b) REQUIREMENTS FOR CENTERS.—

(1) GENERAL REQUIREMENT.—Each area health education center that receives funds under this section shall encourage the regionalization of health professions schools through the establishment of partnerships with community-based organizations.

(2) SERVICE AREA.—Each area health education center that receives funds under this section shall specifically designate a geographic area or medically underserved population to be served by the center. Such area or population shall be in a location removed from the main location of the teaching facilities of the schools participating in the program with such center.

(3) OTHER REQUIREMENTS.—Each area health education center that receives funds under this section shall—

(A) 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;

(B) arrange and support rotations for students and residents in family medicine, general internal medicine or general pediatrics, with at least one center in each program being affiliated with or conducting a rotating osteopathic internship or medical residency training program in family medicine (including geriatrics), general internal medicine (including geriatrics), or general pediatrics in which no fewer than 4 individuals are enrolled in first-year positions;

(C) conduct and participate in interdisciplinary training that involves physicians and other health personnel including, where practicable, public health professionals, physician assistants, nurse practitioners, nurse midwives, and behavioral and mental health providers; and

(D) have an advisory board, at least 75 percent of the members of which shall be individuals, including both health service providers and consumers, from the area served by the center.

(c) CERTAIN PROVISIONS REGARDING FUNDING.—

(1) ALLOCATION TO CENTER.—Not less than 75 percent of the total amount of Federal funds provided to an entity under this section shall be allocated by an area health education center program to the area health education center. Such entity shall enter into an agreement with each center for purposes of specifying the allocation of such 75 percent of funds.

(2) OPERATING COSTS.—With respect to the operating costs of the area health education center program of an entity receiving funds under this section, the entity shall make available (directly or through contributions from State, county or municipal governments, or the private sector) non-Federal contributions in cash toward such costs in an amount that is equal to not less than 50 percent of such costs, except that the Secretary may grant a waiver for up to 75 percent of the amount of the required non-Federal match in the first 3 years in which an entity receives funds under this section.

**SEC. 752. [294b] HEALTH EDUCATION AND TRAINING CENTERS.**

(a) IN GENERAL.—To be eligible for funds under this section, a health education training center shall be an entity otherwise eligible for funds under section 751 that—

(1) addresses the persistent and severe unmet health care needs in States along the border between the United States and Mexico and in the State of Florida, and in other urban and rural areas with populations with serious unmet health care needs;

(2) establishes an advisory board comprised of health service providers, educators and consumers from the service area;

(3) conducts training and education programs for health professions students in these areas;

(4) conducts training in health education services, including training to prepare community health workers; and

(5) supports health professionals (including nursing) practicing in the area through educational and other services.

(b) ALLOCATION OF FUNDS.—The Secretary shall make available 50 percent of the amounts appropriated for each fiscal year under section 752 for the establishment or operation of health education training centers through projects in States along the border between the United States and Mexico and in the State of Florida.

**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 [1] (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—

(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;

[1] So in law. Probably should read "paragraph".

(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 mentally retarded individuals; 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, or psychiatry;

(B) have completed an approved fellowship program in geriatrics; and

(C) have a junior faculty appointment at an accredited (as determined by the Secretary) school of medicine or osteopathic medicine.

(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; and

(B) provides, in such form and manner as the Secretary may require, assurances that the individual will meet the service requirement described in subsection (e)[1].

(4) AMOUNT AND TERM.—

(A) AMOUNT.—The amount of an Award under this section shall equal $50,000 for fiscal year 1998, adjusted for subsequent fiscal years to reflect the increase in the Consumer Price Index.

(B) TERM.—The term of any Award made under this subsection shall not exceed 5 years.

(5) 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.

**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] So in law. Probably should refer to "paragraph (5)".

(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. [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[1], 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(a)(1)(A), 751(a)(1)(B), 753(b), 754(3)(A), 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

[1] 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.)

(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 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.

(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; and

(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.

(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[1] 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.

[1] So in law. Probably should be "Advisory Committee". See section 103 of Public Law 105–392 (112 Stat. 3541).

(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.

**SEC. 757. [294g] AUTHORIZATION OF APPROPRIATIONS.**

(a) IN GENERAL.—There are authorized to be appropriated to carry out this part, $55,600,000 for fiscal year 1998, and such sums as may be necessary for each of the fiscal years 1999 through 2002.

(b) ALLOCATION.—

(1) IN GENERAL.—Of the amounts appropriated under subsection (a) for a fiscal year, the Secretary shall make available—

(A) not less than $28,587,000 for awards of grants and contracts under section 751;

(B) not less than $3,765,000 for awards of grants and contracts under section 752, of which not less than 50 percent of such amount shall be made available for centers described in subsection (a)(1) of such section; and

(C) not less than $22,631,000 for awards of grants and contracts under sections 753, 754, and 755.

(2) RATABLE REDUCTION.—If amounts appropriated under subsection (a) for any fiscal year are less than the amount required to comply with paragraph (1), the Secretary shall ratably reduce the amount to be made available under each of subparagraphs (A) through (C) of such paragraph accordingly.

(3) INCREASE IN AMOUNTS.—If amounts appropriated for a fiscal year under subsection (a) exceed the amount authorized under such subsection for such fiscal year, the Secretary may increase the amount to be made available for programs and activities under this part without regard to the amounts specified in each of subparagraphs (A) through (C) of paragraph (2).

(c) OBLIGATION OF CERTAIN AMOUNTS.—

(1) AREA HEALTH EDUCATION CENTER PROGRAMS.—Of the amounts made available under subsection (b)(1)(A) for each fiscal year, the Secretary may obligate for awards under section 751(a)(2)—

(A) not less than 23 percent of such amounts in fiscal year 1998;

(B) not less than 30 percent of such amounts in fiscal year 1999;

(C) not less than 35 percent of such amounts in fiscal year 2000;

(D) not less than 40 percent of such amounts in fiscal year 2001; and

(E) not less than 45 percent of such amounts in fiscal year 2002.

(2) SENSE OF CONGRESS.—It is the sense of the Congress that—

(A) every State have an area health education center program in effect under this section; and

(B) the ratio of Federal funding for the model program under section 751(a)(2) should increase over time and that Federal funding for other awards under this section shall

decrease so that the national program will become entirely comprised of programs that are funded at least 50 percent by State and local partners.

# 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) GRANTS OR CONTRACTS.—The Secretary may award grants or contracts to State or local governments, health professions schools, schools of nursing, academic health centers, community-based health facilities, and other appropriate public or private non-profit entities to provide for—

(1) targeted information collection and analysis activities related to the purposes described in subsection (a);

(2) research on high priority workforce questions;

(3) the development of a non-Federal analytic and research infrastructure related to the purposes described in subsection (a); and

(4) the conduct of program evaluation and assessment.

(c) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—There are authorized to be appropriated to carry out this section, $750,000 for fiscal year 1998, and such sums as may be necessary for each of the fiscal years 1999 through 2002.

(2) RESERVATION.—Of the amounts appropriated under subsection (a) 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.

(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; and

(2) encourage entities providing graduate medical education to conduct activities to voluntarily achieve the recommendations of the Council under paragraph (1)(E).

(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 [1].

(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, 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

[1] 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).

(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; or

(8) 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; DENTAL PUBLIC HEALTH.**

(a) IN GENERAL.—The Secretary may make grants to and enter into contracts with schools of medicine, osteopathic medicine, public health, and dentistry to meet the costs of projects—

(1) to plan and develop new residency training programs and to maintain or improve existing residency training programs in preventive medicine and dental public health; and

(2) to provide financial assistance to residency trainees enrolled in such programs.

(b) ADMINISTRATION.—

(1) AMOUNT.—The amount of any grant under subsection (a) shall be determined by the Secretary.

(2) ELIGIBILITY.—To be eligible for a grant under subsection (a), the applicant must demonstrate to the Secretary that it has or will have available full-time faculty members with training and experience in the fields of preventive medicine or dental public health and support from other faculty members trained in public health and other relevant specialties and disciplines.

(3) OTHER FUNDS.—Schools of medicine, osteopathic medicine, dentistry, and public health may use funds committed by State, local, or county public health officers as matching amounts for Federal grant funds for residency training programs in preventive medicine.

**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 $9,100,000 for fiscal year 1998, and such sums as may be necessary for each of the fiscal years 1999 through 2002.

(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.

## 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; or

(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.

(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 pro-

fessions 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 institutions 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)[1] 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.

[1] So in law. Probably should be redesignated as (c).

(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)[1] 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 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

[1] So in law. Probably should be redesignated as (d).

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)[1] 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)[2] 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.[3] [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, 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,

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[1] So in law. Probably should be redesignated as (e).
[2] So in law. Probably should be redesignated as (f).
[3] Section 793 was repealed by section 106(a)(2)(C) of Public Law 105–392 (112 Stat. 3557).

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.[1] [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 reasonable 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

[1] Section 795 was repealed by section 101(b)(1) of Public Law 105–392 (112 Stat. 3537).

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 program 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 [1] 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

(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] So in law. Probably should read "section".

(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) [1] The term "graduate program in behavioral health and mental health practice" means a graduate program in clinical 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 consulta-

[1] 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 amendment cannot be executed because the amendment does not specify to which instance of the term "clinical" the amendment applies.

tion 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) The term "program for the training of physician assistants" means an educational program that—

(A) has as its objective the education of individuals who will, upon completion of their studies in the program, be qualified to provide primary care under the supervision of a physician;

(B) extends for at least one academic year and consists of—

(i) supervised clinical practice; and

(ii) at least four months (in the aggregate) of classroom instruction, directed toward preparing students to deliver health care;

(C) has an enrollment of not less than eight students; and

(D) trains students in primary care, disease prevention, health promotion, geriatric medicine, and home health care.

(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

(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 de-

gree, 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)[1] 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.

(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 Is-

[1] See footnote for section 224(g)(1)(G)(ii).

lands, 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.

# 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 a collegiate, associate degree, or diploma school of nursing in a State.

(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 recog-

nized 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.

**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 nonprofit 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) GRANTS FOR HEALTH PROFESSIONS EDUCATION IN HEALTH DISPARITIES AND CULTURAL COMPETENCY.—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 purpose of carrying out research and demonstration projects (including research and demonstration projects for continuing health professions education) for training and education for the reduction of disparities in health care outcomes and the provision of culturally competent health care. Grants under this section shall be the same as provided in section 741.

(b) AUTHORIZATION OF APPROPRIATIONS.—There are to be appropriated to carry out subsection (a) such sums as may be necessary for each of the fiscal years 2001 through 2004.

**SEC. 808.[1] [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.

## 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 AND NURSE MIDWIFERY PROGRAMS.—Nurse practitioner and nurse midwifery 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 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.

(e) OTHER AUTHORIZED EDUCATIONAL PROGRAMS.—The Secretary shall prescribe guidelines as appropriate for other advanced nurse education programs eligible for support under this section.

(f) TRAINEESHIPS.—

(1) IN GENERAL.—The Secretary may not award a grant to an applicant under subsection (a) unless the applicant involved

[1] Section 810 appears on page 807.

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) DOCTORAL PROGRAMS.—The Secretary may not obligate more than 10 percent of the traineeships under subsection (a) for individuals in doctorate degree programs.

(3) 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) IN GENERAL.—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, pre-entry preparation, and retention activities.

(b) GUIDANCE.—In carrying out subsection (a), the Secretary shall take into consideration the recommendations of the First, Second and Third Invitational Congresses for Minority Nurse Leaders on "Caring for the Emerging Majority," in 1992, 1993 and 1997, and consult with nursing associations including the 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.

(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, 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 RETENTION 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;

(2) developing and implementing internship and residency programs to encourage mentoring and the development of specialties; or

(3) 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 managed care, quality improvement, 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 activities 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, 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 2003 through 2007.

## PART E—STUDENT LOANS [1]

LOAN AGREEMENTS

SEC. 835. [297a] (a) The Secretary is authorized to enter into an agreement for the establishment and operation of a student loan

[1] 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 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 [July 27, 1975]".

fund in accordance with this subpart [1] 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 841, 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 841, 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 subpart [1] 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 subpart [1] 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 subpart [1] 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 [1] 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;

(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

[1] So in law. Probably should read "part".

(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 subpart [1] 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 subpart [1] may not exceed $2,500 in the case of any student, except that for the final two academic years of the program involved, such total may not exceed $4,000. The aggregate of the loans for all years from such funds may not exceed $13,000 in the case of any student. In the granting of such loans, a school shall give preference to licensed practical nurses, to persons with exceptional financial need, and to persons who enter as first-year students after enactment of this title.

(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, 1986, 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 bor-

[1] So in law. Probably should read "part".

rower 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 the date of enactment of the Nurse Training Amendments of 1979, 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 subpart [1], 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 subpart [1] shall be made in such installments as may be provided in regulations of the

[1] So in law. Probably should be "part".

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 subpart [1] 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 subpart [1] 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 subpart [1] 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 subpart [1], 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 subpart [1] 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

[1] So in law. Probably should read "part".

of providing such loan cancellation until he terminates such service.

Nothing in this subsection shall be construed to prevent any person from entering into an agreement for loan cancellation under subsection (h)[1] (as amended by section 6(b)(2) of the Nurse Training Act of 1971).

(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 subpart[2], 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 subpart[2], 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[2]. 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.

(l)[3] 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 repay-

[1] Section 211(a)(1)(A) of Public Law 102–408 (106 Stat. 2078) struck former subsection (h), but did not amend the above reference.

[2] So in law. Probably should be "part".

[3] So in law. Probably should be subsection (k). The subsection was added by paragraph (1) of section 133(c) of Public Law 105–392 (112 Stat. 3575). Paragraph (2) of such section 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.".

ment of the amount due from a borrower on a loan made under this subpart[1] after the default of the borrower on such loan.

ALLOTMENTS AND PAYMENTS OF FEDERAL CAPITAL CONTRIBUTIONS

SEC. 838.[2] **[**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[2] 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 subpart[1].

(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 subpart[1] 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)[3] 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

[1] So in law. Probably should read "part".
[2] Section 837 was repealed by section 123(3) of Public Law 105–392 (112 Stat. 3562).
[3] Separate indentation of subsection (a) is so in law. See section 133(e)(1)(A) of Public Law 105–392 (112 Stat. 3577).

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).

(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 [1], 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 subpart [1], and may compromise, waive, or release any right, title, claim, or demand of the United States arising or acquired under this subpart.

PROCEDURES FOR APPEAL OF TERMINATIONS

SEC. 842. [2] [297i] In any case in which the Secretary intends to terminate an agreement with a school of nursing under this subpart [1], 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.

[1] So in law. Probably should read "part".
[2] There is no section 841 between sections 840 and 842. A section 841 appears in part F.

LOAN REPAYMENT AND SCHOLARSHIP PROGRAMS

SEC. 846.[1] [297n] (a) IN GENERAL.—In the case of any individual—

(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[2], 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;

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] Title VIII does not contain a section 843 or 844. A section 845 appears in part G on page 810. See footnote for section 810 on page 807.

[2] So in law. Probably should read "part".

(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 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 accred-

ited 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) ESTABLISHMENT.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, may enter into an agreement with any 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 $30,000, plus any amount determined by the Secretary on an annual basis to reflect inflation;

(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 a 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 a 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 2003 through 2007.

PROHIBITION AGAINST DISCRIMINATION BY SCHOOLS ON THE BASIS OF SEX

SEC. 810.[1] [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 F—FUNDING

**SEC. 841. [297q] FUNDING.**

(a) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out parts B, C, and D (subject to section 845(g)), there are authorized to be appropriated $65,000,000 for fiscal year 1998, and such sums as may be necessary for each of the fiscal years 1999 through 2002.

(b) ALLOCATIONS FOR FISCAL YEARS 1998 THROUGH 2002.—

(1) NURSE PRACTITIONERS; NURSE MIDWIVES.—

(A) FISCAL YEAR 1998.—Of the amount appropriated under subsection (a) for fiscal year 1998, the Secretary shall reserve not less than $17,564,000 for making awards of grants and contracts under section 822 as such section was in effect for fiscal year 1998.

(B) FISCAL YEARS 1999 THROUGH 2002.—Of the amount appropriated under subsection (a) for fiscal year 1999 or any of the fiscal years 2000 through 2002, the Secretary, subject to subsection (d), shall reserve for the fiscal year involved, for making awards of grants and contracts under part B with respect to nurse practitioners and nurse midwives, not less than the percentage constituted by the ratio of the amount appropriated under section 822 as such section was in effect for fiscal year 1998 to the total of the amounts appropriated under this title for such fiscal year. For purposes of the preceding sentence, the Secretary, in determining the amount that has been reserved for the fiscal year involved, shall include any amounts appropriated under subsection (a) for the fiscal year that are obligated by the Secretary to continue in effect grants or contracts

[1] As a result of the amendments made by section 123 of Public Law 105–392 (112 Stat. 3562), sections 846 and 810 follow section 842. Paragraphs (1) through (3) of such section 123 struck all of this title (title VIII) other than sections 835, 836, 838, 839, 840, 842, 846, and 855, and these sections were grouped together as part E. Paragraph (5) of such section 123 then added at the end of this title parts F and G, thereby inserting those parts after section 855. Paragraph (6) of such section 123 provided that this title is amended "by redesignating section 855 as section 810, and transferring such section so as to appear after section 809". The instruction of paragraph (6) to redesignate section 855 as section 810 has been executed, but the instruction to transfer and insert the section after section 809 cannot be excecuted because there is no section 809. (Paragraph (4) of such section 123 added part A of this title, consisting of sections 801 through 807.)

under section 822 as such section was in effect for fiscal year 1998.

(2) NURSE ANESTHETISTS.—

(A) FISCAL YEAR 1998.—Of the amount appropriated under subsection (a) for fiscal year 1998, the Secretary shall reserve not less than $2,761,000 for making awards of grants and contracts under section 831 as such section was in effect for fiscal year 1998.

(B) FISCAL YEARS 1999 THROUGH 2002.—Of the amount appropriated under subsection (a) for fiscal year 1999 or any of the fiscal years 2000 through 2002, the Secretary, subject to subsection (d), shall reserve for the fiscal year involved, for making awards of grants and contracts under part B with respect to nurse anesthetists, not less than the percentage constituted by the ratio of the amount appropriated under section 831 as such section was in effect for fiscal year 1998 to the total of the amounts appropriated under this title for such fiscal year. For purposes of the preceding sentence, the Secretary, in determining the amount that has been reserved for the fiscal year involved, shall include any amounts appropriated under subsection (a) for the fiscal year that are obligated by the Secretary to continue in effect grants or contracts under section 831 as such section was in effect for fiscal year 1998.

(c) ALLOCATIONS AFTER FISCAL YEAR 2002.—

(1) IN GENERAL.—For fiscal year 2003 and subsequent fiscal years, amounts appropriated under subsection (a) for the fiscal year involved shall be allocated by the Secretary among parts B, C, and D (and programs within such parts) according to a methodology that is developed in accordance with paragraph (2). The Secretary shall enter into a contract with a public or private entity for the purpose of developing the methodology. The contract shall require that the development of the methodology be completed not later than February 1, 2002.

(2) USE OF CERTAIN FACTORS.—The contract under paragraph (1) shall provide that the methodology under such paragraph will be developed in accordance with the following:

(A) The methodology will take into account the need for and the distribution of health services among medically underserved populations, as determined according to the factors that apply under section 330(b)(3).

(B) The methodology will take into account the need for and the distribution of health services in health professional shortage areas, as determined according to the factors that apply under section 332(b).

(C) The methodology will take into account the need for and the distribution of mental health services among medically underserved populations and in health professional shortage areas.

(D) The methodology will be developed in consultation with individuals in the field of nursing, including registered nurses, nurse practitioners, nurse midwives, nurse anesthetists, clinical nurse specialists, nursing educators and educational institutions, nurse executives, pediatric

nurse associates and practitioners, and women's health, obstetric, and neonatal nurses.

(E) The methodology will take into account the following factors with respect to the States:

(i) A provider population ratio equivalent to a managed care formula of 1/1,500 for primary care services.

(ii) The use of whole rather than fractional counts in determining the number of health care providers.

(iii) The counting of only employed health care providers in determining the number of health care providers.

(iv) The number of families whose income is less than 200 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).

(v) The rate of infant mortality and the rate of low-birthweight births.

(vi) The percentage of the general population constituted by individuals who are members of racial or ethnic minority groups, stated both by minority group and in the aggregate.

(vii) The percentage of the general population constituted by individuals who are of Hispanic ethnicity.

(viii) The number of individuals residing in health professional shortage areas, and the number of individuals who are members of medically underserved populations.

(ix) The percentage of the general population constituted by elderly individuals.

(x) The extent to which the populations served have a choice of providers.

(xi) The impact of care on hospitalizations and emergency room use.

(xii) The number of individuals who lack proficiency in speaking the English language.

(xiii) Such additional factors as the Secretary determines to be appropriate.

(3) REPORT TO CONGRESS.—Not later than 30 days after the completion of the development of the methodology required in paragraph (1), the Secretary shall submit to the Committee on Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report describing the methodology and explaining the effects of the methodology on the allocation among parts B, C, and D (and programs within such parts) of amounts appropriated under subsection (a) for the first fiscal year for which the methodology will be in effect. Such explanation shall include a comparison of the allocation for such fiscal year with the allocation made under this section for the preceding fiscal year.

(d) USE OF METHODOLOGY BEFORE FISCAL YEAR 2003.—With respect to the fiscal years 1999 through 2002, if the report required

in subsection (c)(3) is submitted in accordance with such subsection not later than 90 days before the beginning of such a fiscal year, the Secretary may for such year implement the methodology described in the report (rather than implementing the methodology in fiscal year 2003), in which case subsection (b) ceases to be in effect. The authority under the preceding sentence is subject to the condition that the fiscal year for which the methodology is implemented be the same fiscal year identified in such report as the fiscal year for which the methodology will first be in effect.

(e) AUTHORITY FOR USE OF ADDITIONAL FACTORS IN METHODOLOGY.—

(1) IN GENERAL.—The Secretary shall make the determinations specified in paragraph (2). For any fiscal year beginning after the first fiscal year for which the methodology under subsection (c)(1) is in effect, the Secretary may alter the methodology by including the information from such determinations as factors in the methodology.

(2) RELEVANT DETERMINATIONS.—The determinations referred to in paragraph (1) are as follows:

(A) The need for and the distribution of health services among populations for which it is difficult to determine the number of individuals who are in the population, such as homeless individuals; migratory and seasonal agricultural workers and their families; individuals infected with the human immunodeficiency virus, and individuals who abuse drugs.

(B) In the case of a population for which the determinations under subparagraph (A) are made, the extent to which the population includes individuals who are members of racial or ethnic minority groups and a specification of the skills needed to provide health services to such individuals in the language and the educational and cultural context that is most appropriate to the individuals.

(C) Data, obtained from the Director of the Centers for Disease Control and Prevention, on rates of morbidity and mortality among various populations (including data on the rates of maternal and infant mortality and data on the rates of low-birthweight births of living infants).

(D) Data from the Health Plan Employer Data and Information Set, as appropriate.

## PART G—NATIONAL ADVISORY COUNCIL ON NURSE EDUCATION AND PRACTICE

### SEC. 845. [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[1], 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

[1] 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.)

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 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 H—PUBLIC SERVICE ANNOUNCEMENTS

**SEC. 851. [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. 852. [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 I—COMPREHENSIVE GERIATRIC EDUCATION

**SEC. 855. [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; or

(4) provide continuing education to individuals who provide geriatric care.

(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 2003 through 2007.

# 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;

(2) the synthesis and dissemination of available scientific evidence for use by patients, consumers, practitioners, providers, purchasers, policy makers, and educators; and

[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).

(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 reduc-

ing 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 485E, except that in addition to the meaning so given, the Director may determine that such term includes populations for which there is a significant disparity 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 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 may periodically convene a Preventive Services Task Force to be composed of individuals with appropriate expertise. Such a task force shall review the scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of clinical preventive services for the purpose of developing recommendations for the health care community, and updating previous clinical preventive recommendations.

(2) ROLE OF AGENCY.—The Agency shall provide ongoing administrative, research, and technical support for the operations of the Preventive Services Task Force, including coordinating and supporting the dissemination of the recommendations of the Task Force.

(3) OPERATION.—In carrying out its responsibilities under paragraph (1), the Task Force is not subject to the provisions of Appendix 2 of title 5, United States Code.

(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 Insti-

tutes 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 So-

cial 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—GENERAL PROVISIONS

**SEC. 921. [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. 922. [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) un-

less 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. 923. [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. 924. [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 im-

provement 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 purpose 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. 925. [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. 926. [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 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) 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. 927. [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 pur-

suant 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.

**SEC. 928. [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 921.

(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.

# 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; $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.

[1] So in law. See section 931(b)(1) of Public Law 97–35 (95 Stat. 570). Probably should be "family".

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.[1] [300a–6] None of the funds appropriated under this title shall be used in programs where abortion is a method of family planning.

[1] Section 1009 was repealed by section 601(a)(1)(G) of Public Law 105–362 (112 Stat. 3285).

# 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. [Repealed].

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) IN GENERAL.—The Secretary shall award grants to eligible entities 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.

(b) USE OF FUNDS.—Amounts provided under a grant awarded under subsection (a) shall be used to—

(1) establish, expand, or improve systems or programs to provide screening, counseling, testing or specialty services for newborns and children at risk for heritable disorders;

(2) establish, expand, or improve programs or services to reduce mortality or morbidity from heritable disorders;

(3) establish, expand, or improve systems or programs to provide information and counseling on available therapies for newborns and children with heritable disorders;

(4) improve the access of medically underserved populations to screening, counseling, testing and specialty services for newborns and children having or at risk for heritable disorders; or

(5) conduct such other activities as may be necessary to enable newborns and children having or at risk for heritable disorders to receive screening, counseling, testing or specialty services, regardless of income, race, color, religion, sex, national origin, age, or disability.

(c) ELIGIBLE ENTITIES.—To be eligible to receive a grant under subsection (a) an entity shall—

(1) be a State or political subdivision of a State, or a consortium of two or more States or political subdivisions of States; and

(2) prepare and submit to the Secretary an application that includes—

(A) a plan to use amounts awarded under the grant to meet specific health status goals and objectives relative to heritable disorders, including attention to needs of medically underserved populations;

(B) a plan for the collection of outcome data or other methods of evaluating the degree to which amounts awarded under this grant will be used to achieve the goals and objectives identified under subparagraph (A);

(C) a plan for monitoring and ensuring the quality of services provided under the grant;

(D) an assurance that amounts awarded under the grant will be used only to implement the approved plan for the State;

(E) an assurance that the provision of services under the plan is coordinated with services provided under programs implemented in the State under title V, XVIII, XIX, XX, or XXI of the Social Security Act (subject to Federal regulations applicable to such programs) so that the coverage of services under such titles is not substantially diminished by the use of granted funds; and

(F) such other information determined by the Secretary to be necessary.

(d) 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.

(e) 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.

(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 of the type described in this section.

(g) PUBLICATION.—

(1) IN GENERAL.—An application submitted under subsection (c)(2) 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).

(h) TECHNICAL ASSISTANCE.—The Secretary shall provide to entities receiving grants under subsection (a) such technical assist-

ance as may be necessary to ensure the quality of programs conducted under this section.

(i) 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. 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.

**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").

(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; and

(3) 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.

(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) 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;

(F) members of the public having special expertise about or concern with heritable disorders; and

(G) 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).

## PART B—SUDDEN INFANT DEATH SYNDROME

### SUDDEN INFANT DEATH SYNDROME RESEARCH AND RESEARCH REPORTS

SEC. 1122. [300c–12] (a) From the sums appropriated to the 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.

(b)(1) Not later than ninety days after the close of the fiscal year ending September 30, 1979, and of each fiscal year thereafter, the Secretary shall report to the Committees on Appropriations of the Senate and the House of Representatives, the Committee on Labor and Human Resources of the Senate, and the Committee on Energy and Commerce of the House of Representatives specific information for such fiscal year on—

(A) the (i) number of applications approved by the Secretary in the fiscal year reported on for grants and contracts under this Act for research which relates specifically to sudden infant death syndrome, (ii) total amount requested under such applications, (iii) number of such applications for which funds were provided in such fiscal year, and (iv) total amount of such funds; and

(B) the (i) number of applications approved by the Secretary in such fiscal year for grants and contracts under this Act for research which relates generally to sudden infant death syndrome, including high-risk pregnancy and high-risk infancy research which directly relates to sudden infant death syndrome, (ii) relationship of the high-risk pregnancy and high-

risk infancy research to sudden infant death syndrome, (iii) total amount requested under such applications, (iv) number of such applications for which funds were provided in such fiscal year, and (v) total amount of such funds.

(2) Each report submitted under paragraph (1) of this subsection shall—

(A) contain a summary of the findings of intramural and extramural research supported by the National Institute of Child Health and Human Development relating to sudden infant death syndrome as described in subparagraphs (A) and (B) of such paragraph (1), and the plan of such Institute for taking maximum advantage of such research leads and findings; and

(B) provide an estimate of the need for additional funds over each of the next five fiscal years for grants and contracts under this Act for research activities described in such subparagraphs.

(c) Within five days after the Budget is transmitted by the President to the Congress for each fiscal year after fiscal year 1980, the Secretary shall transmit to the Committees on Appropriations of the Senate and the House of Representatives, the Committee on Labor and Human Resources of the Senate, and the Committee on Energy and Commerce of the House of Representatives an estimate of the amounts requested for the National Institute of Child Health and Human Development and any other Institutes of the National Institutes of Health, respectively, for research relating to sudden infant death syndrome as described in subparagraphs (A) and (B) of subsection (b)(1) of this section, and a comparison of such amounts with the amounts requested for the preceding fiscal year.

## 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 appropriated $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.

# 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) provide to State and local agencies technical assistance; and

(4) sponsor workshops and conferences.

(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).

(c) ADMINISTRATION.—The Administrator of the Health Resources and Services Administration shall ensure that this title is administered by the Division of Trauma and Emergency Medical Systems within such Administration. Such Division shall be headed by a director appointed by the Secretary from among individuals who are knowledgeable by training or experience in the development and operation of trauma and emergency medical systems.

**SEC. 1202. [300d–2] CLEARINGHOUSE ON TRAUMA CARE AND EMERGENCY MEDICAL SERVICES.**

(a) ESTABLISHMENT.—The Secretary shall by contract provide for the establishment and operation of a National Clearinghouse on Trauma Care and Emergency Medical Services (hereafter in this section referred to as the "Clearinghouse").

(b) DUTIES.—The Clearinghouse shall—

(1) foster the development of appropriate, modern trauma care and emergency medical services (including the development of policies for the notification of family members of individuals involved in medical emergencies) through the sharing of information among agencies and individuals involved in planning, furnishing, and studying such services and care;

(2) 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 of the unique needs of rural areas;

(3) provide technical assistance relating to trauma care and emergency medical services to State and local agencies; and

(4) sponsor workshops and conferences on trauma care and emergency medical services.

(c) FEES AND ASSESSMENTS.—A contract entered into by the Secretary under this section may provide that the Clearinghouse charge fees or assessments in order to defray, and beginning with fiscal year 1992, to cover, the costs of operating the Clearinghouse.

**SEC. 1203. [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 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 during 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; and

(5) by evaluating the effectiveness of protocols with respect to emergency medical services and 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(c)(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.

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 unless 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 equal to—

(A) for the second fiscal year of such payments to the State, not less than $1 for each $1 of Federal funds provided in such payments for such fiscal year; and

(B) for any subsequent fiscal year of such payments to the State, not less than $3 for each $1 of Federal funds provided in such payments for such fiscal year.

(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;

(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; and

(3) the Secretary shall, in making such a determination, include only non-Federal contributions in excess of the amount of non-Federal contributions made by the State during fiscal year 1990 toward—

(A) the costs of providing trauma care in the State; and

(B) the costs of improving the quality and availability of emergency medical services in rural areas of the State.

**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 (10) will be implemented by the principal State agency with respect to emergency medical services or by the designee of such agency;

(2) specifies any public or private entity that will designate trauma care regions and trauma centers in the State;

(3) subject to subsection (b), contains standards and requirements 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 the pediatric trauma patient), 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) subject to subsection (b), 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 standards and requirements for medically directed triage and transport of severely injured children to designated trauma centers with specified capabilities and expertise in the care of the pediatric trauma patient;

(6) specifies 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 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 within regional 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;

(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; and

(11) 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 concerning such;

(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 1992, 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 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 1991 and subsequent fiscal years, the State has not taken into account 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 1992 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.—Not later than 1 year after the date of the enactment of the Trauma Care Systems Planning and Development Act of 1990 [1], the Secretary shall develop a 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—

(1) take into account national standards, including those of the American College of Surgeons, American College of Emergency Physicians and the American Academy of Pediatrics;

(2) take into account existing State plans;

(3) 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

(4) 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.

Standards described in paragraph (4) 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) TRAUMA PLAN.—

(1) IN GENERAL.—For fiscal year 1991 and subsequent fiscal years, the Secretary may not make payments under section 1211(a) unless, subject to paragraph (2), the State involved

[1] Enacted November 16, 1990.

submits to the Secretary the trauma care component of the State plan for the provision of emergency medical services.

(2) INTERIM PLAN OR DESCRIPTION OF EFFORTS.—For fiscal year 1991, if a State has not completed the trauma care component of the State plan described in paragraph (1), the State may provide, in lieu of a completed such component, an interim component or a description of efforts made toward the completion of the component.

(b) INFORMATION RECEIVED BY STATE REPORTING AND ANALYSIS SYSTEM.—The Secretary may not make payments under section 1211(a) for a fiscal year unless the State involved 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).

(c) AVAILABILITY OF EMERGENCY MEDICAL SERVICES IN RURAL AREAS.—The Secretary may not make payments under section 1211(a) for a fiscal year unless—

(1) the State involved 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) subject to section 1233, 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. [1]

(2) to make cash payments to intended recipients of services provided pursuant to such section;

(3) to purchase or improve real property (other than minor remodeling of existing improvements to real property) or to purchase major medical or communication equipment, ambulances, or aircraft;

(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) EXCEPTION.—If the Secretary finds that the purpose described in section 1211(b) cannot otherwise be carried out, the Secretary may, with respect to an otherwise qualified State, waive the restriction established in subsection (a)(3).

[1] So in law. See Public Law 101–590. Probably should be a semicolon.

**SEC. 1216. [300d–16] REQUIREMENT OF REPORTS BY STATES.**

(a) IN GENERAL.—The Secretary may not make payments under section 1211(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 (after consultation with the States) 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; and

(2) determining whether the payments were expended in accordance with the purpose of the program involved.

(b) AVAILABILITY TO PUBLIC OF REPORTS.—The Secretary may not make payments under section 1211(a) unless the State involved agrees that the State will make copies of the report described in subsection (a) available for public inspection.

(c) EVALUATIONS BY COMPTROLLER GENERAL.—The Comptroller General of the United States shall evaluate the expenditures by States of payments under section 1211(a) in order to assure that expenditures are consistent with the provisions of this part, and not later than December 1, 1994, 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 concerning such evaluation.

**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, 1995, 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, there are authorized to be appropriated $6,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 through 2002.

(b) ALLOCATION OF FUNDS BY SECRETARY.—

(1) GENERAL AUTHORITY.—For the purpose of carrying out part A, the Secretary shall make available 10 percent of the amounts appropriated for a fiscal year under subsection (a).

(2) RURAL GRANTS.—For the purpose of carrying out section 1204, the Secretary shall make available 10 percent of the amounts appropriated for a fiscal year under subsection (a).

(3) FORMULA GRANTS.—

(A) For the purpose of making allotments under section 1211(a), the Secretary shall, subject to subsection (c), make available 80 percent of the amounts appropriated for a fiscal year pursuant to subsection (a).

(B) Amounts paid to a State under section 1211(a) for a fiscal year shall, for the purposes for which the amounts were paid, remain available for obligation until the end of the fiscal year immediately following the fiscal year for which the amounts were paid.

(c) EFFECT OF INSUFFICIENT APPROPRIATIONS FOR MINIMUM ALLOTMENTS.—

(1) IN GENERAL.—If the amounts made available under subsection (b)(3)(A) for a fiscal year are insufficient for providing each State with an allotment under section 1211(a) of not less than the applicable amount under section 1218(a)(2), the Secretary shall, from such amounts as are made available under subsection (b)(3)(A), make grants to States described in paragraph (2) for carrying out part B.

(2) ELIGIBLE STATES.—The States referred to in paragraph (1) are States that—

(A) have the greatest need to develop, implement, and maintain trauma care systems; and

(B) demonstrate in their applications under section 1217 the greatest commitment to establishing and maintaining such systems.

(3) 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—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 may make grants for the purpose of providing for the operating expenses of trauma centers that have incurred substantial uncompensated costs in providing trauma care in geographic areas with a significant incidence of violence arising directly or indirectly from illicit trafficking in drugs. Grants under this subsection may be made only to such trauma centers.

(b) MINIMUM QUALIFICATIONS OF CENTERS.—

(1) SIGNIFICANT INCIDENCE OF TREATING CERTAIN PATIENTS.—

(A) The Secretary may not make a grant under subsection (a) to a trauma center unless the population of patients that has been served by the center for the period

specified in subparagraph (B) includes a significant number of patients who were treated for—

(i) trauma resulting from the penetration of the skin by knives, bullets, or any other implement that can be used as a weapon; or

(ii) trauma that the center reasonably believes results from violence arising directly or indirectly from illicit trafficking in drugs.

(B) The period specified in this subparagraph is the 2-year period preceding the fiscal year for which the trauma center involved is applying to receive a grant under subsection (a).

(2) PARTICIPATION IN TRAUMA CARE SYSTEM OPERATING UNDER CERTAIN PROFESSIONAL GUIDELINES.—The Secretary may not make a grant under subsection (a) unless the trauma center involved is a participant in a system that—

(A) provides comprehensive medical care to victims of trauma in the geographic area in which the trauma center is located;

(B) is established by the State or political subdivision in which such center is located; and

(C)(i) has adopted guidelines for the designation of trauma centers, and for triage, transfer, and transportation policies, equivalent to (or more protective than) the applicable guidelines developed by the American College of Surgeons or utilized in the model plan established under section 1213(c); or

(ii) agrees that such guidelines will be adopted by the system not later than 6 months after the date on which the trauma center submits to the Secretary the application for the grant.

(3) SUBMISSION AND APPROVAL OF LONG-TERM PLAN.—The Secretary may not make a grant under subsection (a) unless the trauma center involved—

(A) submits to the Secretary a plan satisfactory to the Secretary that—

(i) is developed on the assumption that the center will continue to incur substantial uncompensated costs in providing trauma care; and

(ii) provides for the long-term continued operation of the center with an acceptable standard of medical care, notwithstanding such uncompensated costs; and

(B) agrees to implement the plan according to a schedule approved by the Secretary.

**SEC. 1242. [300d–42] PREFERENCES IN MAKING GRANTS.**

(a) IN GENERAL.—In making grants under section 1241(a), the Secretary shall give preference to any application—

(1) made by a trauma center that, for the purpose specified in such section, will receive financial assistance from the State or political subdivision involved for each fiscal year during which payments are made to the center from the grant, which financial assistance is exclusive of any assistance provided by

the State or political subdivision as a non-Federal contribution under any Federal program requiring such a contribution; or

(2) made by a trauma center that, with respect to the system described in section 1241(b)(2) in which the center is a participant—

(A) is providing trauma care in a geographic area in which the availability of trauma care has significantly decreased as a result of a trauma center in the area permanently ceasing participation in such system as of a date occurring during the 2-year period specified in section 1241(b)(1)(B); or

(B) will, in providing trauma care during the 1-year period beginning on the date on which the application for the grant is submitted, incur uncompensated costs in an amount rendering the center unable to continue participation in such system, resulting in a significant decrease in the availability of trauma care in the geographic area.

(b) FURTHER PREFERENCE FOR CERTAIN APPLICATIONS.—With respect to applications for grants under section 1241 that are receiving preference for purposes of subsection (a), the Secretary shall give further preference to any such application made by a trauma center for which a disproportionate percentage of the uncompensated costs of the center result from the provision of trauma care to individuals who neither are citizens nor aliens lawfully admitted to the United States for permanent residence.

**SEC. 1243. [300d–43] CERTAIN AGREEMENTS.**

(a) COMMITMENT REGARDING CONTINUED PARTICIPATION IN TRAUMA CARE SYSTEM.—The Secretary may not make a grant under subsection (a) of section 1241 unless the trauma center involved agrees that—

(1) the center will continue participation in the system described in subsection (b) of such section throughout the 3-year period beginning on the date that the center first receives payments under the grant; and

(2) if the agreement made pursuant to paragraph (1) is violated by the center, the center will be liable to the United States for an amount equal to the sum of—

(A) the amount of assistance provided to the center under subsection (a) of such section; and

(B) an amount representing interest on the amount specified in subparagraph (A).

(b) MAINTENANCE OF FINANCIAL SUPPORT.—With respect to activities for which a grant under section 1241 is authorized to be expended, the Secretary may not make such a grant unless the trauma center involved agrees that, during the period in which the center is receiving payments under the grant, the center will maintain expenditures for such activities at a level that is not less than the level maintained by the center during the fiscal year preceding the first fiscal year for which the center receives such payments.

(c) TRAUMA CARE REGISTRY.—The Secretary may not make a grant under section 1241(a) unless the trauma center involved agrees that—

(1) the center will operate a registry of trauma cases in accordance with the applicable guidelines described in section 1241(b)(2)(C), and will begin operation of the registry not later than 6 months after the date on which the center submits to the Secretary the application for the grant; and

(2) in carrying out paragraph (1), the center will maintain information on the number of trauma cases treated by the center and, for each such case, the extent to which the center incurs uncompensated costs in providing trauma care.

**SEC. 1244. [300d–44] GENERAL PROVISIONS.**

(a) APPLICATION.—The Secretary may not make a grant under section 1241(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 part.

(b) LIMITATION ON DURATION OF SUPPORT.—The period during which a trauma center receives payments under section 1241(a) may not exceed 3 fiscal years, except that the Secretary may waive such requirement for the center and authorize the center to receive such payments for 1 additional fiscal year.

(c) LIMITATION ON AMOUNT OF GRANT.—A grant under section 1241 may not be made in an amount exceeding $2,000,000.

**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 1993, and such sums as may be necessary for fiscal year 1994. Such authorization of appropriations is in addition to any other authorization of appropriations or amounts that are available for such purpose.

## Part E—Miscellaneous Programs [1]

**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 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 1993 through 1995.

[1] So in law. Typeface and capitalization are inconsistent with the other parts in this title. See section 304 of Public Law 102–408 (106 Stat. 2084).

**SEC. 1252. [300d–52] STATE GRANTS FOR DEMONSTRATION[1] 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 for the purpose of carrying out projects to improve access to health 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 involved agrees to establish an advisory board within the appropriate health department of the State or within another department as designated by the chief executive officer of the State.

(2) FUNCTIONS.—An advisory board established under paragraph (1) shall advise and make recommendations to the State 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 agencies involved;

(ii) public and nonprofit private health related organizations;

(iii) other disability advisory or planning groups within the State;

(iv) members of an organization or foundation representing individuals with traumatic brain injury in that State; 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 in carrying out the purpose described in subsection (a), the Secretary may make a grant under such subsection only if the State 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.

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[1]Section 1304(1) of Public Law 106–310 (114 Stat. 1139) attempts to amend the section heading by striking "**demonstration**". The amendment probably should have been to strike "**DEMONSTRATION**".

(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 that received a grant under this section prior to the date of the enactment of the Children's Health Act of 2000 may compete for new project grants under this section after such date of the enactment.

(f) USE OF STATE GRANTS.—

(1) COMMUNITY SERVICES AND SUPPORTS.—A State 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 and other individuals 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 involved.

(2) BEST PRACTICES.—

(A) IN GENERAL.—State 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 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 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 systems to provide accommodations to the needs of individuals with brain injury (including systems administered by the State departments responsible for health, mental health, labor/employment, education, mental retardation/developmental disorders, transportation, and correctional systems);

(F) improve data sets coordinated across systems and other needs identified by a State 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 later than 2 years after the date of the enactment of this section, the Secretary shall submit to the Committee on Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report describing the findings and results of the programs established under this section, including measures of outcomes and consumer and surrogate satisfaction.

(i) 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.

(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.

**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

(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 (i) 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 (i) 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 (i) 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 (i) 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 appro-

priated under subsection (i) 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, 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) 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 2002 through 2005.

(j) 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 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 Labor and Human Resources 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 [1], 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 head

[1] 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".)

brain injury treatment[1] 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:

(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

[1] The term "head brain injury treatment" is so in law. Section 1303(a)(3) of Public Law 106–310 (114 Stat. 1138) provides that subparagraph (D) is amended by striking "injury treatment" and inserting "brain injury treatment". The amendment probably should have been to strike "head injury treatment" and insert "brain injury treatment".

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.

## PART G—POISON CONTROL

### SEC. 1271. [300d–71] MAINTENANCE OF A NATIONAL TOLL-FREE NUMBER.

(a) IN GENERAL.—The Secretary shall provide coordination and assistance to regional poison control centers for the establishment of a nationwide toll-free phone number to be used to access such centers.

(b) RULE OF CONSTRUCTION.—Nothing in this section shall be construed as prohibiting the establishment or continued operation of any privately funded nationwide toll-free phone number used to provide advice and other assistance for poisonings or accidental exposures.

(c) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $2,000,000 for each of the fiscal years 2000 through 2009. Funds appropriated under this subsection shall not be used to fund any toll-free phone number described in subsection (b).

### SEC. 1272. [300d–72] NATIONWIDE MEDIA CAMPAIGN TO PROMOTE POISON CONTROL CENTER UTILIZATION.

(a) IN GENERAL.—The Secretary shall establish a national media campaign to educate the public and health care providers about poison prevention and the availability of poison control resources in local communities and to conduct advertising campaigns concerning the nationwide toll-free number established under section 1271.

(b) CONTRACT WITH ENTITY.—The Secretary may carry out subsection (a) by entering into contracts with one or more nationally recognized media firms for the development and distribution of monthly television, radio, and newspaper public service announcements.

(c) EVALUATION.—The Secretary shall—

(1) establish baseline measures and benchmarks to quantitatively evaluate the impact of the nationwide media campaign established under this section; and

(2) prepare and submit to the appropriate congressional committees an evaluation of the nationwide media campaign on an annual basis.

(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $600,000 for each of fiscal years 2000 through 2005 and such sums as may be necessary for each of fiscal years 2006 through 2009.

### SEC. 1273. [300d–73] MAINTENANCE OF THE POISON CONTROL CENTER GRANT PROGRAM.

(a) REGIONAL POISON CONTROL CENTERS.—The Secretary shall award grants to certified regional poison control centers for the purposes of achieving the financial stability of such centers, and for

preventing and providing treatment recommendations for poisonings.

(b) OTHER IMPROVEMENTS.—The Secretary shall also use amounts received under this section to—

(1) develop standardized poison prevention and poison control promotion programs;

(2) develop standard patient management guidelines for commonly encountered toxic exposures;

(3) improve and expand the poison control data collection systems, including, at the Secretary's discretion, by assisting the poison control centers to improve data collection activities;

(4) improve national toxic exposure surveillance by enhancing activities at the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry;

(5) expand the toxicologic expertise within poison control centers; and

(6) improve the capacity of poison control centers to answer high volumes of calls during times of national crisis.

(c) CERTIFICATION.—Except as provided in subsection (d), the Secretary may make a grant to a center under subsection (a) only if—

(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 requirement of subsection (c) with respect to a noncertified poison control center or a newly established 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 instance 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 if enacted on February 25, 2000.

(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 such expenditures maintained by the

center for the fiscal year preceding the fiscal year for which the grant is received.

(g) MATCHING REQUIREMENT.—The Secretary may impose a matching requirement with respect to amounts provided under a grant under this section if the Secretary determines appropriate.

(h) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $25,000,000 for each of the fiscal years 2000 through 2004 and $27,500,000 for each of fiscal years 2005 through 2009.

**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.

# 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 re-

specting 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, podia-

trists, 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 population group resides, and (B) each health systems agency designated for a health service area which covers (in whole or in part)

[1] So in law. Probably should be "organization".

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 organization, (C) methods, terms, and periods of the enrollment of members of such organization, (D) estimated costs per mem-

ber 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 appli-

cant 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)[1] 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) 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).

[1] Former subsection (c) was repealed by section 803(a) of Public Law 99–660.

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 interest) 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.[1] [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.

(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

[1] 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 [October 24, 1988], 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 [October 24, 1988].

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 [October 24, 1988].".

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 meeting 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)[1] 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.

[1] Subsection (e) was repealed by section 810 of Public Law 99–660.

# TITLE XIV—SAFETY OF PUBLIC WATER SYSTEMS

**[For Text of This Title See Volume 2 of the Environmental Law Compilation]**

# 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 2000 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 2000. 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

[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

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.

**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).

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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.".

(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 the extent to which States carrying out such programs are in compliance with section 1501(a)(2) and with section 1504(c).

(b) REPORT TO CONGRESS.—The Secretary shall, not later than 1 year after the date on which amounts are first appropriated pursuant to section 1509(a), 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, and such sums as may be necessary for each of the fiscal years 1995 through 2003.

(b) SET-ASIDE FOR TECHNICAL ASSISTANCE AND PROVISION OF SUPPLIES AND SERVICES.—Of the amounts appropriated under subsection (a) for a fiscal year, the Secretary shall reserve not more than 20 percent for carrying out section 1507.

# 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 Sec-

retary 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 ending 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 connec-

tion 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 facility 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 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.

[1] So in law. Probably should be "professional".

(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,"[1] 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 Secretary 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

[1] So in law. The comma probably should follow the ending quotations.

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 receiving 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 an-

other 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 inpa-

tient 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 application 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.

# 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 in-

surance 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 within the Office of Public Health and Science. There shall be in the Department of Health and Human Services a Deputy Assistant Secretary for Minority Health, who shall be the head of the Office of Minority Health. The Secretary, acting through such Deputy Assistant Secretary, shall carry out this section.

(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 appoint 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) FUNDING.—

(1)[1] AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $30,000,000 for fiscal year 1998, and such sums as may be necessary for each of the fiscal years 1999 through 2002.

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-

[1] So in law. This subsection was added without a paragraph (2). See section 201 of Public Law 105–392 (112 Stat. 3582).

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 403A. 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.

# 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,

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

[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).

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[1] in such records,[2] and

(F) such other matters relating to medicine or biomedical or behavioral research as the President may designate for study by the Commission.

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

[1] So in law. Probably should be "contained".
[2] So in law. The comma should probably be a semicolon.

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 activities 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 [1] 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.

(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.

[1] So in law. Probably should be "pursuant".

(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.

# 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 activities 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 para-

graph 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 3-year period (with an optional 4th 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, and such sums as may be necessary for each of the fiscal years 1993 through 2005.

PART B—BLOCK GRANTS REGARDING MENTAL HEALTH AND SUBSTANCE ABUSE

## Subpart I—Block Grants for Community Mental Health Services

**SEC. 1911. [300x–1] 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–2] 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 regarding 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 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.

[1] Enacted July 10, 1992.

**SEC. 1913. [300x–3] 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 [1], 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) 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] So in law. See section 201 of Public Law 102–321 (106 Stat. 381). Probably should be "disturbance".

(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–4] 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 main-

tained 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 [1] 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;

(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

[1] So in law. See section 201 of Public Law 102–321 (106 Stat. 384). Probably should be "is in accordance with".

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:

$$A \left( \frac{X}{U} \right)$$

(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:

$$1 - .35 \left( \frac{R\%}{P\%} \right)$$

(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)[1] ALLOCATIONS REGARDING WOMEN.—

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[1] 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—

(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.

(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.

(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 intra-

venous 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[1] 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 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[2] that is receiving amounts from a grant under section 1921, a funding agreement for

[1] So in law. See section 202 of Public Law 102–321 (106 Stat. 396). Probably should be "woman".

[2] So in law. See section 202 of Public Law 102–321 (106 Stat. 396). Probably should be "activities".

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)[1] 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;

(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.

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[1]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.

**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; [1]

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 [2] 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:

(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.

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[1] So in law. See section 102 of Public Law 102–321 (106 Stat. 402). Probably should be "under this subpart".

[2] So in law. See section 102 of Public Law 102–321 (106 Stat. 402). Probably should be "subsection".

(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 [1] 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 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

[1] 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.

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 in-

volved 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.[1] [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[2], 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 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

[1] 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:".

[2] 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.)

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.[1] [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[2], 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.

(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.

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[1] 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:".

[2] So in law. See section 203 of Public Law 102–321 (106 Stat. 409). Probably should be "section".

(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.[1]**

(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 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.

[1] 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).

(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[1]. 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.

(3) The term "treatment program" means a public or nonprofit private program of treatment for dependence on heroin or other morphine-like drugs.

[1] Enacted July 10, 1992.

# 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 de-

scribed 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 dis-

tribute 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.

# 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 sec-

tion 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[1], 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[1].

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.

(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.

[1] Section 2104 was repealed by section 601(a)(1)(H) of Public Law 105–362.

(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. [1]

(4) If in a civil action brought against a vaccine administrator or manufacturer before the effective date of this part [1] damages were denied for a vaccine-related injury or death or 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 [1] has pending a civil action for damages for a vaccine-related injury or death may, at any time within 2 years after the effec-

tive date of this part [1] 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 [2] 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.

(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] Effective October 1, 1988.
[2] So in law. Probably should be followed by a comma.

(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) suffered 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 [1] 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 Judicial Conference of the United States. The Conference rules and regulations pertaining to United States magistrates shall be applied to the special masters.

[1] So in law. Probably should be "United States Court of Federal Claims".

(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 [1] judgment with such court of appeals.

(g) [2] 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 section 2121(b) or the petitioner may choose under section 2121(b) to

[1] So in law. Probably should be a reference to the United States Court of Federal Claims.

[2] 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).

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 injury, disability, illness, condition, or death described in a peti-

tion 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)[1] 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

[1] 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 [1] 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.

[1] 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 [1] 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) [2].

(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

[1] Effective October 1, 1988.

[2] 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, [1] 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 [1] 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) [1] 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 [2] the compensation shall be determined on the basis of the net present value of the elements of

[1] See footnote for section 2112(g).
[2] Effective October 1, 1988.

compensation and paid in 4 equal annual installments of which all or a portion of the proceeds [1] 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 [1] shall be made by the Secretary from appropriations under subsection (j).

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[1] 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".)

(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 [1] 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 [1] 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, [1] 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 [1] 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, [1] 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, [1] 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

[1] 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)[1] 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[2] 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.

[1] See footnote for section 2112(g).
[2] 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.[1] 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

[1] 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[1], see section 2111(a)(2).

(b)[2] CONTINUANCE OR WITHDRAWAL OF PETITION.[3]—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

[1] Effective October 1, 1988.

[2] See footnote for section 2112(g).

[3] 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 [1] 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 [1] 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 resulting 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 [1] 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.

[1] Effective October 1, 1988.

## 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. [1] 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. [1]

(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

(B) the legal representative of such person.

[1] Effective December 22, 1987.

(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,[1] 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 materials 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 [1] 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, [1] 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]

(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,

(2) if a safety test on such batch, lot, or other quantity indicates a potential imminent or substantial public health haz-

[1] Effective December 22, 1987.

ard 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 reg-

ulation or after such date if such petition is based solely on grounds arising after such 60th day.

DEFINITIONS

SEC. 2133. [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)[1] 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)[1] 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.

(B) The term "Vaccine Injury Table" means the table set out in section 2114.

(7)[1] The term "vaccine" means any preparation or suspension, including but not limited to a preparation or suspension containing an attenuated or inactive microorganism or subunit thereof or toxin, developed or administered to produce or en-

[1] 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.".

hance the body's immune response to a disease or diseases and includes all components and ingredients listed in the vaccines's product license application and product label.

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 [1] 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. [1]

(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 [1] 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. |

[1] Effective December 22, 1987.

## 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.—

(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

[1] So in law. This title is not divided into parts.

(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) 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.

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[1] 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.

(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

[1] 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".)

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 beneficiary 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 period 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-re-

lated 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, [1]

(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

(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. [1]

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. [2] [300bb–7] ENFORCEMENT.**

Any individual who is aggrieved by the failure of a State, political subdivision, or agency or instrumentality thereof, to comply

[1] So in law. Probably should be "this title".

[2] Section 13631(d) of Public Law 103-66 (107 Stat. 643) provides as follows:

Continued

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)[1] 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.[2]

(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.

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(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.

[1] So in law. The word "section" does not appear. See section 102(d) of Public Law 104–191 (110 Stat. 1978).

[2] Indentation is so in law. See section 401(a)(3) of Public Law 104–191 (110 Stat. 2085).

# TITLE XXIII—RESEARCH WITH RESPECT TO ACQUIRED IMMUNE DEFICIENCY SYNDROME [1]

## PART A—ADMINISTRATION OF RESEARCH PROGRAMS

### SEC. 2301. [300cc] REQUIREMENT OF ANNUAL COMPREHENSIVE REPORT ON ALL EXPENDITURES BY SECRETARY WITH RESPECT TO ACQUIRED IMMUNE DEFICIENCY SYNDROME.

(a) IN GENERAL.—Not later than December 1 of each fiscal year, the Secretary shall prepare and submit to the Congress a report on the expenditures by the Secretary of amounts appropriated for the preceding fiscal year with respect to acquired immune deficiency syndrome.

(b) INCLUSION OF CERTAIN INFORMATION.—The report required in subsection (a) shall, with respect to acquired immune deficiency syndrome, include—

(1) for each program, project, or activity with respect to such syndrome, a specification of the amount obligated by each office and agency of the Department of Health and Human Services;

(2) a summary description of each such program, project, or activity;

(3) a list of such programs, projects, or activities that are directed towards members of minority groups;

(4) a description of the extent to which programs, projects, and activities described in paragraph (3) have been coordinated between the Director of the Office of Minority Health and the Director of the Centers for Disease Control and Prevention;

(5) a summary of the progress made by each such program, project, or activity with respect to the prevention and control of acquired immune deficiency syndrome;

(6) a summary of the evaluations conducted under this title; and

(7) any report required in this Act to be submitted to the Secretary for inclusion in the report required in subsection (a).

### 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 applica-

[1] Subtitle E of title II of Public Law 100–607 (102 Stat. 3108) established various authorities regarding acquired immune deficiency syndrome.

tion 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 applicant 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)[1] 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.

[1] 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.

**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 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; 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 infec-

tion 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 immune 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 [1] 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

[1] 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).)

(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 organized 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 financial 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 immuno-

deficiency 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 sup-

port 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, physicians, 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, profes-

sional, 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 [1] 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.

## 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 [2], shall establish fellowship and training programs to be conducted by the Centers for Disease Control [2] 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.

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[1] So in law. Probably should be "agreements".

[2] 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.

(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.

(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. 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); [1]

(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

[1] 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) REPORT TO SECRETARY.—The Director of the Office shall each fiscal year prepare and submit to the Secretary, for inclusion in the comprehensive report required in section 2301(a), a report—

(1) describing and evaluating the progress made in such fiscal year in research, treatment, and training with respect to acquired immune deficiency syndrome conducted or supported by the Institutes;

(2) summarizing and analyzing expenditures made in such fiscal year for activities with respect to acquired immune deficiency syndrome conducted or supported by the National Institutes of Health; and

(3) containing such recommendations as the Director considers appropriate.

(c) 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 established by law prior to, on, or after the date of the enactment of the National Institutes of Health Revitalization Act of 1993. [1]

(e) REPORT TO CONGRESS.—Not later than February 1 of each fiscal year, the Director of the Office 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 on the identified sets of AIDS activities carried out during the preceding fiscal year with amounts in the Fund. The report shall provide a description of each such set of activities and an explanation of the reasons underlying the use of the Fund for the set.

(f) 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).

(g) 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 AND REPORT.—

(1) EVALUATION.—Not later than 5 years after the date of the enactment of National Institutes of Health Revitalization Act of 1993, [1] the Secretary shall conduct an evaluation to—

(A) determine the effect of this section on the planning and coordination of the AIDS research programs at the in-

[1] Enacted June 10, 1993.

stitutes, centers and divisions of the National Institutes of Health;

(B) evaluate the extent to which this part has eliminated the duplication of administrative resources among such Institutes, centers and divisions; and

(C) provide recommendations concerning future alterations with respect to this part.

(2) REPORT.—Not later than 1 year after the date on which the evaluation is commenced under paragraph (1), 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 concerning the results of such evaluation.

(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 opportunistic 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.

# 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 least 2 of the following activities of daily living: bathing, dressing, toileting, transferring, and eating, or

[1] See footnote at beginning of title XXIII.

(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 community-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)[1] 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 syndrome at a level equal to not less than the average level of such expenditures maintained by the State for the 2-year pe-

[1] So in law. This section does not contain a subsection (b).

riod 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 program 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; [1] 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

[1] 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 [1] 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 [1] 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 [1] 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.

[1] Probably should be "part". See section 118(b)(1)(B) of Public Law 102–321 (106 Stat. 348).

# 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.

**SEC. 2502. [300ee–12] PROVISIONS WITH RESPECT TO CARRYING OUT PURPOSE OF GRANTS.**

A State may expend payments received under section 2501(a)—

[1] See footnote at beginning of title XXIII.

(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[1] 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.

**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] So in law. Probably should be "data".

(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))[1], 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—

(i) appropriate local officials and community groups for the area to be served by the program;

[1] See footnote for section 217(a).

(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 deficiency 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 [1] 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) [2]), to community health centers (as defined in section 330(a)) [2], 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 respect to programs providing information on the prevention of expo-

[1] So in law. The word "the" appears twice.
[2] See footnote for section 217(a).

sure 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,[1] publish guidelines to provide procedures for applications for funding pursuant to paragraph (1) and for public comment.

[1] Enacted on November 4, 1988.

# TITLE XXVI—HIV HEALTH CARE SERVICES PROGRAM[1, 2]

## PART A—EMERGENCY RELIEF FOR AREAS WITH SUBSTANTIAL NEED FOR SERVICES[3]

**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 (d), 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 the Director of the Centers for Disease Control and Prevention a cumulative total of more than 2,000 cases of acquired immune deficiency syndrome for the most recent period of 5 calendar years for which such data are available.

(b) REQUIREMENT REGARDING CONFIRMATION OF CASES.—The Secretary may not make a grant under subsection (a) for a metropolitan area unless, before making any payments under the grant, the cases of acquired immune deficiency syndrome reported for purposes of such subsection have been confirmed by the Secretary, acting through the Director of the Centers for Disease Control and Prevention.

(c) REQUIREMENTS REGARDING POPULATION.—

(1) NUMBER OF INDIVIDUALS.—

(A) IN GENERAL.—Except as provided in subparagraph (B), the Secretary may not make a grant under this section for a metropolitan area unless the area has a population of 500,000 or more individuals.

(B) LIMITATION.—Subparagraph (A) does not apply to any metropolitan area that was an eligible area under this part for fiscal year 1995 or any prior fiscal year.

(2) GEOGRAPHIC BOUNDARIES.—For purposes of eligibility under this part, the boundaries of each metropolitan area are the boundaries that were in effect for the area for fiscal year 1994.

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[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.

[3] 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.

(d) CONTINUED STATUS AS ELIGIBLE AREA.—Notwithstanding any other provision of this section, a metropolitan area that was an eligible area under this part for fiscal year 1996 is an eligible area for fiscal year 1997 and each subsequent fiscal year.

**SEC. 2602. [300ff–12] ADMINISTRATION AND PLANNING COUNCIL.**

(a) ADMINISTRATION.—

(1) IN GENERAL.—Assistance made available under grants awarded under this part 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 part, 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 disease 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 criteria. 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 disease 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 disease 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 disease;

(B) determine the needs of such population, with particular attention to—

(i) individuals with HIV disease who know their HIV status and are not receiving HIV-related services; and

(ii) disparities in access and services among affected subpopulations and historically underserved communities;

(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 disease (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 disease 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 disease; 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 discrete 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); and

(iii) is compatible with any State or local plan for the provision of services to individuals with HIV disease;

(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 disease 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 part, 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)[1] GRIEVANCE PROCEDURES.—

(1) FEDERAL RESPONSIBILITY.—

(A) MODELS.—The Secretary shall, through a process that includes consultations with grantees under this part 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 part. 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 part to determine if such procedures are

[1] 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).

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 part, 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 [1] (relating to the relationship between epidemiological measures and health care for certain individuals with HIV disease), 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 disease 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 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 part for a fiscal year, the Secretary shall, except in the case of waivers granted under section 2605(c), disburse 50 percent of the amount appropriated under section 2677 for such fiscal year through grants to eligible areas under section 2601(a), in accordance with paragraph (3). The Secretary shall reserve an additional percentage of the amount appropriated under section 2677 for a fiscal year for grants under part A to make grants to eligible areas under section 2601(a) in accordance with paragraph (4).

(3) AMOUNT OF GRANT.—

(A) IN GENERAL.—Subject to the extent of amounts made available in appropriations Acts, a grant made for

[1] 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.

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.

(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 acquired immune deficiency syndrome in the eligible area involved, as determined under subparagraph (C).

(C) ESTIMATE OF LIVING CASES.—The amount determined in this subparagraph is an amount equal to the product of—

(i) the number of cases of acquired immune deficiency syndrome in the eligible area during each year in the most recent 120-month period for which data are available with respect to all eligible areas, as indicated by the number of such cases reported to and confirmed by the Director of the Centers for Disease Control and Prevention for each year during such period, except that (subject to subparagraph (D)), for grants made pursuant to this paragraph for fiscal year 2005 and subsequent fiscal years, the cases counted for each 12-month period beginning on or after July 1, 2004, shall be cases of HIV disease (as reported to and confirmed by such Director) rather than cases of acquired immune deficiency syndrome; and

(ii) with respect to—

(I) the first year during such period, .06;

(II) the second year during such period, .06;

(III) the third year during such period, .08;

(IV) the fourth year during such period, .10;

(V) the fifth year during such period, .16;

(VI) the sixth year during such period, .16;

(VII) the seventh year during such period, .24;

(VIII) the eighth year during such period, .40;

(IX) the ninth year during such period, .57; and

(X) the tenth year during such period, .88.

The yearly percentage described in subparagraph (ii) shall be updated biennially by the Secretary, after consultation with the Centers for Disease Control and Prevention, and shall be reported to the congressional committees of jurisdiction. The first such update shall occur prior to the determination of grant awards under this part for fiscal year 1998. Updates shall as applicable take into account the counting of cases of HIV disease pursuant to clause (i).

(D) DETERMINATION OF SECRETARY REGARDING DATA ON HIV CASES.—

(i) IN GENERAL.—Not later than July 1, 2004, the Secretary shall determine whether there is data on

cases of HIV disease from all eligible areas (reported to and confirmed by the Director of the Centers for Disease Control and Prevention) sufficiently accurate and reliable for use for purposes of subparagraph (C)(i). In making such a determination, the Secretary shall take into consideration the findings of the study under section 501(b) of the Ryan White CARE Act Amendments of 2000 [1] (relating to the relationship between epidemiological measures and health care for certain individuals with HIV disease).

(ii) EFFECT OF ADVERSE DETERMINATION.—If under clause (i) the Secretary determines that data on cases of HIV disease is not sufficiently accurate and reliable for use for purposes of subparagraph (C)(i), then notwithstanding such subparagraph, for any fiscal year prior to fiscal year 2007 the references in such subparagraph to cases of HIV disease do not have any legal effect.

(iii) GRANTS AND TECHNICAL ASSISTANCE REGARDING COUNTING OF HIV CASES.—Of the amounts appropriated under section 318B for a fiscal year, the Secretary shall reserve amounts to make grants and provide technical assistance to States and eligible areas with respect to obtaining data on cases of HIV disease to ensure that data on such cases is available from all States and eligible areas as soon as is practicable but not later than the beginning of fiscal year 2007.

(E) UNEXPENDED FUNDS.—The Secretary may, in determining the amount of a grant for a fiscal year under this paragraph, adjust the grant amount to reflect the amount of unexpended and uncanceled grant funds remaining at the end of the fiscal year preceding the year for which the grant determination is to be made. The amount of any such unexpended funds shall be determined using the financial status report of the grantee.

(4) INCREASES IN GRANT.—

(A) IN GENERAL.—For each fiscal year in a protection period for an eligible area, the Secretary shall increase the amount of the grant made pursuant to paragraph (2) for the area to ensure that—

(i) for the first fiscal year in the protection period, the grant is not less than 98 percent of the amount of the grant made for the eligible area pursuant to such paragraph for the base year for the protection period;

(ii) for any second fiscal year in such period, the grant is not less than 95 percent of the amount of such base year grant;

(iii) for any third fiscal year in such period, the grant is not less than 92 percent of the amount of the base year grant;

[1] See footnote for section 2602(d).

(iv) for any fourth fiscal year in such period, the grant is not less than 89 percent of the amount of the base year grant; and

(v) for any fifth or subsequent fiscal year in such period, if, pursuant to paragraph (3)(D)(ii), the references in paragraph (3)(C)(i) to HIV disease do not have any legal effect, the grant is not less than 85 percent of the amount of the base year grant.

(B) SPECIAL RULE.—If for fiscal year 2005, pursuant to paragraph (3)(D)(ii), data on cases of HIV disease are used for purposes of paragraph (3)(C)(i), the Secretary shall increase the amount of a grant made pursuant to paragraph (2) for an eligible area to ensure that the grant is not less than 98 percent of the amount of the grant made for the area in fiscal year 2004.

(C) BASE YEAR; PROTECTION PERIOD.—With respect to grants made pursuant to paragraph (2) for an eligible area:

(i) The base year for a protection period is the fiscal year preceding the trigger grant-reduction year.

(ii) The first trigger grant-reduction year is the first fiscal year (after fiscal year 2000) for which the grant for the area is less than the grant for the area for the preceding fiscal year.

(iii) A protection period begins with the trigger grant-reduction year and continues until the beginning of the first fiscal year for which the amount of the grant determined pursuant to paragraph (2) for the area equals or exceeds the amount of the grant determined under subparagraph (A).

(iv) Any subsequent trigger grant-reduction year is the first fiscal year, after the end of the preceding protection period, for which the amount of the grant is less than the amount of the grant for the preceding fiscal year.

(b) SUPPLEMENTAL GRANTS.—

(1) IN GENERAL.—Not later than 150 days after the date on which appropriations are made under section 2677 for a fiscal year, 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 severe need in such area 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 disease;

(F) demonstrates the inclusiveness of the planning council membership, with particular emphasis on affected communities and individuals with HIV disease; and

(G) demonstrates the manner in which the proposed services are consistent with the local needs assessment and the statewide coordinated statement of need.

(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 severe need under subparagraph (B) of such paragraph counting one-third.

(B) SEVERE NEED.—In determining severe need in accordance with paragraph (1)(B), the Secretary shall consider the ability of the qualified applicant to expend funds efficiently and the impact of relevant factors on the cost and complexity of delivering health care and support services to individuals with HIV disease in the eligible area, including factors such as—

(i) sexually transmitted diseases, substance abuse, tuberculosis, severe mental illness, or other comorbid factors determined relevant by the Secretary;

(ii) new or growing subpopulations of individuals with HIV disease;

(iii) homelessness;

(iv) the current prevalence of HIV disease;

(v) an increasing need for HIV-related services, including relative rates of increase in the number of cases of HIV disease; and

(vi) unmet need for such services, as determined under section 2602(b)(4).

(C) PREVALENCE.—In determining the impact of the factors described in subparagraph (B), the Secretary shall, to the extent practicable, use national, quantitative incidence data that are available for each eligible area. Not later than 18 months after the date of the enactment of the Ryan White CARE Act Amendments of 2000, the Secretary shall develop a mechanism to utilize such data. Such a mechanism shall be modified to reflect the findings of the study under section 501(b) of the Ryan White CARE Act Amendments of 2000 [1] (relating to the relationship between epidemiological measures and health care for certain individuals with HIV disease). In the absence of such data, the Secretary may consider a detailed description and qualitative analysis of severe need, as determined under subparagraph (B), including any local prevalence data gathered and analyzed by the eligible area.

[1] See footnote for section 2602(d).

(D) PRIORITY.—Subsequent to the development of the quantitative mechanism described in subparagraph (C), the Secretary shall phase in, over a 3-year period beginning in fiscal year 1998, the use of such a mechanism to determine the severe need of an eligible area compared to other eligible areas and to determine, in part, the amount of supplemental funds awarded to the eligible area under this part.

(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) COMPLIANCE WITH PRIORITIES OF HIV PLANNING COUNCIL.—Notwithstanding any other provision of this part, 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.

**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)(3)(A), by the HIV health services planning council that serves such eligible area; and

(2) funds provided under section 2601 will be expended only for the purposes described in subsections (b) and (c).

(b) PRIMARY PURPOSES.—

(1) IN GENERAL.—The chief elected official shall use amounts received under a grant under section 2601 to provide direct financial assistance to entities described in paragraph

(2) for the purpose of delivering or enhancing HIV-related services, as follows:

(A) Outpatient and ambulatory health services, including substance abuse treatment, mental health treatment, and comprehensive treatment services, which shall include treatment education and prophylactic treatment for opportunistic infections, for individuals and families with HIV disease.

(B) Outpatient and ambulatory support services (including case management), to the extent that such services facilitate, enhance, support, or sustain the delivery, continuity, or benefits of health services for individuals and families with HIV disease.

(C) Inpatient case management services that prevent unnecessary hospitalization or that expedite discharge, as medically appropriate, from inpatient facilities.

(D) Outreach activities that are intended to identify individuals with HIV disease who know their HIV status and are not receiving HIV-related services, and that are—

(i) necessary to implement the strategy under section 2602(b)(4)(D), including activities facilitating the access of such individuals to HIV-related primary care services at entities described in paragraph (3)(A);

(ii) conducted in a manner consistent with the requirements under sections 2605(a)(3) and 2651(b)(2); and

(iii) supplement, and do not supplant, such activities that are carried out with amounts appropriated under section 317.

(2) APPROPRIATE ENTITIES.—

(A) IN GENERAL.—Subject to subparagraph (B), direct financial assistance may be provided under paragraph (1) to public or nonprofit private entities,,[1] or private for-profit entities if such entities are the only available provider of quality HIV care in the area, including hospitals (which may include Department of Veterans Affairs facilities), community-based organizations, hospices, ambulatory care facilities, community health centers, migrant health centers, homeless health centers, substance abuse treatment programs, and mental health programs.

(B) PRIORITY.—In providing direct financial assistance under paragraph (1) the chief elected official shall give priority to entities that are currently participating in Health Resources and Services Administration HIV health care demonstration projects.

(3) EARLY INTERVENTION SERVICES.—

(A) IN GENERAL.—The purposes for which a grant under section 2601 may be used include providing to individuals with HIV disease early intervention services described in section 2651(b)(2), with follow-up referral provided for the purpose of facilitating the access of individ-

[1] The superfluous comma is so in law. See the amendment made by section 3(b)(4)(B)(i) of Public Law 104–146 (110 Stat. 1351).

uals 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 disease 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.

(B) CONDITIONS.—With respect to an entity that proposes to provide early intervention services under subparagraph (A), such subparagraph applies only if the entity demonstrates to the satisfaction of the chief elected official for the eligible area involved that—

(i) Federal, State, or local funds are otherwise inadequate for the early intervention services the entity proposes to provide; and

(ii) 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.

(4) PRIORITY FOR WOMEN, INFANTS AND CHILDREN.—

(A) IN GENERAL.—For the purpose of providing health and support services to infants, children, youth, and women with HIV disease, 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 acquired immune deficiency syndrome to the general population in such area of individuals with such syndrome.

(B) 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 subparagraph (A) 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.

(c) QUALITY MANAGEMENT.—

(1) REQUIREMENT.—The chief elected official of an eligible area that receives a grant under this part shall provide for the establishment of a 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 disease 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.

(2) USE OF FUNDS.—From amounts received under a grant awarded under this part for a fiscal year, the chief elected official of an eligible area may (in addition to amounts to which subsection (f)(1) applies) use for activities associated with the quality management program required in paragraph (1) not more than the lesser of—

(A) 5 percent of amounts received under the grant; or

(B) $3,000,000.

(d) LIMITED EXPENDITURES FOR PERSONNEL NEEDS.—

(1) IN GENERAL.—A chief elected official, in accordance with paragraph (3), may use not to exceed 10 percent of amounts received under a grant under section 2601 to provide financial assistance or services, for the purposes described in paragraph (2), to any public or nonprofit private entity, including hospitals (which may include Veterans Administration facilities), nursing homes, subacute and transitional care facilities, and hospices that—

(A) provide HIV-related care or services to a disproportionate share of low-income individuals and families with HIV disease;

(B) incur uncompensated costs in the provision of such care or services to such individuals and families;

(C) have established, and agree to implement, a plan to evaluate the utilization of services provided in the care of individuals and families with HIV disease; and

(D) have established a system designed to ensure that such individuals and families are referred to the most medically appropriate level of care as soon as such referral is medically indicated.

(2) USE.—A chief elected official may use amounts referred to in paragraph (1) to—

(A) provide direct financial assistance to institutions and entities of the type referred to in such paragraph to assist such institutions and entities in recruiting or training and paying compensation to qualified personnel determined, under paragraph (3), to be necessary by the HIV health services planning council, specifically for the care of individuals with HIV disease; or

(B) in lieu of providing direct financial assistance, make arrangements for the provision of the services of such qualified personnel to such institutions and entities.

(3) REQUIREMENT OF DETERMINATION BY COUNCIL.—A chief elected official shall not use any of the amounts received under a grant under section 2601(a) to provide assistance or services under paragraph (2) unless the HIV health services planning council of the eligible area has made a determination that, with respect to the care of individuals with HIV disease—

(A) a shortage of specific health, mental health or support service personnel exists within specific institutions or entities in the eligible area;

(B) the shortage of such personnel has resulted in the inappropriate utilization of inpatient services within the area; and

(C) assistance or services provided to an institution or entity under paragraph (2), will not be used to supplant the existing resources devoted by such institution or entity to the uses described in such paragraph.

(e) 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.

(f) ADMINISTRATION.— [1]

(1) IN GENERAL.—The chief executive officer of an eligible area shall not use in excess of 5 percent of amounts received under a grant awarded under this part for administration,. [2] In the case of entities and subcontractors to which such officer allocates amounts received by the officer under the grant, the officer 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

[1] The heading for subsection (f) (as redesignated by section 121(d)(1) of Public Law 106–345) appears according to the probable intent of the Congress. Certain words in the heading were struck by clause (i) of the second subparagraph (C) of section 3(b)(4) of Public Law 104–146 (110 Stat. 1351), but there were no closing quotes with respect to the words to be struck.

[2] The superfluous comma is so in law. See the amendment made by clause (iii) of the second subparagraph (C) of section 3(b)(4) of Public Law 104–146 (110 Stat. 1352).

whether particular entities expend more than 10 percent for such expenses).

(2) ADMINISTRATIVE ACTIVITIES.—For the 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 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 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.

(3) SUBCONTRACTOR ADMINISTRATIVE COSTS.—For the purposes of this subsection, subcontractor administrative activities include—

(A) usual and recognized overhead, 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.

(g) CONSTRUCTION.—A State may not use amounts received under a grant awarded under this part 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 part 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 part

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 agreements 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 part 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 disease (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 disease 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 part 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; 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 part 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; and

(9) that the eligible area has procedures in place to ensure that services provided with funds received under this part meet the criteria specified in section 2604(b)(1).

(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;

(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; and

(4) the aggregate amounts expended for each such category of services.

(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 part 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 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 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 part in order to make such entities eligible to receive a grant under this part. 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 part:

(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 referred to in the HIV/AIDS Surveillance Report of the Centers for Disease Control and Prevention as a metropolitan area.

## PART B—CARE GRANT PROGRAM [1, 2]

## Subpart I—General Grant Provisions

**SEC. 2611. [300ff–21] GRANTS.**

(a) IN GENERAL.—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 disease. 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 disease).

(b) PRIORITY FOR WOMEN, INFANTS AND CHILDREN.—

(1) IN GENERAL.—For the purpose of providing health and support services to infants, children, youth, and women with HIV disease, including treatment measures to prevent the perinatal transmission of HIV, a State shall for each of such populations use, of the funds allocated under this part to the State for a fiscal year, not less than the percentage constituted by the ratio of the population involved (infants, children,

[1] 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.

[2] See footnote at the beginning of part A.

youth, or women in the State) with acquired immune deficiency syndrome to the general population in the State of individuals with such syndrome.

(2) WAIVER.—With respect to the population involved, the Secretary may provide to a State a waiver of the requirement of paragraph (1) if the 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.

**SEC. 2612. [300ff–22] GENERAL USE OF GRANTS.**

(a) IN GENERAL.—A State may use amounts provided under grants made under this part—

(1) to provide the services described in section 2604(b)(1) for individuals with HIV disease;

(2) to establish and operate HIV care consortia within areas most affected by HIV disease that shall be designed to provide a comprehensive continuum of care to individuals and families with HIV disease in accordance with section 2613;

(3) to provide home- and community-based care services for individuals with HIV disease in accordance with section 2614;

(4) to provide assistance to assure the continuity of health insurance coverage for individuals with HIV disease in accordance with section 2615; and

(5) to provide therapeutics to treat HIV disease to individuals with HIV disease in accordance with section 2616.

Services described in paragraph (1) shall be delivered through consortia designed as described in paragraph (2), where such consortia exist, unless the State demonstrates to the Secretary that delivery of such services would be more effective when other delivery mechanisms are used. In making a determination regarding the delivery of services, the State shall consult with appropriate representatives of service providers and recipients of services who would be affected by such determination, and shall include in its demonstration to the Secretary the findings of the State regarding such consultation.

(b) SUPPORT SERVICES; OUTREACH.—The purposes for which a grant under this part may be used include delivering or enhancing the following:

(1) Outpatient and ambulatory support services under section 2611(a) (including case management) to the extent that such services facilitate, enhance, support, or sustain the delivery, continuity, or benefits of health services for individuals and families with HIV disease.

(2) Outreach activities that are intended to identify individuals with HIV disease who know their HIV status and are not receiving HIV-related services, and that are—

(A) necessary to implement the strategy under section 2617(b)(4)(B), including activities facilitating the access of such individuals to HIV-related primary care services at entities described in subsection (c)(1);

(B) conducted in a manner consistent with the requirement under section 2617(b)(6)(G) and 2651(b)(2); and

(C) supplement, and do not supplant, such activities that are carried out with amounts appropriated under section 317.

(c) EARLY INTERVENTION SERVICES.—

(1) IN GENERAL.—The purposes for which a grant under this part may be used include providing to individuals with HIV disease early intervention services described in section 2651(b)(2), 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 disease counseling and testing sites, health care points of entry specified by States or 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 applies only if the entity demonstrates to the satisfaction of 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 paragraph to supplement and not supplant other funds available to the entity for the provision of early intervention services for the fiscal year involved.

(d) QUALITY MANAGEMENT.—

(1) REQUIREMENT.—Each State that receives a grant under this part shall provide for the establishment of a 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 disease 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.

(2) USE OF FUNDS.—From amounts received under a grant awarded under this part for a fiscal year, the State may (in addition to amounts to which section 2618(b)(5) applies) use for activities associated with the quality management program required in paragraph (1) not more than the lesser of—

(A) 5 percent of amounts received under the grant; or

(B) $3,000,000.

**SEC. 2613. [300ff–23] GRANTS TO ESTABLISH HIV CARE CONSORTIA.**

(a) CONSORTIA.—A State may use amounts provided under a grant awarded under this part to provide assistance under section 2612(a)(1) 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 disease; 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 disease 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 disease 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 deter-

mines 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 disease 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 disease;

(C) demonstrates that adequate planning has occurred to meet the special needs of families with HIV disease, 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 sub-

paragraph (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 disease;

(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 this part, 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 disease.

(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.

**SEC. 2614. [300ff–24] GRANTS FOR HOME- AND COMMUNITY-BASED CARE.**

(a) USES.—A State may use amounts provided under a grant awarded under this part to make grants under section 2612(a)(2) to entities to—

(1) provide home- and community-based health services for individuals with HIV disease 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 disease, 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 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 disease.

(c) DEFINITION.—As used in this part, the term "home- and community-based health services"—

(1) means, with respect to an individual with HIV disease, 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) homemaker or 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 this part to establish a program of financial assistance under section 2612(a)(3) to assist eligible low-income individuals with HIV disease 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 this part to establish a program under section 2612(a)(5) to provide therapeutics to treat HIV disease or prevent the serious deterioration of health arising from HIV disease 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 disease; and

(2) be a low-income individual, as defined by the State.

(c) STATE DUTIES.—In carrying out this section the State shall—

(1) determine, in accordance with guidelines issued by the Secretary, which treatments are eligible to be included under the program established under 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 disease, 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) USE OF HEALTH INSURANCE AND PLANS.—

(1) IN GENERAL.—In carrying out subsection (a), a State may expend a grant under this part to provide the therapeutics described in such subsection by paying on behalf of individuals with HIV disease 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).

**SEC. 2617. [300ff–27] STATE APPLICATION.**

(a) IN GENERAL.—The Secretary shall not make a grant to a State under this part 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 this part.

(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 disease 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 disease in the State;

(3) a determination of the needs of such population, with particular attention to—

(A) individuals with HIV disease 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) a comprehensive plan that describes the organization and delivery of HIV health care and support services to be funded with assistance received under this part that shall include a description of the purposes for which the State intends to use such assistance, and that—

(A)[1] establishes priorities for the allocation of funds within the State based on—

[1]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

(i) size and demographics of the population of individuals with HIV disease (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 disease;

(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 disease throughout the State;

(E) provides a description of the manner in which services funded with assistance provided under this part will be coordinated with other available related services for individuals with HIV disease; and

(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

(5) an assurance that the public health agency administering the grant for the State will periodically convene a meeting of individuals with HIV disease, representatives of grantees under each part under this title, providers, and public

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amendment probably should have instructed that the new subparagraphs be inserted before subparagraph (D), as redesignated.

agency representatives for the purpose of developing a statewide coordinated statement of need; and

(6) 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 (5), and the types of entities described in section 2602(b)(2), in developing the comprehensive plan under paragraph (4) 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 this part 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 disease;

(ii) ensure that such services will be provided in a setting that is accessible to low-income individuals with HIV disease;

(iii) provide outreach to low-income individuals with HIV disease to inform such individuals of the services available under this part; and

(iv) in the case of a State that intends to use amounts provided under the grant for purposes described in 2615 [1], 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 this part;

(D) the State will permit and cooperate with any Federal investigations undertaken regarding programs conducted under this part;

(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

[1] 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).

the fiscal year for which the State is applying to receive a grant under this part;

(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; 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 disease (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 disease and individuals knowledgeable of their HIV status but not in care.

(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 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 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 this part 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 this part) 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 acquired immune deficiency syndrome 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 acquired immune deficiency syndrome 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 this part, 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 2677, the amount of a grant to be made under this part for—

(A) each of the several States and the District of Columbia for a fiscal year shall be the greater of—

(i)(I) with respect to a State or District that has less than 90 living cases of acquired immune deficiency syndrome, as determined under paragraph (2)(D), $200,000; or

(II) with respect to a State or District that has 90 or more living cases of acquired immune deficiency syndrome, as determined under paragraph (2)(D), $500,000;

(ii) an amount determined under paragraph (2) and then, as applicable, increased under paragraph (2)(H); and

(B) each territory of the United States, as defined in paragraph (3), shall be the greater of $50,000 or an amount determined under paragraph (2).

(2) DETERMINATION.—

(A) FORMULA.—The amount referred to in paragraph (1)(A)(ii) for a State and paragraph (1)(B) for a territory of the United States shall be the product of—

(i) an amount equal to the amount appropriated under section 2677 for the fiscal year involved for grants under part B, subject to subparagraphs (H) and (I); and

(ii) the percentage constituted by the sum of—

(I) the product of .80 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; and

(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 distribution factors for all States or territories.

(B) STATE DISTRIBUTION FACTOR.—For purposes of subparagraph (A)(ii)(I), the term "State distribution factor" means an amount equal to the estimated number of living cases of acquired immune deficiency syndrome in the eligible area 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 estimated number of living cases of acquired immune deficiency syndrome in the State or territory involved, as determined under subparagraph (D); less

(ii) the estimated number of living cases of acquired immune deficiency syndrome in such State or territory that are within an eligible area (as determined under part A).

(D) ESTIMATE OF LIVING CASES.—The amount determined in this subparagraph is an amount equal to the product of—

(i) the number of cases of acquired immune deficiency syndrome in the State or territory during each year in the most recent 120-month period for which data are available with respect to all States and territories, as indicated by the number of such cases reported to and confirmed by the Director of the Centers for Disease Control and Prevention for each year during such period, except that (subject to subparagraph (E)), for grants made pursuant to this paragraph or section 2620 for fiscal year 2005 and subsequent fiscal years, the cases counted for each 12-month period beginning on or after July 1, 2004, shall be cases of HIV disease (as reported to and confirmed by such Director) rather than cases of acquired immune deficiency syndrome; and

(ii) with respect to each of the first through the tenth year during such period, the amount referred to in section 2603(a)(3)(C)(ii).

(E) DETERMINATION OF SECRETARY REGARDING DATA ON HIV CASES.—If under section 2603(a)(3)(D)(i) the Secretary determines that data on cases of HIV disease are not sufficiently accurate and reliable, then notwithstanding subparagraph (D) of this paragraph, for any fiscal year prior to fiscal year 2007 the references in such subparagraph to cases of HIV disease do not have any legal effect.

(F) PUERTO RICO, VIRGIN ISLANDS, GUAM.—For purposes of subparagraph (D), the cost index for Puerto Rico, the Virgin Islands, and Guam shall be 1.0.

(G) UNEXPENDED FUNDS.—The Secretary may, in determining the amount of a grant for a fiscal year under this subsection, adjust the grant amount to reflect the amount of unexpended and uncanceled grant funds remaining at the end of the fiscal year preceding the year for which the grant determination is to be made. The amount of any such unexpended funds shall be determined using the financial status report of the grantee.

(H) LIMITATION.—

(i) IN GENERAL.—The Secretary shall ensure that the amount of a grant awarded to a State or territory under section 2611 or subparagraph (I)(i) for a fiscal year is not less than—

(I) with respect to fiscal year 2001, 99 percent;

(II) with respect to fiscal year 2002, 98 percent;

(III) with respect to fiscal year 2003, 97 percent;

(IV) with respect to fiscal year 2004, 96 percent; and

(V) with respect to fiscal year 2005, 95 percent,

of the amount such State or territory received for fiscal year 2000 under section 2611 or subparagraph (I)(i), respectively (notwithstanding such subparagraph). In administering this subparagraph, the Secretary shall, with respect to States or territories that will under such section receive grants in amounts that exceed the amounts that such States received under such section or subparagraph for fiscal year 2000, proportionally reduce such amounts to ensure compliance with this subparagraph. In making such reductions, the Secretary shall ensure that no such State receives less than that State received for fiscal year 2000.

(ii) RATABLE REDUCTION.—If the amount appropriated under section 2677 for a fiscal year and available for grants under section 2611 or subparagraph (I)(i) is less than the amount appropriated and available for fiscal year 2000 under section 2611 or subparagraph (I)(i), respectively, the limitation contained in clause (i) for the grants involved shall be reduced by a percentage equal to the percentage of the reduction in such amounts appropriated and available.

(I) APPROPRIATIONS FOR TREATMENT DRUG PROGRAM.—

(i) FORMULA GRANTS.—With respect to the fiscal year involved, if under section 2677 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)[1] 100 percent of such amount, less the percentage reserved under clause (ii)(V); and

(II)[1] the percentage constituted by the ratio of the State distribution factor for the State (as determined under subparagraph (B)) to the sum of the State distribution factors for all States.

(ii) SUPPLEMENTAL TREATMENT DRUG GRANTS.—

(I) IN GENERAL.—From amounts made available under subclause (V), the Secretary shall make supplemental grants to States described in subclause (II) to enable such States to increase access to therapeutics described in section 2616(a), as provided by the State under section 2616(c)(2).

[1] Indentation of subclauses (I) and (II) are so in law. See section 206(e)(1) of Public Law 106–345 (114 Stat. 1336).

(II) ELIGIBLE STATES.—For purposes of subclause (I), a State described in this subclause is a State that, in accordance with criteria established by the Secretary, demonstrates a severe need for a grant under such subclause. In developing such criteria, the Secretary shall consider eligibility standards, formulary composition, and the number of eligible individuals at or below 200 percent of the official poverty line to whom the State is unable to provide therapeutics described in section 2616(a).

(III) STATE REQUIREMENTS.—The Secretary may not make a grant to a State under this clause unless the State agrees that—

(aa) the State will make available (directly or through donations from 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; and

(bb) the State will not impose eligibility requirements for services or scope of benefits limitations under section 2616(a) that are more restrictive than such requirements in effect as of January 1, 2000.

(IV)[1] 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 3 percent of the amount referred to in clause (i) with respect to section 2616, subject to subclause (VI).

(VI) LIMITATION.—In reserving amounts under subclause (V) and making grants under this clause for a fiscal year, the Secretary shall ensure for each State that the total of the grant under section 2611 for the State for the fiscal year and the grant under clause (i) for the State for the fiscal year is not less than such total for the State for the preceding fiscal year.

(3) DEFINITIONS.—As used in this subsection—

(A) the term "State" means each of the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, and Guam; and

(B) the term "territory of the United States" means,[2] American Samoa, the Commonwealth of the Northern

[1] Indentation is so in law. See section 206(e)(4) of Public Law 106–345 (114 Stat. 1336).
[2] The comma is so in law. See section 417(2) of Public Law 105–392 (112 Stat. 3591).

Mariana Islands, the Republic of the Marshall Islands, the Federated States of Micronesia, and the Republic of Palau, and only for purposes of paragraph (1) the Commonwealth of Puerto Rico.

(b) ALLOCATION OF ASSISTANCE BY STATES.—

(2)[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.

(3) PLANNING AND EVALUATIONS.—Subject to paragraph (5) and except as provided in paragraph (6), a State may not use more than 10 percent of amounts received under a grant awarded under this part for planning and evaluation activities.

(4) ADMINISTRATION.—

(A) IN GENERAL.—Subject to paragraph (5) and except as provided in paragraph (6), a State may not use more than 10 percent of amounts received under a grant awarded under this part for administration. In the case of entities and subcontractors to which the State allocates amounts received by the State under the grant (including consortia under section 2613), 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).

(B) ADMINISTRATIVE ACTIVITIES.—For the purposes of subparagraph (A), amounts may be used for administrative activities that include routine grant administration and monitoring activities.

(C) 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.

(5) LIMITATION ON USE OF FUNDS.—Except as provided in paragraph (6), a State may not use more than a total of 15 percent of amounts received under a grant awarded under this part for the purposes described in paragraphs (3) and (4).

(6) 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 this part for such fiscal year for the activities described in paragraphs (3) and (4), may, notwithstanding paragraphs (3), (4), and (5), use not more than that amount required to support one full-time-equivalent employee.

(7) CONSTRUCTION.—A State may not use amounts received under a grant awarded under this part to purchase or improve land, or to purchase, construct, or permanently im-

[1] Paragraph (1) was struck by section 3(c)(5)(A) of Public Law 104–146 (110 Stat. 1355).

prove (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 this part 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 amounts appropriated in any fiscal year and made available to a State under this part that have not been obligated as described in subsection (d) shall be repaid to the Secretary and reallotted to other States in proportion to the original grants made to such States.

**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–30] SUPPLEMENTAL GRANTS.**

(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); and

(3) 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 this part;

(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 disease;

(6) a demonstration of the inclusiveness of the planning process, with particular emphasis on affected communities and individuals with HIV disease; 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) DEFINITION OF EMERGING COMMUNITY.—In this section, the term "emerging community" means a metropolitan area—

(1) that is not eligible for a grant under part A; and

(2) for which there has been reported to the Director of the Centers for Disease Control and Prevention a cumulative total of between 500 and 1,999 cases of acquired immune deficiency syndrome for the most recent period of 5 calendar years for which such data are available (except that, for fiscal year 2005 and subsequent fiscal years, cases of HIV disease shall be counted rather than cases of acquired immune deficiency syndrome if cases of HIV disease are being counted for purposes of section 2618(a)(2)(D)(i)).

(e) FUNDING.—

(1) IN GENERAL.—Subject to paragraph (2), with respect to each fiscal year beginning with fiscal year 2001, the Secretary, to carry out this section, shall utilize—

(A) the greater of—

(i) 25 percent of the amount appropriated under section 2677 to carry out part B, excluding the amount appropriated under section 2618(a)(2)(I), for such fiscal year that is in excess of the amount appropriated to carry out such part in the fiscal year preceding the fiscal year involved; or

(ii) $5,000,000,

to provide funds to States for use in emerging communities with at least 1,000, but less than 2,000, cases of AIDS as reported to and confirmed by the Director of the Centers for Disease Control and Prevention for the five year period preceding the year for which the grant is being awarded; and

(B) the greater of—

(i) 25 percent of the amount appropriated under section 2677 to carry out part B, excluding the amount appropriated under section 2618(a)(2)(I), for such fiscal year that is in excess of the amount appropriated to carry out such part in the fiscal year preceding the fiscal year involved; or

(ii) $5,000,000,

to provide funds to States for use in emerging communities with at least 500, but less than 1,000, cases of AIDS reported to and confirmed by the Director of the Centers for Disease Control and Prevention for the five year period preceding the year for which the grant is being awarded.

(2) TRIGGER OF FUNDING.—This section shall be effective only for fiscal years beginning in the first fiscal year in which the amount appropriated under section 2677 to carry out part B, excluding the amount appropriated under section 2618(a)(2)(I), exceeds by at least $20,000,000 the amount appropriated under section 2677 to carry out part B in fiscal year 2000, excluding the amount appropriated under section 2618(a)(2)(I).

(3) MINIMUM AMOUNT IN FUTURE YEARS.—Beginning with the first fiscal year in which amounts provided for emerging communities under paragraph (1)(A) equals $5,000,000 and under paragraph (1)(B) equals $5,000,000, the Secretary shall ensure that amounts made available under this section for the types of emerging communities described in each such paragraph in subsequent fiscal years is at least $5,000,000.

(4) DISTRIBUTION.—Grants under this section for emerging communities shall be formula grants. There shall be two categories of such formula grants, as follows:

(A) One category of such grants shall be for emerging communities for which the cumulative total of cases for purposes of subsection (d)(2) is 999 or fewer cases. The grant made to such an emerging community for a fiscal year shall be the product of—

(i) an amount equal to 50 percent of the amount available pursuant to this subsection for the fiscal year involved; and

(ii) a percentage equal to the ratio constituted by the number of cases for such emerging community for the fiscal year over the aggregate number of such cases for such year for all emerging communities to which this subparagraph applies.

(B) The other category of formula grants shall be for emerging communities for which the cumulative total of cases for purposes of subsection (d)(2) is 1,000 or more cases. The grant made to such an emerging community for a fiscal year shall be the product of—

(i) an amount equal to 50 percent of the amount available pursuant to this subsection for the fiscal year involved; and

(ii) a percentage equal to the ratio constituted by the number of cases for such community for the fiscal year over the aggregate number of such cases for the fiscal year for all emerging communities to which this subparagraph applies.

## Subpart II—Provisions Concerning Pregnancy and Perinatal Transmission of HIV

**SEC. 2625. [300ff–33] CDC GUIDELINES FOR PREGNANT WOMEN.**

(a) REQUIREMENT.—Notwithstanding any other provision of law, a State shall, not later than 120 days after the date of enactment of this subpart, certify to the Secretary that such State has in effect regulations or measures to adopt the guidelines issued by the Centers for Disease Control and Prevention concerning recommendations for human immunodeficiency virus counseling and voluntary testing for pregnant women.

(b) NONCOMPLIANCE.—If a State does not provide the certification required under subsection (a) within the 120-day period described in such subsection, such State shall not be eligible to receive assistance for HIV counseling and testing under this section until such certification is provided.

(c) ADDITIONAL FUNDS REGARDING WOMEN AND INFANTS.—

(1) IN GENERAL.—If a State provides the certification required in subsection (a) and is receiving funds under part B for a fiscal year, the Secretary may (from the amounts available pursuant to paragraph (2)) make a grant to the State for the fiscal year for the following purposes:

(A) Making available to pregnant women appropriate counseling on HIV disease.

(B) Making available outreach efforts to pregnant women at high risk of HIV who are not currently receiving prenatal care.

(C) Making available to such women voluntary HIV testing for such disease.

(D) Offsetting other State costs associated with the implementation of this section and subsections (a) and (b) of section 2626.

(E) Offsetting State costs associated with the implementation of mandatory newborn testing in accordance with this title or at an earlier date than is required by this title.

(F) Making available to pregnant women with HIV disease, and to the infants of women with such disease, treatment services for such disease in accordance with applicable recommendations of the Secretary.

(2) FUNDING.—

(A) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this subsection, there are authorized to be appropriated $30,000,000 for each of the fiscal years 2001 through 2005. Amounts made available under section 2677 for carrying out this part are not available for carrying out this section unless otherwise authorized.

(B) ALLOCATIONS FOR CERTAIN STATES.—

(i) IN GENERAL.—Of the amounts appropriated under subparagraph (A) for a fiscal year in excess of $10,000,000—

(I) the Secretary shall reserve the applicable percentage under clause (iv) for making grants

under paragraph (1) both to States described in clause (ii) and States described in clause (iii); and

(II) the Secretary shall reserve the remaining amounts for other States, taking into consideration the factors described in subparagraph (C)(iii), except that this subclause does not apply to any State that for the fiscal year involved is receiving amounts pursuant to subclause (I).

(ii) REQUIRED TESTING OF NEWBORNS.—For purposes of clause (i)(I), the States described in this clause are States that under law (including under regulations or the discretion of State officials) have—

(I) a requirement that all newborn infants born in the State be tested for HIV disease and that the biological mother of each such infant, and the legal guardian of the infant (if other than the biological mother), be informed of the results of the testing; or

(II) a requirement that newborn infants born in the State be tested for HIV disease in circumstances in which the attending obstetrician for the birth does not know the HIV status of the mother of the infant, and that the biological mother of each such infant, and the legal guardian of the infant (if other than the biological mother), be informed of the results of the testing.

(iii) MOST SIGNIFICANT REDUCTION IN CASES OF PERINATAL TRANSMISSION.—For purposes of clause (i)(I), the States described in this clause are the following (exclusive of States described in clause (ii)), as applicable:

(I) For fiscal years 2001 and 2002, the two States that, relative to other States, have the most significant reduction in the rate of new cases of the perinatal transmission of HIV (as indicated by the number of such cases reported to the Director of the Centers for Disease Control and Prevention for the most recent periods for which the data are available).

(II) For fiscal years 2003 and 2004, the three States that have the most significant such reduction.

(III) For fiscal year 2005, the four States that have the most significant such reduction.

(iv) APPLICABLE PERCENTAGE.—For purposes of clause (i), the applicable amount for a fiscal year is as follows:

(I) For fiscal year 2001, 33 percent.
(II) For fiscal year 2002, 50 percent.
(III) For fiscal year 2003, 67 percent.
(IV) For fiscal year 2004, 75 percent.
(V) For fiscal year 2005, 75 percent.

(C) CERTAIN PROVISIONS.—With respect to grants under paragraph (1) that are made with amounts reserved under subparagraph (B) of this paragraph:

(i) Such a grant may not be made in an amount exceeding $4,000,000.

(ii) If pursuant to clause (i) or pursuant to an insufficient number of qualifying applications for such grants (or both), the full amount reserved under subparagraph (B) for a fiscal year is not obligated, the requirement under such subparagraph to reserve amounts ceases to apply.

(iii) In the case of a State that meets the conditions to receive amounts reserved under subparagraph (B)(i)(II), the Secretary shall in making grants consider the following factors:

(I) The extent of the reduction in the rate of new cases of the perinatal transmission of HIV.

(II) The extent of the reduction in the rate of new cases of perinatal cases of acquired immune deficiency syndrome.

(III) The overall incidence of cases of infection with HIV among women of childbearing age.

(IV) The overall incidence of cases of acquired immune deficiency syndrome among women of childbearing age.

(V) The higher acceptance rate of HIV testing of pregnant women.

(VI) The extent to which women and children with HIV disease are receiving HIV-related health services.

(VII) The extent to which HIV-exposed children are receiving health services appropriate to such exposure.

(3) PRIORITY.—In awarding grants under this subsection the Secretary shall give priority to States that have the greatest proportion of HIV seroprevalance among child bearing women using the most recent data available as determined by the Centers for Disease Control and Prevention.

(4) MAINTENANCE OF EFFORT.—A condition for the receipt of a grant under paragraph (1) is that the State involved agree that the grant will be used to supplement and not supplant other funds available to the State to carry out the purposes of the grant.

**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 disease 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 de-

scribing 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 disease 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 disease, 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 disease 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 disease.

(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 disease, 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 disease 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 disease 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 are authorized to be appropriated $30,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 through 2005.

## PART C—EARLY INTERVENTION SERVICES

### Subpart I—Categorical Grants

**SEC. 2651. [300ff–51] ESTABLISHMENT OF 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) PURPOSES OF GRANTS.—

(1) IN GENERAL.—The Secretary may not make a grant under subsection (a) unless the applicant for the grant agrees to expend the grant for the purposes of providing, on an outpatient basis, each of the early intervention services specified in paragraph (2) with respect to HIV disease, and unless the applicant agrees to expend not less than 50 percent of the grant for such services that are specified in subparagraphs (B) through (E) of such paragraph for individuals with HIV disease.

(2) SPECIFICATION OF EARLY INTERVENTION SERVICES.—The early intervention services referred to in paragraph (1) are—

(A) counseling individuals with respect to HIV disease in accordance with section 2662;

(B) 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;

(C) referrals described in paragraph (3);

(D) other clinical and diagnostic services regarding HIV disease, and periodic medical evaluations of individuals with the disease;

(E) providing the therapeutic measures described in subparagraph (B).

(3) REFERRALS.—The services referred to in paragraph (2)(C) are referrals of individuals with HIV disease 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.

(4) 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) paragraphs (1), (2), (5), and (6) of section 2652(a) 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 section 2651(b)(2) directly and on-site or at sites where other primary care services are rendered; and

(ii) paragraphs (3) and (4) of section 2652(a) 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 section 2651(b)(2)(C), and for follow-up concerning such referrals.

(5) OPTIONAL SERVICES.—A grantee under subsection (a)—

(A) may expend the grant to provide outreach services to individuals who may have HIV disease or may be at risk of the disease, and who may be unaware of the availability and potential benefits of early treatment of the disease, and to provide outreach services to health care professionals who may be unaware of such availability and potential benefits; and

(B) may, in the case of individuals who seek early intervention services from the grantee, expend the grant—

(i) for case management to provide coordination in the provision of health care services to the individuals and to review the extent of utilization of the services by the individuals; and

(ii) to provide assistance to the individuals regarding establishing the eligibility of the individuals for financial assistance and services under Federal, State, or local programs providing for health services, mental health services, social services, or other appropriate services.

(c) PARTICIPATION IN CERTAIN CONSORTIUM.—The Secretary may not make a grant under subsection (a) unless the applicant for the grant agrees to make reasonable efforts to participate in a consortium established with a grant under section 2612(a)(1) regarding comprehensive services to individuals with HIV disease, if such a consortium exists in the geographic area with respect to which the applicant is applying to receive such a grant.

**SEC. 2652. [300ff–52] MINIMUM QUALIFICATIONS OF GRANTEES.**

(a) IN GENERAL.—The entities referred to in section 2651(a) are public entities and nonprofit private entities that are—

(1) migrant health centers under section 329 or community health centers under section 330; [1];

(2) grantees under section 330(h) (regarding health services for the homeless);

(3) grantees under section 1001 (regarding family planning) other than States;

(4) comprehensive hemophilia diagnostic and treatment centers;

(5) Federally-qualified health centers under section 1905(l)(2)(B) of the Social Security Act; or

(6) nonprofit private entities that provide comprehensive primary care services to populations at risk of HIV disease.

(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 disease, as indicated by the factors specified in subsection (b).

(b) SPECIFICATION OF FACTORS.—

[1] See footnote for section 217(a).

(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 acquired immune deficiency syndrome;

(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 drug abuse;

(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 special consideration 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 HIV early intervention services; and

(B) assisting the entities in expanding their capacity to provide HIV-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 or underserved communities.

(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 such sums as may be necessary for each of the fiscal years 2001 through 2005.

## 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.—

(1) IN GENERAL.—The Secretary may not make a grant under this part unless the applicant for the grant agrees that, in testing an individual for HIV disease, the applicant will test an individual only after obtaining from the individual a statement, made in writing and signed by the individual, declaring that the individual has undergone the counseling described in section 2662(a) and that the decision of the individual with respect to undergoing such testing is voluntarily made.

(2) PROVISIONS REGARDING ANONYMOUS TESTING.—

(A) If, pursuant to section 2664(b), an individual will undergo testing pursuant to this part through the use of a pseudonym, a grantee under such section shall be considered to be in compliance with the agreement made under paragraph (1) if the individual signs the statement described in such subsection using the pseudonym.

(B) If, pursuant to section 2664(b), an individual will undergo testing pursuant to this part without providing any information relating to the identity of the individual, a grantee under such section shall be considered to be in compliance with the agreement made under paragraph (1) if the individual orally provides the declaration described in such paragraph.

**SEC. 2662. [300ff–62] PROVISION OF CERTAIN COUNSELING SERVICES.**

(a) COUNSELING BEFORE TESTING.—The Secretary may not make a grant under this part unless the applicant for the grant agrees that, before testing an individual for HIV disease, the applicant will provide to the individual appropriate counseling regarding the disease (based on the most recently available scientific data), including counseling on—

(1) measures for the prevention of exposure to, and the transmission of, HIV;

(2) the accuracy and reliability of the results of testing for HIV disease;

(3) the significance of the results of such testing, including the potential for developing acquired immune deficiency syndrome;

(4) encouraging the individual, as appropriate, to undergo such testing;

(5) the benefits of such testing, including the medical benefits of diagnosing HIV disease in the early stages and the medical benefits of receiving early intervention services during such stages;

(6) provisions of law relating to the confidentiality of the process of receiving such services, including information regarding any disclosures that may be authorized under applicable law and information regarding the availability of anonymous counseling and testing pursuant to section 2664(b); and

(7) provisions of applicable law relating to discrimination against individuals with HIV disease.

(b) 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 disease indicate that an individual does not have the disease, the applicant will review for the individual the information provided pursuant to subsection (a), 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 regarding such disease.

(c) 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 disease indicate that the individual has the disease, the applicant will provide to the individual appropriate counseling regarding such disease, 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 regarding such disease; 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 and any individual whom the infected individual may have exposed to HIV; 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. [1]

(D) on the availability of the services of public health authorities with respect to locating and counseling any individual described in subparagraph (C).

(d) 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 disease, the applicant will ensure that the counseling is provided under conditions appropriate to the needs of the individuals.

(e) 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 disease, 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.

(f) 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 disease as a result of the grantee or the individual determining that such testing of the individual is not appropriate.

[1] The period is so in law. Should probably be a "; and". See the amendment made by section 321(3) of Public Law 106–345 (114 Stat. 1346).

**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 disease, any such testing carried out by the applicant will, without regard to whether such testing is carried out with Federal funds, 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; and

(B) an estimate of the number of individuals to whom the applicant has provided such services for such fiscal year; and

(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.

(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 disease 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 expendi-

tures 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 characterized 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; 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 including planning and evaluation of the grant for administrative expenses with respect to the grant;

(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 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 disease and related opportunistic 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 disease by providing accurate information; and

(3) shall provide information on the health risks of promiscuous sexual activity and intravenous drug abuse.

## PART D—GENERAL PROVISIONS

**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 and in consultation with the Director of the National Institutes of Health,

shall make grants to public and nonprofit private entities that provide primary care (directly or through contracts) for the following purposes:

(1) Providing through such entities, in accordance with this section, opportunities for women, infants, children, and youth to be voluntary participants in research of potential clinical benefit to individuals with HIV disease.

(2) In the case of women, infants, children, and youth with HIV disease, and the families of such individuals, providing to such individuals—

(A) health care on an outpatient basis; and

(B) additional services in accordance with subsection (d).

(b) PROVISIONS REGARDING PARTICIPATION IN RESEARCH.—

(1) IN GENERAL.—With respect to the projects of research with which an applicant under subsection (a) is concerned, the Secretary may make a grant under such subsection to the applicant only if the following conditions are met:

(A) The applicant agrees to make reasonable efforts—

(i) to identify which of the patients of the applicant are women, infants, children, and youth who would be appropriate participants in the projects;

(ii) to carry out clause (i) through the use of criteria provided for such purpose by the entities that will be conducting the projects of research; and

(iii) to offer women, infants, children, and youth the opportunity to participate in the projects (as appropriate), including the provision of services under subsection (d)(3).

(B) The applicant agrees that, in the case of the research-related functions to be carried out by the applicant pursuant to subsection (a)(1), the applicant will comply with accepted standards that are applicable to such functions (including accepted standards regarding informed consent and other protections for human subjects).

(C) The applicant will demonstrate linkages to research and how access to such research is being offered to patients.

(2) PROHIBITION.—Receipt of services by a patient shall not be conditioned upon the consent of the patient to participate in research.

(c) PROVISIONS REGARDING CONDUCT OF RESEARCH.—

(1) IN GENERAL.—With respect to eligibility for a grant under subsection (a):

(A) A project of research for which subjects are sought pursuant to such subsection may be conducted by the applicant for the grant, or by an entity with which the applicant has made arrangements for purposes of the grant. The grant may not be expended for the conduct of any project of research, except for such research-related functions as are appropriate for providing opportunities under subsection (a)(1) (including the functions specified in subsection (b)(1)).

(B) The grant may be made only if the Secretary makes the following determinations:

(i) The applicant or other entity (as the case may be under subparagraph (A)) is appropriately qualified to conduct the project of research. An entity shall be considered to be so qualified if any research protocol of the entity has been recommended for funding under this Act pursuant to technical and scientific peer review through the National Institutes of Health.

(ii) The project of research is being conducted in accordance with a research protocol to which the Secretary gives priority regarding the prevention or treatment of HIV disease in women, infants, children, or youth, subject to paragraph (2).

(2) LIST OF RESEARCH PROTOCOLS.—

(A) IN GENERAL.—From among the research protocols described in paragraph (1)(B)(ii), the Secretary shall establish a list of research protocols that are appropriate for purposes of subsection (a)(1). Such list shall be established only after consultation with public and private entities that conduct such research, and with providers of services under subsection (a) and recipients of such services.

(B) DISCRETION OF SECRETARY.—The Secretary may authorize the use, for purposes of subsection (a)(1), of a research protocol that is not included on the list under subparagraph (A). The Secretary may waive the requirement specified in paragraph (1)(B)(ii) in such circumstances as the Secretary determines to be appropriate.

(d) ADDITIONAL SERVICES FOR PATIENTS AND FAMILIES.—A grant under subsection (a) may be made only if the applicant for the grant agrees as follows:

(1) The applicant will provide for the case management of the patient involved and the family of the patient.

(2) The applicant will provide for the patient and the family of the patient—

(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) The applicant will provide the patient and the family of the patient with such transportation, child care, and other incidental services as may be necessary to enable the patient and the family to participate in the program established by the applicant pursuant to such subsection.

(4) The applicant will provide individuals with information and education on opportunities to participate in HIV/AIDS-related clinical research.

(e) COORDINATION WITH OTHER ENTITIES.—A grant under subsection (a) may be made only if the applicant for the grant agrees as follows:

(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.

(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.

(f) ADMINISTRATION.—

(1) APPLICATION.—A grant under subsection (a) may be made 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.

(2) QUALITY MANAGEMENT PROGRAM.—A grantee under this section shall implement a 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 disease 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) COORDINATION WITH NATIONAL INSTITUTES OF HEALTH.—The Secretary shall develop and implement a plan that provides for the coordination of the activities of the National Institutes of Health with the activities carried out under this section. In carrying out the preceding sentence, the Secretary shall ensure that projects of research conducted or supported by such Institutes are made aware of applicants and grantees under subsection (a), shall require that the projects, as appropriate, enter into arrangements for purposes of such subsection, and shall require that each project entering into such an arrangement inform the applicant or grantee under such subsection of the needs of the project for the participation of women, infants, children, and youth. The Secretary acting through the Director of NIH, shall examine the distribution and availability of ongoing and appropriate HIV/AIDS-related research projects to existing sites under this section for purposes of enhancing and expanding voluntary access to HIV-related research, especially within communities that are not reasonably served by such projects. Not later than 12 months after the date of the enactment of the Ryan White CARE Act Amendments of 2000, the Secretary shall prepare and submit to the appropriate committees of Congress a report that describes the findings made by the Director and the manner in which the conclusions based on those findings can be addressed.

(h) 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.—The Secretary shall, directly or through contracts with public and private entities, provide for evaluations of programs carried out pursuant to subsection (a).

(i) LIMITATION ON ADMINISTRATIVE EXPENSES.—

(1) DETERMINATION BY SECRETARY.—Not later than 12 months after the date of the enactment of the Ryan White CARE Act Amendments of 2000, the Secretary, in consultation with grantees under this part, shall conduct a review of the administrative, program support, and direct service-related activities that are carried out under this part to ensure that eligible individuals have access to quality, HIV-related health and support services and research opportunities under this part, and to support the provision of such services.

(2) REQUIREMENTS.—

(A) IN GENERAL.—Not later than 180 days after the expiration of the 12-month period referred to in paragraph (1) the Secretary, in consultation with grantees under this part, shall determine the relationship between the costs of the activities referred to in paragraph (1) and the access of eligible individuals to the services and research opportunities described in such paragraph.

(B) LIMITATION.—After a final determination under subparagraph (A), the Secretary may not make a grant under this part unless the grantee complies with such requirements as may be included in such determination.

(j) TRAINING AND TECHNICAL ASSISTANCE.—Of the amounts appropriated under subsection (j) for a fiscal year, the Secretary may use not more than five 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.

(k) 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 1996 through 2000 [1].

**SEC. 2672. [300ff–72] PROVISIONS RELATING TO BLOOD BANKS.**

(a) INFORMATIONAL AND TRAINING PROGRAMS.—The Secretary shall—

(1) develop and make available to technical and supervisory personnel employed at blood banks and facilities that produce blood products, materials and information concerning measures that may be implemented to protect the safety of the

[1] The probable intent of the Congress is that the authorization of appropriations be such sums as may be necessary for each of the fiscal years 2001 through 2005. Section 401(f) of Public Law 106–345 (114 Stat. 1348) attempted to amend "subsection (j) (as redesignated...)" regarding additional authorizations of appropriations, but the amendment cannot be executed because section 401(e) of such Public Law made redesignations with the result that subsection (k) of section 2671 contains the authorization of appropriations, not subsection (j).

blood supply with respect to the activities of such personnel, including—

(A) state-of-the-art diagnostic and testing procedures relating to pathogens in the blood supply; and

(B) quality assurance procedures relating to the safety of the blood supply and of blood products; and

(2) develop and implement a training program that is designed to increase the number of employees of the Department of Health and Human Services who are qualified to conduct inspections of blood banks and facilities that produce blood products.

(b) UPDATES.—The Secretary shall periodically review and update the materials and information made available under informational or training programs conducted under subsection (a).

(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, $1,500,000 for fiscal year 1991, and such sums as may be necessary in each of the fiscal years 1992 through 1995.

**SEC. 2673. [300ff–73] RESEARCH, EVALUATION, AND ASSESSMENT PROGRAM.**

(a) ESTABLISHMENT.—The Secretary, acting through the Director of the Agency for Healthcare Research and Quality, shall establish a program to enable independent research to be conducted by individuals and organizations with appropriate expertise in the fields of health, health policy, and economics (particularly health care economics) to develop—

(1) a comparative assessment of the impact and cost-effectiveness of major models for organizing and delivering HIV-related health care, mental health care, early intervention, and support services, that shall include a report concerning patient outcomes, satisfaction, perceived quality of care, and total cumulative cost, and a review of the appropriateness of such models for the delivery of health and support services to infants, children, women, and families with HIV disease;

(2) through a review of private sector financing mechanisms for the delivery of HIV-related health and support services, an assessment of strategies for maintaining private health benefits for individuals with HIV disease and an assessment of specific business practices or regulatory barriers that could serve to reduce access to private sector benefit programs;

(3) an assessment of the manner in which different points-of-entry to the health care system affect the cost, quality, and outcome of the care and treatment of individuals and families with HIV disease; and

(4) a summary report concerning the major and continuing unmet needs in health care, mental health care, early intervention, and support services for individuals and families with HIV disease in urban and rural areas.

(b) REPORT.—Not later than 2 years after the date of enactment of this title, and periodically thereafter, the Secretary shall 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 progress report that contains the findings and assessments developed under subsection (a).

(c) 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 1991 through 1995.

**SEC. 2674. [300ff–74] EVALUATIONS AND REPORTS.**

(a) EVALUATIONS.—The Secretary shall, directly or through grants and contracts, evaluate programs carried out under this title.

(b) REPORT TO CONGRESS.—The Secretary shall, not later than October 1, 1996, and annually thereafter, prepare and submit to the appropriate Committees of Congress a report—

(1) evaluating the programs carried out under this title; and

(2) making such recommendations for administrative and legislative initiatives with respect to this title as the Secretary determines to be appropriate.

(c) 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.

(d) ALLOCATION OF FUNDS.—The Secretary shall carry out this section with amounts available under section 241. Such amounts are in addition to any other amounts that are available to the Secretary for such purpose.

**SEC. 2675. [300ff–75] 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 to enhance the continuity of care and prevention services for individuals with HIV disease 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 support.

(b)[1] 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 disease or those at risk of such disease.

(c) INTEGRATION BY STATE.—As a condition of receipt of funds under this title, a State shall assure the Secretary that health support services funded under this title will be integrated with each other, that programs will be coordinated with other available programs (including Medicaid) and that the continuity of care and prevention services of individuals with HIV disease is enhanced.

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[1]The placement of subsection (b) is according to the probable intent of the Congress. Section 413(2) of Public Law 106–345 (114 Stat. 1350) amended section 2675 by redesignating subsections (b) and (c) as subsections (c) and (d), and then instructed that a new subsection (b) be inserted after "subsection (b)". The amendment probably should have instructed that the new subsection (b) be inserted after subsection (a).

(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 assure the Secretary that services funded under this title will be integrated with each other, 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.

(e) RECOMMENDATIONS REGARDING RELEASE OF PRISONERS.—After consultation with the Attorney General and the Director of the Bureau of Prisons, with States, with eligible areas under part A, and with entities that receive amounts from grants under part A or B, the Secretary, consistent with the coordination required in subsection (a), shall develop a plan for the medical case management of and the provision of support services to individuals who were Federal or State prisoners and had HIV disease as of the date on which the individuals were released from the custody of the penal system. The Secretary shall submit the plan to the Congress not later than 2 years after the date of the enactment of the Ryan White CARE Act Amendments of 2000.

**SEC. 2675A. [300ff–75a] AUDITS.**

For fiscal year 2002 and subsequent fiscal years, 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.

**SEC. 2675B. [300ff–75b] ADMINISTRATIVE SIMPLIFICATION REGARDING PARTS A AND B.**

(a) COORDINATED DISBURSEMENT.—After consultation with the States, with eligible areas under part A, and with entities that receive amounts from grants under part A or B, the Secretary shall develop a plan for coordinating the disbursement of appropriations for grants under part A with the disbursement of appropriations for grants under part B in order to assist grantees and other recipients of amounts from such grants in complying with the requirements of such parts. The Secretary shall submit the plan to the Congress not later than 18 months after the date of the enactment of the Ryan White CARE Act Amendments of 2000. Not later than 2 years after the date on which the plan is so submitted, the Secretary shall complete the implementation of the plan, notwithstanding any provision of this title that is inconsistent with the plan.

(b) BIENNIAL APPLICATIONS.—After consultation with the States, with eligible areas under part A, and with entities that receive amounts from grants under part A or B, the Secretary shall make a determination of whether the administration of parts A and B by the Secretary, and the efficiency of grantees under such parts in complying with the requirements of such parts, would be improved by requiring that applications for grants under such parts be submitted biennially rather than annually. The Secretary shall

submit such determination to the Congress not later than 2 years after the date of the enactment of the Ryan White CARE Act Amendments of 2000.

(c) APPLICATION SIMPLIFICATION.—After consultation with the States, with eligible areas under part A, and with entities that receive amounts from grants under part A or B, the Secretary shall develop a plan for simplifying the process for applications under parts A and B. The Secretary shall submit the plan to the Congress not later than 18 months after the date of the enactment of the Ryan White CARE Act Amendments of 2000. Not later than 2 years after the date on which the plan is so submitted, the Secretary shall complete the implementation of the plan, notwithstanding any provision of this title that is inconsistent with the plan.

**SEC. 2676. [300ff–76] DEFINITIONS.**

For purposes of this title:

(1) COUNSELING.—The term "counseling" means such counseling provided by an individual trained to provide such counseling.

(2) DESIGNATED OFFICER OF EMERGENCY RESPONSE EMPLOYEES.—The term "designated officer of emergency response employees" means an individual designated under section 2686 by the public health officer of the State involved.

(3) EMERGENCY.—The term "emergency" means an emergency involving injury or illness.

(4) EMERGENCY RESPONSE EMPLOYEE.—The term "emergency response employees" means firefighters, law enforcement officers, paramedics, emergency medical technicians, funeral-service practitioners, and other individuals (including employees of legally organized and recognized volunteer organizations, without regard to whether such employees receive nominal compensation) who, in the course of professional duties, respond to emergencies in the geographic area involved.

(5) EMPLOYER OF EMERGENCY RESPONSE EMPLOYEES.—The term "employer of emergency response employees" means an organization that, in the course of professional duties, responds to emergencies in the geographic area involved.

(6) EXPOSED.—The term "exposed", with respect to HIV disease or any other infectious disease, means to be in circumstances in which there is a significant risk of becoming infected with the etiologic agent for the disease involved.

(7) FAMILIES WITH HIV DISEASE.—The term "families with HIV disease" means families in which one or more members have HIV disease.

(8) HIV.—The term "HIV" means infection with the etiologic agent for acquired immune deficiency syndrome.

(9) HIV DISEASE.—The term "HIV disease" means infection with the etiologic agent for acquired immune deficiency syndrome, and includes any condition arising from such syndrome.

(10) 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.

(11) 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.

(12) STATE.—The term "State", except as otherwise specifically provided, means each of the 50 States, the District of Columbia, the Virgin Islands, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, Puerto Rico, and the Republic of the Marshall Islands.

**SEC. 2677. [300ff–77] AUTHORIZATION OF APPROPRIATIONS.[1]**

(a) PART A.—For the purpose of carrying out part A, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005.

(b) PART B.—For the purpose of carrying out part B, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005.

**SEC. 2678. [300ff–78] PROHIBITION ON PROMOTION OF CERTAIN ACTIVITIES.**

None of the funds authorized 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.

## PART E—EMERGENCY RESPONSE EMPLOYEES

### Subpart I—Guidelines and Model Curriculum

**SEC. 2680. [300ff–80] GRANTS FOR IMPLEMENTATION.**

(a) IN GENERAL.—With respect to the recommendations contained in the guidelines and the model curriculum developed under section 253 of Public Law 100-607, the Secretary shall make grants to States and political subdivisions of States for the purpose of assisting grantees regarding the initial implementation of such portions of the recommendations as are applicable to emergency response employees.

(b) 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.

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[1] Section 11 of Public Law 104–146 (110 Stat. 1373) provides as follows:
"Notwithstanding any other provision of law, the total amounts of Federal funds expended in any fiscal year for AIDS and HIV activities may not exceed the total amounts expended in such fiscal year for activities related to cancer.".

(c) 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 1991 through 1995.

## Subpart II—Notifications of Possible Exposure to Infectious Diseases

### SEC. 2681. [300ff–81] INFECTIOUS DISEASES AND CIRCUMSTANCES RELEVANT TO NOTIFICATION REQUIREMENTS.

(a) IN GENERAL.—Not later than 180 days after the date of the enactment of the Ryan White Comprehensive AIDS Resources Emergency Act of 1990, the Secretary shall complete the development of—

(1) a list of potentially life-threatening 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 2683(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. 2682. [300ff–82] 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), 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. 2683. [300ff–83] REQUEST FOR NOTIFICATIONS 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 2681(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 2681(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 2681(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 subpart 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 med-

ical 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 paragraph (1), 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. 2684. [300ff–84] PROCEDURES FOR NOTIFICATION OF EXPOSURE.**

(a) CONTENTS OF NOTIFICATION TO OFFICER.—In making a notification required under section 2682 or section 2683(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 2682 or section 2683(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 notifica-

tion has been sent, inform such medical facility whether the designated officer has received the notification.

**SEC. 2685. [300ff–85] NOTIFICATION OF EMPLOYEE.**

(a) IN GENERAL.—After receiving a notification for purposes of section 2682 or 2683(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 2683, 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. 2686. [300ff–86] SELECTION OF DESIGNATED OFFICERS.**

(a) IN GENERAL.—For the purposes of receiving notifications and responses and making requests under this subpart 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. 2687. [300ff–87] LIMITATIONS WITH RESPECT TO DUTIES OF MEDICAL FACILITIES.**

The duties established in this subpart 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 2683(c) received by a medical facility before the expiration of such 30-day period.

**SEC. 2688. [300ff–88] RULES OF CONSTRUCTION.**

(a) LIABILITY OF MEDICAL FACILITIES AND DESIGNATED OFFICERS.—This subpart may not be construed to authorize any cause

of action for damages or any civil penalty against any medical facility, or any designated officer, for failure to comply with the duties established in this subpart.

(b) TESTING.—This subpart 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 subpart 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 subpart may not be construed to authorize any emergency response employee to fail to respond, or to deny services, to any victim of an emergency.

**SEC. 2689. [300ff–89] 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 subpart.

(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 subpart. As appropriate, the Secretary shall investigate alleged such violations and seek appropriate injunctive relief.

**SEC. 2690. [300ff–90] APPLICABILITY OF SUBPART.**

This subpart 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 in substantial compliance with this subpart.

# 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 of this title for each fiscal year, the Secretary shall use the greater of $20,000,000 or 3 percent of such amount appropriated under each such part, but not to exceed $25,000,000, to administer a special projects of national significance program to award direct grants to public and nonprofit private entities including community-based organizations to fund special programs for the care and treatment of individuals with HIV disease.

(b) GRANTS.—The Secretary shall award grants under subsection (a) based on—

(1) the need to assess the effectiveness of a particular model for the care and treatment of individuals with HIV disease;

(2) the innovative nature of the proposed activity; and

(3) the potential replicability of the proposed activity in other similar localities or nationally.

(c) SPECIAL PROJECTS.—Special projects of national significance shall include the development and assessment of innovative service delivery models that are designed to—

(1) address the needs of special populations;

(2) assist in the development of essential community-based service delivery infrastructure; and

(3) ensure the ongoing availability of services for Native American communities to enable such communities to care for Native Americans with HIV disease.

(d) SPECIAL POPULATIONS.—Special projects of national significance may include the delivery of HIV health care and support services to traditionally underserved populations including—

(1) individuals and families with HIV disease living in rural communities;

(2) adolescents with HIV disease;

(3) Indian individuals and families with HIV disease;

(4) homeless individuals and families with HIV disease;

(5) hemophiliacs with HIV disease; and

(6) incarcerated individuals with HIV disease.

(e) SERVICE DEVELOPMENT GRANTS.—Special projects of national significance may include the development of model approaches to delivering HIV care and support services including—

(1) programs that support family-based care networks and programs that build organizational capacity critical to the delivery of care in minority communities;

(2) programs designed to prepare AIDS service organizations and grantees under this title for operation within the changing health care environment; and

(3) programs designed to integrate the delivery of mental health and substance abuse treatment with HIV services.

(f) 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.

(g) REPLICATION.—The Secretary shall make information concerning successful models 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 from 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 disease, 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 disease;

(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 disease;

(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 disease, 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 with HIV disease and other individuals who are at high risk of contracting such disease; and

(B) train, or result in the training of, minority health professionals and minority allied health professionals to provide treatment for individuals with such disease.

(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 disease.

(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 [1] 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 disease 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 disease 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 disease 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 grants under subsection (a), there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005.

(2) DENTAL SCHOOLS.—

(A) IN GENERAL.—For the purpose of grants under paragraphs (1) through (4) of subsection (b), there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005.

(B) COMMUNITY-BASED CARE.—For the purpose of grants under subsection (b)(5), there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005.

[1] So in law. See section 402(b)(2) of Public Law 106–345 (114 Stat. 1349).

# TITLE XXVII—REQUIREMENTS RELATING TO HEALTH INSURANCE COVERAGE

## PART A—GROUP MARKET REFORMS [1]

### 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

[1] Section 102(c) of Public Law 104–191 (110 Stat. 1976) provides in part as follows:
"(c) EFFECTIVE DATE.—
"(1) IN GENERAL.—Except as provided in this subsection, part A of title XXVII of the Public Health Service Act (as added by subsection (a)) shall apply with respect to group health plans, and health insurance coverage offered in connection with group health plans, for plan years beginning after June 30, 1997.".
Paragraph (2) of such section 102(c) relates to the determination of creditable coverage, including provisions regarding certifications.

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).

(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 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.

(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; 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.

## Subpart 2—Other Requirements [1]

### SEC. 2704. [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

(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.

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[1] Section 604(a)(3) of Public Law 104–204 (110 Stat. 2939) adds this subpart to part A. Subsection (c) of section 604 provides as follows:

(c) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to group health plans for plan years beginning on or after January 1, 1998.

(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. 2705. [300gg–5] PARITY IN THE APPLICATION OF CERTAIN LIMITS TO MENTAL HEALTH BENEFITS.[1]**

(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 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 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 benefits and not distinguish in the application of such limit between such medical and surgical benefits and mental health benefits; or

(ii) not include any aggregate lifetime limit on mental health 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 life-

[1] Section 703(a) of Public Law 104–204 (110 Stat. 2947) adds this section to subpart 2. Subsection (b) of such section provides as follows:

(b) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to group health plans for plan years beginning on or after January 1, 1998.

time 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 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 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 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 benefits and not distinguish in the application of such limit between such medical and surgical benefits and mental health benefits; or

(ii) not include any annual limit on mental health 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 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.

(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 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 benefits, as affecting the terms and conditions (including cost sharing, limits on numbers of visits or days of coverage, and requirements relating to medical necessity) relating to the amount, duration, or scope of mental health benefits under the plan or coverage, except as specifically provided in subsection (a) (in regard to parity in the imposition of aggregate lifetime limits and annual limits for mental health benefits).

(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.

(2) INCREASED COST EXEMPTION.—This section shall not apply with respect to a group health plan (or health insurance coverage offered in connection with a group health plan) if the application of this section to such plan (or to such coverage) results in an increase in the cost under the plan (or for such coverage) of at least 1 percent.

(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 benefits.

(4) MENTAL HEALTH BENEFITS.—The term "mental health benefits" means benefits with respect to mental health services, as defined under the terms of the plan or coverage (as the case may be), but does not include benefits with respect to treatment of substance abuse or chemical dependency.

(f) SUNSET.—This section shall not apply to benefits for services furnished after December 31, 2005.

**SEC. 2706. [300gg–6] REQUIRED COVERAGE FOR RECONSTRUCTIVE SURGERY FOLLOWING MASTECTOMIES.[1]**

The provisions of section 713 of the Employee Retirement Income Security Act of 1974 shall apply to group health plans, and

[1] 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

health insurance issuers providing health insurance coverage in connection with group health plans, as if included in this subpart.

Subpart 3—Provisions Applicable Only to Health Insurance Issuers

**SEC. 2711. [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 in-

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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.

clude 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 coverage 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. 2712. [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. 2713. [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. 2721. [300gg–21] EXCLUSION OF CERTAIN PLANS.[1]**

(a) EXCEPTION FOR CERTAIN SMALL GROUP HEALTH PLANS.—The requirements of subparts 1 and 3[1] 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.—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.

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[1] Section 604(b) of Public Law 104–204 (110 Stat. 2940) provided that various provisions of section 2721 are amended by striking "subparts 1 and 2" and inserting "subparts 1 and 3". Subsection (c) of such section provides as follows:

(c) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to group health plans for plan years beginning on or after January 1, 1998.

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).

(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. 2722. [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 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.

**SEC. 2723. [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)[1] substitutes for the reference to "6-month period" in section 2701(a)(1) a reference to any shorter period of time;

(ii)[1] substitutes for the reference to "12 months" and "18 months" in section 2701(a)(2) a reference to any shorter period of time;

(iii)[1] 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)[1] substitutes for the reference to "30-day period" in sections 2701(b)(2) and 2701(d)(1) a reference to any greater period;

(v)[1] 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)[1] requires special enrollment periods in addition to those required under section 2701(f); or

(vii)[1] 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)[2] 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 applica-

[1] 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).

[2] Section 604(b)(2) of Public Law 104–204 (110 Stat. 2941) inserted "(other than section 2704)" after "part". Subsection (c) of such section provides as follows:

(c) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to group health plans for plan years beginning on or after January 1, 1998.

ble 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.

## PART B—INDIVIDUAL MARKET RULES [1]

### 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 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;

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[1] 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.

(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 eligi-

ble 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)[1] MARKET REQUIREMENTS.—

(1) IN GENERAL.—The provisions of subsection (a) shall not be construed to require that a health insurance issuer offering 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)[1] 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

[1] 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).

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 associations, 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] PROMOTION OF QUALIFIED HIGH RISK POOLS.**

(a) SEED GRANTS TO STATES.—The Secretary shall provide from the funds appropriated under subsection (c)(1) 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 the enactment of this section for the State's costs of creation and initial operation of such a pool.

(b) MATCHING FUNDS FOR OPERATION OF POOLS.—

(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 150 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 after the end of fiscal year 2004 in connection with operation of the pool;

the Secretary shall provide, from the funds appropriated under subsection (c)(2) and allotted to the State under paragraph (2), a grant of up to 50 percent of the losses incurred by the State in connection with the operation of the pool.

(2) ALLOTMENT.—The amounts appropriated under subsection (c)(2) for a fiscal year shall be made available to the States in accordance with a formula that is based upon the number of uninsured individuals in the States.

(c) FUNDING.—Out of any money in the Treasury of the United States not otherwise appropriated, there are authorized and appropriated—

(1) $20,000,000 for fiscal year 2003 to carry out subsection (a); and

(2) $40,000,000 for each of fiscal years 2003 and 2004 to carry out subsection (b).

Funds appropriated under this subsection for a fiscal year shall remain available for obligation through the end of the following fiscal year. Nothing in this section shall be construed as providing a State with an entitlement to a grant under this section.

(d) QUALIFIED HIGH RISK POOL AND STATE DEFINED.—For purposes of this section, the term "qualified high risk pool" has the meaning given such term in section 2744(c)(2) and the term "State" means any of the 50 States and the District of Columbia.

## Subpart 3—Other Requirements [1]

**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.

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[1] So in law. Probably should be designated as subpart 2. See paragraphs (3) and (4) of section 605(a) of Public Law 104–204 (110 Stat. 2941).

Regarding the effective date for the subpart, section 605(c) of such Public Law provides as follows:

(c) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market on or after January 1, 1998.

(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.[1]**

The provisions of section 2706 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.

## Subpart 3—General Provisions[2]

**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 under section 2722(b)(2) 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.**

(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 indi-

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[1] 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:

"(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.

[2] Section 605(a)(3) of Public Law 104–204 (110 Stat. 2941) adds this subpart designation and heading to part B.

vidual market to provide specific benefits under the terms of such coverage.

**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.

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 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) 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.

(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.

(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 employees on business days during the preceding calendar year and who employs at least 2 employees on the first day of the plan year.

(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) 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.

(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.

(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.

# TITLE XXVIII—NATIONAL PREPAREDNESS FOR BIOTERRORISM AND OTHER PUBLIC HEALTH EMERGENCIES

## Subtitle A—National Preparedness and Response Planning, Coordinating, and Reporting

**SEC. 2801. [300hh] NATIONAL PREPAREDNESS PLAN.**

(a) IN GENERAL.—

(1) PREPAREDNESS AND RESPONSE REGARDING PUBLIC HEALTH EMERGENCIES.—The Secretary shall further develop and implement a coordinated strategy, building upon the core public health capabilities established pursuant to section 319A, for carrying out health-related activities to prepare for and respond effectively to bioterrorism and other public health emergencies, including the preparation of a plan under this section. The Secretary shall periodically thereafter review and, as appropriate, revise the plan.

(2) NATIONAL APPROACH.—In carrying out paragraph (1), the Secretary shall collaborate with the States toward the goal of ensuring that the activities of the Secretary regarding bioterrorism and other public health emergencies are coordinated with activities of the States, including local governments.

(3) EVALUATION OF PROGRESS.—The plan under paragraph (1) shall provide for specific benchmarks and outcome measures for evaluating the progress of the Secretary and the States, including local governments, with respect to the plan under paragraph (1), including progress toward achieving the goals specified in subsection (b).

(b) PREPAREDNESS GOALS.—The plan under subsection (a) should include provisions in furtherance of the following:

(1) Providing effective assistance to State and local governments in the event of bioterrorism or other public health emergency.

(2) Ensuring that State and local governments have appropriate capacity to detect and respond effectively to such emergencies, including capacities for the following:

(A) Effective public health surveillance and reporting mechanisms at the State and local levels.

(B) Appropriate laboratory readiness.

(C) Properly trained and equipped emergency response, public health, and medical personnel.

(D) Health and safety protection of workers responding to such an emergency.

(E) Public health agencies that are prepared to coordinate health services (including mental health services) during and after such emergencies.

(F) Participation in communications networks that can effectively disseminate relevant information in a timely and secure manner to appropriate public and private entities and to the public.

(3) Developing and maintaining medical countermeasures (such as drugs, vaccines and other biological products, medical devices, and other supplies) against biological agents and toxins that may be involved in such emergencies.

(4) Ensuring coordination and minimizing duplication of Federal, State, and local planning, preparedness, and response activities, including during the investigation of a suspicious disease outbreak or other potential public health emergency.

(5) Enhancing the readiness of hospitals and other health care facilities to respond effectively to such emergencies.

(c) REPORTS TO CONGRESS.—

(1) IN GENERAL.—Not later than one year after the date of the enactment of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, and biennially thereafter, the Secretary 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 concerning progress with respect to the plan under subsection (a), including progress toward achieving the goals specified in subsection (b).

(2) ADDITIONAL AUTHORITY.—Reports submitted under paragraph (1) by the Secretary (other than the first report) shall make recommendations concerning—

(A) any additional legislative authority that the Secretary determines is necessary for fully implementing the plan under subsection (a), including meeting the goals under subsection (b); and

(B) any additional legislative authority that the Secretary determines is necessary under section 319 to protect the public health in the event of an emergency described in section 319(a).

(d) RULE OF CONSTRUCTION.—This section may not be construed as expanding or limiting any of the authorities of the Secretary that, on the day before the date of the enactment of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, were in effect with respect to preparing for and responding effectively to bioterrorism and other public health emergencies.

# Subtitle B—Emergency Preparedness and Response

**SEC. 2811. [300hh–11] COORDINATION OF PREPAREDNESS FOR AND RESPONSE TO BIOTERRORISM AND OTHER PUBLIC HEALTH EMERGENCIES.**

(a) ASSISTANT SECRETARY FOR PUBLIC HEALTH EMERGENCY PREPAREDNESS.—

(1) IN GENERAL.—There is established within the Department of Health and Human Services the position of Assistant Secretary for Public Health Emergency Preparedness. The President shall appoint an individual to serve in such position. Such Assistant Secretary shall report to the Secretary.

(2) DUTIES.—Subject to the authority of the Secretary, the Assistant Secretary for Public Health Emergency Preparedness shall carry out the following duties with respect to bioterrorism and other public health emergencies:

(A) Coordinate on behalf of the Secretary—

(i) interagency interfaces between the Department of Health and Human Services (referred to in this paragraph as the "Department") and other departments, agencies, and offices of the United States; and

(ii) interfaces between the Department and State and local entities with responsibility for emergency preparedness.

(B) Coordinate the operations of the National Disaster Medical System and any other emergency response activities within the Department of Health and Human Services that are related to bioterrorism and other public health emergencies.

(C) Coordinate the efforts of the Department to bolster State and local emergency preparedness for a bioterrorist attack or other public health emergency, and evaluate the progress of such entities in meeting the benchmarks and other outcome measures contained in the national plan and in meeting the core public health capabilities established pursuant to 319A.

(D) Any other duties determined appropriate by the Secretary.

(b) 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 Public Health Emergency Preparedness 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 Federal Emergency Management Agency, 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 (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) TEST FOR MOBILIZATION OF SYSTEM.—During the one-year period beginning on the date of the enactment of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 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.

(c) CRITERIA.—

(1) IN GENERAL.—The Secretary shall establish criteria for the operation of the National Disaster Medical System.

(2) 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 criteria 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 (b)(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.

(d) 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 Public Health Emergency Preparedness or a comparable official of any Federal agency specified in subsection (b)(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).

(e) 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 (d).

(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 (d) in training programs authorized by the Assistant Secretary for Public Health Emergency Preparedness or a comparable official of any Federal agency specified in subsection (b)(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 Public Health Emergency Preparedness or a comparable official of any Federal agency specified in subsection (b)(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.

(f) 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).

(g) 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 (b)(3)(A).

(h) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of providing for the Assistant Secretary for Public Health Emergency Preparedness and the operations of the National Disaster Medical System, other than purposes for which amounts in the Public Health Emergency Fund under section 319 are available, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2002 through 2006.

# DEVELOPMENTAL DISABILITIES ASSISTANCE AND BILL OF RIGHTS ACT OF 2000

# DEVELOPMENTAL DISABILITIES ASSISTANCE AND BILL OF RIGHTS ACT OF 2000 [1]

**(References in black brackets [ ] are to title 42, United States Code)**

**SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

(a) [15001 note] SHORT TITLE.—This Act may be cited as the "Developmental Disabilities Assistance and Bill of Rights Act of 2000".

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:


Sec. 1. Short title; table of contents.

TITLE I—PROGRAMS FOR INDIVIDUALS WITH DEVELOPMENTAL DISABILITIES

Subtitle A—General Provisions

Sec. 101. Findings, purposes, and policy.
Sec. 102. Definitions.
Sec. 103. Records and audits.
Sec. 104. Responsibilities of the Secretary.
Sec. 105. Reports of the Secretary.
Sec. 106. State control of operations.
Sec. 107. Employment of individuals with disabilities.
Sec. 108. Construction.
Sec. 109. Rights of individuals with developmental disabilities.

Subtitle B—Federal Assistance to State Councils on Developmental Disabilities

Sec. 121. Purpose.
Sec. 122. State allotments.
Sec. 123. Payments to the States for planning, administration, and services.
Sec. 124. State plan.
Sec. 125. State Councils on Developmental Disabilities and designated State agencies.
Sec. 126. Federal and non-Federal share.
Sec. 127. Withholding of payments for planning, administration, and services.
Sec. 128. Appeals by States.
Sec. 129. Authorization of appropriations.

Subtitle C—Protection and Advocacy of Individual Rights

Sec. 141. Purpose.
Sec. 142. Allotments and payments.
Sec. 143. System required.
Sec. 144. Administration.
Sec. 145. Authorization of appropriations.

Subtitle D—National Network of University Centers for Excellence in Developmental Disabilities Education, Research, and Service

Sec. 151. Grant authority.
Sec. 152. Grant awards.
Sec. 153. Purpose and scope of activities.
Sec. 154. Applications.
Sec. 155. Definition.
Sec. 156. Authorization of appropriations.


[1] Public Law 106–402 (114 Stat. 1677). (Section 401(a) of such Public Law repealed the Developmental Disabilities Assistance and Bill of Rights Act (42 U.S.C. 6000 et seq.), which was title I of Public Law 88–164, as added by section 2 of Public Law 98–527.)

Subtitle E—Projects of National Significance

Sec. 161. Purpose.
Sec. 162. Grant authority.
Sec. 163. Authorization of appropriations.

TITLE II—FAMILY SUPPORT

Sec. 201. Short title.
Sec. 202. Findings, purposes, and policy.
Sec. 203. Definitions and special rule.
Sec. 204. Grants to States.
Sec. 205. Application.
Sec. 206. Designation of the lead entity.
Sec. 207. Authorized activities.
Sec. 208. Reporting.
Sec. 209. Technical assistance.
Sec. 210. Evaluation.
Sec. 211. Projects of national significance.
Sec. 212. Authorization of appropriations.

TITLE III—PROGRAM FOR DIRECT SUPPORT WORKERS WHO ASSIST INDIVIDUALS WITH DEVELOPMENTAL DISABILITIES

Sec. 301. Findings.
Sec. 302. Definitions.
Sec. 303. Reaching up scholarship program.
Sec. 304. Staff development curriculum authorization.
Sec. 305. Authorization of appropriations.

TITLE IV—REPEAL

Sec. 401. Repeal.

# TITLE I—PROGRAMS FOR INDIVIDUALS WITH DEVELOPMENTAL DISABILITIES

## Subtitle A—General Provisions

**SEC. 101. [15001] FINDINGS, PURPOSES, AND POLICY.**

(a) FINDINGS.—Congress finds that—

(1) disability is a natural part of the human experience that does not diminish the right of individuals with developmental disabilities to live independently, to exert control and choice over their own lives, and to fully participate in and contribute to their communities through full integration and inclusion in the economic, political, social, cultural, and educational mainstream of United States society;

(2) in 1999, there were between 3,200,000 and 4,500,000 individuals with developmental disabilities in the United States, and recent studies indicate that individuals with developmental disabilities comprise between 1.2 and 1.65 percent of the United States population;

(3) individuals whose disabilities occur during their developmental period frequently have severe disabilities that are likely to continue indefinitely;

(4) individuals with developmental disabilities often encounter discrimination in the provision of critical services, such as services in the areas of emphasis (as defined in section 102);

(5) individuals with developmental disabilities are at greater risk than the general population of abuse, neglect,

financial and sexual exploitation, and the violation of their legal and human rights;

(6) a substantial portion of individuals with developmental disabilities and their families do not have access to appropriate support and services, including access to assistive technology, from generic and specialized service systems, and remain unserved or underserved;

(7) individuals with developmental disabilities often require lifelong community services, individualized supports, and other forms of assistance, that are most effective when provided in a coordinated manner;

(8) there is a need to ensure that services, supports, and other assistance are provided in a culturally competent manner, that ensures that individuals from racial and ethnic minority backgrounds are fully included in all activities provided under this title;

(9) family members, friends, and members of the community can play an important role in enhancing the lives of individuals with developmental disabilities, especially when the family members, friends, and community members are provided with the necessary community services, individualized supports, and other forms of assistance;

(10) current research indicates that 88 percent of individuals with developmental disabilities live with their families or in their own households;

(11) many service delivery systems and communities are not prepared to meet the impending needs of the 479,862 adults with developmental disabilities who are living at home with parents who are 60 years old or older and who serve as the primary caregivers of the adults;

(12) in almost every State, individuals with developmental disabilities are waiting for appropriate services in their communities, in the areas of emphasis;

(13) the public needs to be made more aware of the capabilities and competencies of individuals with developmental disabilities, particularly in cases in which the individuals are provided with necessary services, supports, and other assistance;

(14) as increasing numbers of individuals with developmental disabilities are living, learning, working, and participating in all aspects of community life, there is an increasing need for a well trained workforce that is able to provide the services, supports, and other forms of direct assistance required to enable the individuals to carry out those activities;

(15) there needs to be greater effort to recruit individuals from minority backgrounds into professions serving individuals with developmental disabilities and their families;

(16) the goals of the Nation properly include a goal of providing individuals with developmental disabilities with the information, skills, opportunities, and support to—

(A) make informed choices and decisions about their lives;

(B) live in homes and communities in which such individuals can exercise their full rights and responsibilities as citizens;

(C) pursue meaningful and productive lives;

(D) contribute to their families, communities, and States, and the Nation;

(E) have interdependent friendships and relationships with other persons;

(F) live free of abuse, neglect, financial and sexual exploitation, and violations of their legal and human rights; and

(G) achieve full integration and inclusion in society, in an individualized manner, consistent with the unique strengths, resources, priorities, concerns, abilities, and capabilities of each individual; and

(17) as the Nation, States, and communities maintain and expand community living options for individuals with developmental disabilities, there is a need to evaluate the access to those options by individuals with developmental disabilities and the effects of those options on individuals with developmental disabilities.

(b) PURPOSE.—The purpose of this title is to assure that individuals with developmental disabilities and their families participate in the design of and have access to needed community services, individualized supports, and other forms of assistance that promote self-determination, independence, productivity, and integration and inclusion in all facets of community life, through culturally competent programs authorized under this title, including specifically—

(1) State Councils on Developmental Disabilities in each State to engage in advocacy, capacity building, and systemic change activities that—

(A) are consistent with the purpose described in this subsection and the policy described in subsection (c); and

(B) contribute to a coordinated, consumer- and family-centered, consumer- and family-directed, comprehensive system that includes needed community services, individualized supports, and other forms of assistance that promote self-determination for individuals with developmental disabilities and their families;

(2) protection and advocacy systems in each State to protect the legal and human rights of individuals with developmental disabilities;

(3) University Centers for Excellence in Developmental Disabilities Education, Research, and Service—

(A) to provide interdisciplinary pre-service preparation and continuing education of students and fellows, which may include the preparation and continuing education of leadership, direct service, clinical, or other personnel to strengthen and increase the capacity of States and communities to achieve the purpose of this title;

(B) to provide community services—

(i) that provide training and technical assistance for individuals with developmental disabilities, their

families, professionals, paraprofessionals, policymakers, students, and other members of the community; and

(ii) that may provide services, supports, and assistance for the persons described in clause (i) through demonstration and model activities;

(C) to conduct research, which may include basic or applied research, evaluation, and the analysis of public policy in areas that affect or could affect, either positively or negatively, individuals with developmental disabilities and their families; and

(D) to disseminate information related to activities undertaken to address the purpose of this title, especially dissemination of information that demonstrates that the network authorized under this subtitle is a national and international resource that includes specific substantive areas of expertise that may be accessed and applied in diverse settings and circumstances; and

(4) funding for—

(A) national initiatives to collect necessary data on issues that are directly or indirectly relevant to the lives of individuals with developmental disabilities;

(B) technical assistance to entities who engage in or intend to engage in activities consistent with the purpose described in this subsection or the policy described in subsection (c); and

(C) other nationally significant activities.

(c) POLICY.—It is the policy of the United States that all programs, projects, and activities receiving assistance under this title shall be carried out in a manner consistent with the principles that—

(1) individuals with developmental disabilities, including those with the most severe developmental disabilities, are capable of self-determination, independence, productivity, and integration and inclusion in all facets of community life, but often require the provision of community services, individualized supports, and other forms of assistance;

(2) individuals with developmental disabilities and their families have competencies, capabilities, and personal goals that should be recognized, supported, and encouraged, and any assistance to such individuals should be provided in an individualized manner, consistent with the unique strengths, resources, priorities, concerns, abilities, and capabilities of such individuals;

(3) individuals with developmental disabilities and their families are the primary decisionmakers regarding the services and supports such individuals and their families receive, including regarding choosing where the individuals live from available options, and play decisionmaking roles in policies and programs that affect the lives of such individuals and their families;

(4) services, supports, and other assistance should be provided in a manner that demonstrates respect for individual dignity, personal preferences, and cultural differences;

(5) specific efforts must be made to ensure that individuals with developmental disabilities from racial and ethnic minority backgrounds and their families enjoy increased and meaningful opportunities to access and use community services, individualized supports, and other forms of assistance available to other individuals with developmental disabilities and their families;

(6) recruitment efforts in disciplines related to developmental disabilities relating to pre-service training, community training, practice, administration, and policymaking must focus on bringing larger numbers of racial and ethnic minorities into the disciplines in order to provide appropriate skills, knowledge, role models, and sufficient personnel to address the growing needs of an increasingly diverse population;

(7) with education and support, communities can be accessible to and responsive to the needs of individuals with developmental disabilities and their families and are enriched by full and active participation in community activities, and contributions, by individuals with developmental disabilities and their families;

(8) individuals with developmental disabilities have access to opportunities and the necessary support to be included in community life, have interdependent relationships, live in homes and communities, and make contributions to their families, communities, and States, and the Nation;

(9) efforts undertaken to maintain or expand community-based living options for individuals with disabilities should be monitored in order to determine and report to appropriate individuals and entities the extent of access by individuals with developmental disabilities to those options and the extent of compliance by entities providing those options with quality assurance standards;

(10) families of children with developmental disabilities need to have access to and use of safe and appropriate child care and before-school and after-school programs, in the most integrated settings, in order to enrich the participation of the children in community life;

(11) individuals with developmental disabilities need to have access to and use of public transportation, in order to be independent and directly contribute to and participate in all facets of community life; and

(12) individuals with developmental disabilities need to have access to and use of recreational, leisure, and social opportunities in the most integrated settings, in order to enrich their participation in community life.

**SEC. 102. [15002] DEFINITIONS.**

In this title:

(1) AMERICAN INDIAN CONSORTIUM.—The term "American Indian Consortium" means any confederation of 2 or more recognized American Indian tribes, created through the official action of each participating tribe, that has a combined total resident population of 150,000 enrolled tribal members and a contiguous territory of Indian lands in 2 or more States.

(2) AREAS OF EMPHASIS.—The term "areas of emphasis" means the areas related to quality assurance activities, education activities and early intervention activities, child care-related activities, health-related activities, employment-related activities, housing-related activities, transportation-related activities, recreation-related activities, and other services available or offered to individuals in a community, including formal and informal community supports, that affect their quality of life.

(3) ASSISTIVE TECHNOLOGY DEVICE.—The term "assistive technology device" means any item, piece of equipment, or product system, whether acquired commercially, modified or customized, that is used to increase, maintain, or improve functional capabilities of individuals with developmental disabilities.

(4) ASSISTIVE TECHNOLOGY SERVICE.—The term "assistive technology service" means any service that directly assists an individual with a developmental disability in the selection, acquisition, or use of an assistive technology device. Such term includes—

(A) conducting an evaluation of the needs of an individual with a developmental disability, including a functional evaluation of the individual in the individual's customary environment;

(B) purchasing, leasing, or otherwise providing for the acquisition of an assistive technology device by an individual with a developmental disability;

(C) selecting, designing, fitting, customizing, adapting, applying, maintaining, repairing or replacing an assistive technology device;

(D) coordinating and using another therapy, intervention, or service with an assistive technology device, such as a therapy, intervention, or service associated with an education or rehabilitation plan or program;

(E) providing training or technical assistance for an individual with a developmental disability, or, where appropriate, a family member, guardian, advocate, or authorized representative of an individual with a developmental disability; and

(F) providing training or technical assistance for professionals (including individuals providing education and rehabilitation services), employers, or other individuals who provide services to, employ, or are otherwise substantially involved in the major life functions of, an individual with developmental disabilities.

(5) CENTER.—The term "Center" means a University Center for Excellence in Developmental Disabilities Education, Research, and Service established under subtitle D.

(6) CHILD CARE-RELATED ACTIVITIES.—The term "child care-related activities" means advocacy, capacity building, and systemic change activities that result in families of children with developmental disabilities having access to and use of child care services, including before-school, after-school, and out-of-school services, in their communities.

(7) CULTURALLY COMPETENT.—The term "culturally competent", used with respect to services, supports, or other assistance, means services, supports, or other assistance that is conducted or provided in a manner that is responsive to the beliefs, interpersonal styles, attitudes, language, and behaviors of individuals who are receiving the services, supports, or other assistance, and in a manner that has the greatest likelihood of ensuring their maximum participation in the program involved.

(8) DEVELOPMENTAL DISABILITY.—

(A) IN GENERAL.—The term "developmental disability" means a severe, chronic disability of an individual that—

(i) is attributable to a mental or physical impairment or combination of mental and physical impairments;

(ii) is manifested before the individual attains age 22;

(iii) is likely to continue indefinitely;

(iv) results in substantial functional limitations in 3 or more of the following areas of major life activity:

(I) Self-care.

(II) Receptive and expressive language.

(III) Learning.

(IV) Mobility.

(V) Self-direction.

(VI) Capacity for independent living.

(VII) Economic self-sufficiency; and

(v) reflects the individual's need for a combination and sequence of special, interdisciplinary, or generic services, individualized supports, or other forms of assistance that are of lifelong or extended duration and are individually planned and coordinated.

(B) INFANTS AND YOUNG CHILDREN.—An individual from birth to age 9, inclusive, who has a substantial developmental delay or specific congenital or acquired condition, may be considered to have a developmental disability without meeting 3 or more of the criteria described in clauses (i) through (v) of subparagraph (A) if the individual, without services and supports, has a high probability of meeting those criteria later in life.

(9) EARLY INTERVENTION ACTIVITIES.—The term "early intervention activities" means advocacy, capacity building, and systemic change activities provided to individuals described in paragraph (8)(B) and their families to enhance—

(A) the development of the individuals to maximize their potential; and

(B) the capacity of families to meet the special needs of the individuals.

(10) EDUCATION ACTIVITIES.—The term "education activities" means advocacy, capacity building, and systemic change activities that result in individuals with developmental disabilities being able to access appropriate supports and modifications when necessary, to maximize their educational potential,

to benefit from lifelong educational activities, and to be integrated and included in all facets of student life.

(11) EMPLOYMENT-RELATED ACTIVITIES.—The term "employment-related activities" means advocacy, capacity building, and systemic change activities that result in individuals with developmental disabilities acquiring, retaining, or advancing in paid employment, including supported employment or self-employment, in integrated settings in a community.

(12) FAMILY SUPPORT SERVICES.—

(A) IN GENERAL.—The term "family support services" means services, supports, and other assistance, provided to families with members who have developmental disabilities, that are designed to—

(i) strengthen the family's role as primary caregiver;

(ii) prevent inappropriate out-of-the-home placement of the members and maintain family unity; and

(iii) reunite families with members who have been placed out of the home whenever possible.

(B) SPECIFIC SERVICES.—Such term includes respite care, provision of rehabilitation technology and assistive technology, personal assistance services, parent training and counseling, support for families headed by aging caregivers, vehicular and home modifications, and assistance with extraordinary expenses, associated with the needs of individuals with developmental disabilities.

(13) HEALTH-RELATED ACTIVITIES.—The term "health-related activities" means advocacy, capacity building, and systemic change activities that result in individuals with developmental disabilities having access to and use of coordinated health, dental, mental health, and other human and social services, including prevention activities, in their communities.

(14) HOUSING-RELATED ACTIVITIES.—The term "housing-related activities" means advocacy, capacity building, and systemic change activities that result in individuals with developmental disabilities having access to and use of housing and housing supports and services in their communities, including assistance related to renting, owning, or modifying an apartment or home.

(15) INCLUSION.—The term "inclusion", used with respect to individuals with developmental disabilities, means the acceptance and encouragement of the presence and participation of individuals with developmental disabilities, by individuals without disabilities, in social, educational, work, and community activities, that enables individuals with developmental disabilities to—

(A) have friendships and relationships with individuals and families of their own choice;

(B) live in homes close to community resources, with regular contact with individuals without disabilities in their communities;

(C) enjoy full access to and active participation in the same community activities and types of employment as individuals without disabilities; and

(D) take full advantage of their integration into the same community resources as individuals without disabilities, living, learning, working, and enjoying life in regular contact with individuals without disabilities.

(16) INDIVIDUALIZED SUPPORTS.—The term "individualized supports" means supports that—

(A) enable an individual with a developmental disability to exercise self-determination, be independent, be productive, and be integrated and included in all facets of community life;

(B) are designed to—

(i) enable such individual to control such individual's environment, permitting the most independent life possible;

(ii) prevent placement into a more restrictive living arrangement than is necessary; and

(iii) enable such individual to live, learn, work, and enjoy life in the community; and

(C) include—

(i) early intervention services;

(ii) respite care;

(iii) personal assistance services;

(iv) family support services;

(v) supported employment services;

(vi) support services for families headed by aging caregivers of individuals with developmental disabilities; and

(vii) provision of rehabilitation technology and assistive technology, and assistive technology services.

(17) INTEGRATION.—The term "integration", used with respect to individuals with developmental disabilities, means exercising the equal right of individuals with developmental disabilities to access and use the same community resources as are used by and available to other individuals.

(18) NOT-FOR-PROFIT.—The term "not-for-profit", used with respect to an agency, institution, or organization, means an agency, institution, or organization that is owned or operated by 1 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.

(19) PERSONAL ASSISTANCE SERVICES.—The term "personal assistance services" means a range of services, provided by 1 or more individuals, designed to assist an individual with a disability to perform daily activities, including activities on or off a job that such individual would typically perform if such individual did not have a disability. Such services shall be designed to increase such individual's control in life and ability to perform everyday activities, including activities on or off a job.

(20) PREVENTION ACTIVITIES.—The term "prevention activities" means activities that address the causes of developmental

disabilities and the exacerbation of functional limitation, such as activities that—

(A) eliminate or reduce the factors that cause or predispose individuals to developmental disabilities or that increase the prevalence of developmental disabilities;

(B) increase the early identification of problems to eliminate circumstances that create or increase functional limitations; and

(C) mitigate against the effects of developmental disabilities throughout the lifespan of an individual.

(21) PRODUCTIVITY.—The term "productivity" means—

(A) engagement in income-producing work that is measured by increased income, improved employment status, or job advancement; or

(B) engagement in work that contributes to a household or community.

(22) PROTECTION AND ADVOCACY SYSTEM.—The term "protection and advocacy system" means a protection and advocacy system established in accordance with section 143.

(23) QUALITY ASSURANCE ACTIVITIES.—The term "quality assurance activities" means advocacy, capacity building, and systemic change activities that result in improved consumer- and family-centered quality assurance and that result in systems of quality assurance and consumer protection that—

(A) include monitoring of services, supports, and assistance provided to an individual with developmental disabilities that ensures that the individual—

(i) will not experience abuse, neglect, sexual or financial exploitation, or violation of legal or human rights; and

(ii) will not be subject to the inappropriate use of restraints or seclusion;

(B) include training in leadership, self-advocacy, and self-determination for individuals with developmental disabilities, their families, and their guardians to ensure that those individuals—

(i) will not experience abuse, neglect, sexual or financial exploitation, or violation of legal or human rights; and

(ii) will not be subject to the inappropriate use of restraints or seclusion; or

(C) include activities related to interagency coordination and systems integration that result in improved and enhanced services, supports, and other assistance that contribute to and protect the self-determination, independence, productivity, and integration and inclusion in all facets of community life, of individuals with developmental disabilities.

(24) RECREATION-RELATED ACTIVITIES.—The term "recreation-related activities" means advocacy, capacity building, and systemic change activities that result in individuals with developmental disabilities having access to and use of recreational, leisure, and social activities, in their communities.

(25) REHABILITATION TECHNOLOGY.—The term "rehabilitation technology" means the systematic application of technologies, engineering methodologies, or scientific principles to meet the needs of, and address the barriers confronted by, individuals with developmental disabilities in areas that include education, rehabilitation, employment, transportation, independent living, and recreation. Such term includes rehabilitation engineering, and the provision of assistive technology devices and assistive technology services.

(26) SECRETARY.—The term "Secretary" means the Secretary of Health and Human Services.

(27) SELF-DETERMINATION ACTIVITIES.—The term "self-determination activities" means activities that result in individuals with developmental disabilities, with appropriate assistance, having—

(A) the ability and opportunity to communicate and make personal decisions;

(B) the ability and opportunity to communicate choices and exercise control over the type and intensity of services, supports, and other assistance the individuals receive;

(C) the authority to control resources to obtain needed services, supports, and other assistance;

(D) opportunities to participate in, and contribute to, their communities; and

(E) support, including financial support, to advocate for themselves and others, to develop leadership skills, through training in self-advocacy, to participate in coalitions, to educate policymakers, and to play a role in the development of public policies that affect individuals with developmental disabilities.

(28) STATE.—The term "State", except as otherwise provided, includes, in addition to each of the several States of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the United States Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

(29) STATE COUNCIL ON DEVELOPMENTAL DISABILITIES.—The term "State Council on Developmental Disabilities" means a Council established under section 125.

(30) SUPPORTED EMPLOYMENT SERVICES.—The term "supported employment services" means services that enable individuals with developmental disabilities to perform competitive work in integrated work settings, in the case of individuals with developmental disabilities—

(A)(i) for whom competitive employment has not traditionally occurred; or

(ii) for whom competitive employment has been interrupted or intermittent as a result of significant disabilities; and

(B) who, because of the nature and severity of their disabilities, need intensive supported employment services or extended services in order to perform such work.

(31) TRANSPORTATION-RELATED ACTIVITIES.—The term "transportation-related activities" means advocacy, capacity

building, and systemic change activities that result in individuals with developmental disabilities having access to and use of transportation.

(32) UNSERVED AND UNDERSERVED.—The term "unserved and underserved" includes populations such as individuals from racial and ethnic minority backgrounds, disadvantaged individuals, individuals with limited English proficiency, individuals from underserved geographic areas (rural or urban), and specific groups of individuals within the population of individuals with developmental disabilities, including individuals who require assistive technology in order to participate in and contribute to community life.

**SEC. 103. [15003] RECORDS AND AUDITS.**

(a) RECORDS.—Each recipient of assistance under this title shall keep such records as the Secretary shall prescribe, including—

(1) records that fully disclose—

(A) the amount and disposition by such recipient of the assistance;

(B) the total cost of the project or undertaking in connection with which such assistance is given or used; and

(C) the amount of that portion of the cost of the project or undertaking that is supplied by other sources; and

(2) such other records as will facilitate an effective audit.

(b) ACCESS.—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 assistance under this title that are pertinent to such assistance.

**SEC. 104. [15004] RESPONSIBILITIES OF THE SECRETARY.**

(a) PROGRAM ACCOUNTABILITY.—

(1) IN GENERAL.—In order to monitor entities that received funds under this Act to carry out activities under subtitles B, C, and D and determine the extent to which the entities have been responsive to the purpose of this title and have taken actions consistent with the policy described in section 101(c), the Secretary shall develop and implement an accountability process as described in this subsection, with respect to activities conducted after October 1, 2001.

(2) AREAS OF EMPHASIS.—The Secretary shall develop a process for identifying and reporting (pursuant to section 105) on progress achieved through advocacy, capacity building, and systemic change activities, undertaken by the entities described in paragraph (1), that resulted in individuals with developmental disabilities and their families participating in the design of and having access to needed community services, individualized supports, and other forms of assistance that promote self-determination, independence, productivity, and integration and inclusion in all facets of community life. Specifically, the Secretary shall develop a process for identifying and reporting on progress achieved, through advocacy, capacity building, and systemic change activities, by the entities in the areas of emphasis.

(3) INDICATORS OF PROGRESS.—

(A) IN GENERAL.—In identifying progress made by the entities described in paragraph (1) in the areas of emphasis, the Secretary, in consultation with the Commissioner of the Administration on Developmental Disabilities and the entities, shall develop indicators for each area of emphasis.

(B) PROPOSED INDICATORS.—Not later than 180 days after the date of enactment of this Act, the Secretary shall develop and publish in the Federal Register for public comment proposed indicators of progress for monitoring how entities described in paragraph (1) have addressed the areas of emphasis described in paragraph (2) in a manner that is responsive to the purpose of this title and consistent with the policy described in section 101(c).

(C) FINAL INDICATORS.—Not later than October 1, 2001, the Secretary shall revise the proposed indicators of progress, to the extent necessary based on public comment, and publish final indicators of progress in the Federal Register.

(D) SPECIFIC MEASURES.—At a minimum, the indicators of progress shall be used to describe and measure—

(i) the satisfaction of individuals with developmental disabilities with the advocacy, capacity building, and systemic change activities provided under subtitles B, C, and D;

(ii) the extent to which the advocacy, capacity building, and systemic change activities provided through subtitles B, C, and D result in improvements in—

(I) the ability of individuals with developmental disabilities to make choices and exert control over the type, intensity, and timing of services, supports, and assistance that the individuals have used;

(II) the ability of individuals with developmental disabilities to participate in the full range of community life with persons of the individuals' choice; and

(III) the ability of individuals with developmental disabilities to access services, supports, and assistance in a manner that ensures that such an individual is free from abuse, neglect, sexual and financial exploitation, violation of legal and human rights, and the inappropriate use of restraints and seclusion; and

(iii) the extent to which the entities described in paragraph (1) collaborate with each other to achieve the purpose of this title and the policy described in section 101(c).

(4) TIME LINE FOR COMPLIANCE WITH INDICATORS OF PROGRESS.—The Secretary shall require entities described in paragraph (1) to meet the indicators of progress described in paragraph (3). For fiscal year 2002 and each year thereafter,

the Secretary shall apply the indicators in monitoring entities described in paragraph (1), with respect to activities conducted after October 1, 2001.

(b) TIME LINE FOR REGULATIONS.—Except as otherwise expressly provided in this title, the Secretary, not later than 1 year after the date of enactment of this Act, shall promulgate such regulations as may be required for the implementation of this title.

(c) INTERAGENCY COMMITTEE.—

(1) IN GENERAL.—The Secretary shall maintain the interagency committee authorized in section 108 of the Developmental Disabilities Assistance and Bill of Rights Act (42 U.S.C. 6007) as in effect on the day before the date of enactment of this Act, except as otherwise provided in this subsection.

(2) COMPOSITION.—The interagency committee shall be composed of representatives of—

(A) the Administration on Developmental Disabilities, the Administration on Children, Youth, and Families, the Administration on Aging, and the Health Resources and Services Administration, of the Department of Health and Human Services; and

(B) such other Federal departments and agencies as the Secretary of Health and Human Services considers to be appropriate.

(3) DUTIES.—Such interagency committee shall meet regularly to coordinate and plan activities conducted by Federal departments and agencies for individuals with developmental disabilities.

(4) MEETINGS.—Each meeting of the interagency committee (except for any meetings of any subcommittees of the committee) shall be open to the public. Notice of each meeting, and a statement of the agenda for the meeting, shall be published in the Federal Register not later than 14 days before the date on which the meeting is to occur.

**SEC. 105. [15005] REPORTS OF THE SECRETARY.**

At least once every 2 years, the Secretary, using information submitted in the reports and information required under subtitles B, C, D, and E, shall prepare and submit to the President, Congress, and the National Council on Disability, a report that describes the goals and outcomes of programs supported under subtitles B, C, D, and E. In preparing the report, the Secretary shall provide—

(1) meaningful examples of how the councils, protection and advocacy systems, centers, and entities funded under subtitles B, C, D, and E, respectively—

(A) have undertaken coordinated activities with each other;

(B) have enhanced the ability of individuals with developmental disabilities and their families to participate in the design of and have access to needed community services, individualized supports, and other forms of assistance that promote self-determination, independence, productivity, and integration and inclusion in all facets of community life;

(C) have brought about advocacy, capacity building, and systemic change activities (including policy reform), and other actions on behalf of individuals with developmental disabilities and their families, including individuals who are traditionally unserved or underserved, particularly individuals who are members of ethnic and racial minority groups and individuals from underserved geographic areas; and

(D) have brought about advocacy, capacity building, and systemic change activities that affect individuals with disabilities other than individuals with developmental disabilities;

(2) information on the extent to which programs authorized under this title have addressed—

(A) protecting individuals with developmental disabilities from abuse, neglect, sexual and financial exploitation, and violations of legal and human rights, so that those individuals are at no greater risk of harm than other persons in the general population; and

(B) reports of deaths of and serious injuries to individuals with developmental disabilities; and

(3) a summary of any incidents of noncompliance of the programs authorized under this title with the provisions of this title, and corrections made or actions taken to obtain compliance.

**SEC. 106. [15006] STATE CONTROL OF OPERATIONS.**

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 programs, services, and supports for individuals with developmental disabilities with respect to which any funds have been or may be expended under this title.

**SEC. 107. [15007] EMPLOYMENT OF INDIVIDUALS WITH DISABILITIES.**

As a condition of providing assistance under this title, the Secretary shall require that each recipient of such assistance take affirmative action to employ and advance in employment qualified individuals with disabilities on the same terms and conditions required with respect to the employment of such individuals under the provisions of title V of the Rehabilitation Act of 1973 (29 U.S.C. 791 et seq.) and the Americans with Disabilities Act of 1990 (42 U.S.C. 12101 et seq.), that govern employment.

**SEC. 108. [15008] CONSTRUCTION.**

Nothing in this title shall be construed to preclude an entity funded under this title from engaging in advocacy, capacity building, and systemic change activities for individuals with developmental disabilities that may also have a positive impact on individuals with other disabilities.

**SEC. 109. [15009] RIGHTS OF INDIVIDUALS WITH DEVELOPMENTAL DISABILITIES.**

(a) IN GENERAL.—Congress makes the following findings respecting the rights of individuals with developmental disabilities:

(1) Individuals with developmental disabilities have a right to appropriate treatment, services, and habilitation for such disabilities, consistent with section 101(c).

(2) The treatment, services, and habitation for an individual with developmental disabilities should be designed to maximize the potential of the individual and should be provided in the setting that is least restrictive of the individual's personal liberty.

(3) The Federal Government and the States both have an obligation to ensure that public funds are provided only to institutional programs, residential programs, and other community programs, including educational programs in which individuals with developmental disabilities participate, that—

(A) provide treatment, services, and habilitation that are appropriate to the needs of such individuals; and

(B) meet minimum standards relating to—

(i) provision of care that is free of abuse, neglect, sexual and financial exploitation, and violations of legal and human rights and that subjects individuals with developmental disabilities to no greater risk of harm than others in the general population;

(ii) provision to such individuals of appropriate and sufficient medical and dental services;

(iii) prohibition of the use of physical restraint and seclusion for such an individual unless absolutely necessary to ensure the immediate physical safety of the individual or others, and prohibition of the use of such restraint and seclusion as a punishment or as a substitute for a habilitation program;

(iv) prohibition of the excessive use of chemical restraints on such individuals and the use of such restraints as punishment or as a substitute for a habilitation program or in quantities that interfere with services, treatment, or habilitation for such individuals; and

(v) provision for close relatives or guardians of such individuals to visit the individuals without prior notice.

(4) All programs for individuals with developmental disabilities should meet standards—

(A) that are designed to assure the most favorable possible outcome for those served; and

(B)(i) in the case of residential programs serving individuals in need of comprehensive health-related, habilitative, assistive technology or rehabilitative services, that are at least equivalent to those standards applicable to intermediate care facilities for the mentally retarded, promulgated in regulations of the Secretary on June 3, 1988, as appropriate, taking into account the size of the institutions and the service delivery arrangements of the facilities of the programs;

(ii) in the case of other residential programs for individuals with developmental disabilities, that assure that—

(I) care is appropriate to the needs of the individuals being served by such programs;

(II) the individuals admitted to facilities of such programs are individuals whose needs can be met through services provided by such facilities; and

(III) the facilities of such programs provide for the humane care of the residents of the facilities, are sanitary, and protect their rights; and

(iii) in the case of nonresidential programs, that assure that the care provided by such programs is appropriate to the individuals served by the programs.

(b) CLARIFICATION.—The rights of individuals with developmental disabilities described in findings made in this section shall be considered to be in addition to any constitutional or other rights otherwise afforded to all individuals.

# Subtitle B—Federal Assistance to State Councils on Developmental Disabilities

**SEC. 121. [15021] PURPOSE.**

The purpose of this subtitle is to provide for allotments to support State Councils on Developmental Disabilities (referred to individually in this subtitle as a "Council") in each State to—

(1) engage in advocacy, capacity building, and systemic change activities that are consistent with the purpose described in section 101(b) and the policy described in section 101(c); and

(2) contribute to a coordinated, consumer- and family-centered, consumer- and family-directed, comprehensive system of community services, individualized supports, and other forms of assistance that enable individuals with developmental disabilities to exercise self-determination, be independent, be productive, and be integrated and included in all facets of community life.

**SEC. 122. [15022] STATE ALLOTMENTS.**

(a) ALLOTMENTS.—

(1) IN GENERAL.—

(A) AUTHORITY.—For each fiscal year, the Secretary shall, in accordance with regulations and this paragraph, allot the sums appropriated for such year under section 129 among the States on the basis of—

(i) the population;

(ii) the extent of need for services for individuals with developmental disabilities; and

(iii) the financial need,

of the respective States.

(B) USE OF FUNDS.—Sums allotted to the States under this section shall be used to pay for the Federal share of the cost of carrying out projects in accordance with State plans approved under section 124 for the provision under such plans of services for individuals with developmental disabilities.

(2) ADJUSTMENTS.—The Secretary may make adjustments in the amounts of State allotments based on clauses (i), (ii), and (iii) of paragraph (1)(A) not more often than annually. The Secretary shall notify each State of any adjustment made under this paragraph and the percentage of the total sums appropriated under section 129 that the adjusted allotment represents not later than 6 months before the beginning of the fiscal year in which such adjustment is to take effect.

(3) MINIMUM ALLOTMENT FOR APPROPRIATIONS LESS THAN OR EQUAL TO $70,000,000.—

(A) IN GENERAL.—Except as provided in paragraph (4), for any fiscal year the allotment under this section—

(i) to each of American Samoa, Guam, the United States Virgin Islands, or the Commonwealth of the Northern Mariana Islands may not be less than $210,000; and

(ii) to any State not described in clause (i) may not be less than $400,000, the amount received by the State for the previous year, or the amount of Federal appropriations received in fiscal year 2000, 2001, or 2002, whichever is greater.

(B) REDUCTION OF ALLOTMENT.—Notwithstanding subparagraph (A), if the aggregate of the amounts to be allotted to the States pursuant to subparagraph (A) for any fiscal year exceeds the total amount appropriated under section 129 for such fiscal year, the amount to be allotted to each State for such fiscal year shall be proportionately reduced.

(4) MINIMUM ALLOTMENT FOR APPROPRIATIONS IN EXCESS OF $70,000,000.—

(A) IN GENERAL.—In any case in which the total amount appropriated under section 129 for a fiscal year is more than $70,000,000, the allotment under this section for such fiscal year—

(i) to each of American Samoa, Guam, the United States Virgin Islands, or the Commonwealth of the Northern Mariana Islands may not be less than $220,000; and

(ii) to any State not described in clause (i) may not be less than $450,000, the amount received by the State for the previous year, or the amount of Federal appropriations received in fiscal year 2000, 2001, or 2002, whichever is greater.

(B) REDUCTION OF ALLOTMENT.—The requirements of paragraph (3)(B) shall apply with respect to amounts to be allotted to States under subparagraph (A), in the same manner and to the same extent as such requirements apply with respect to amounts to be allotted to States under paragraph (3)(A).

(5) STATE SUPPORTS, SERVICES, AND OTHER ACTIVITIES.—In determining, for purposes of paragraph (1)(A)(ii), the extent of need in any State for services for individuals with developmental disabilities, the Secretary shall take into account the scope and extent of the services, supports, and assistance de-

scribed, pursuant to section 124(c)(3)(A), in the State plan of the State.

(6) INCREASE IN ALLOTMENTS.—In any year in which the total amount appropriated under section 129 for a fiscal year exceeds the total amount appropriated under such section (or a corresponding provision) for the preceding fiscal year by a percentage greater than the most recent percentage change in the Consumer Price Index published by the Secretary of Labor under section 100(c)(1) of the Rehabilitation Act of 1973 (29 U.S.C. 720(c)(1)) (if the percentage change indicates an increase), the Secretary shall increase each of the minimum allotments described in paragraphs (3) and (4). The Secretary shall increase each minimum allotment by an amount that bears the same ratio to the amount of such minimum allotment (including any increases in such minimum allotment under this paragraph (or a corresponding provision) for prior fiscal years) as the amount that is equal to the difference between—

(A) the total amount appropriated under section 129 for the fiscal year for which the increase in the minimum allotment is being made; minus

(B) the total amount appropriated under section 129 (or a corresponding provision) for the immediately preceding fiscal year,

bears to the total amount appropriated under section 129 (or a corresponding provision) for such preceding fiscal year.

(b) UNOBLIGATED FUNDS.—Any amount paid to a State for a fiscal year and remaining unobligated at the end of such year shall remain available to such State for the next fiscal year for the purposes for which such amount was paid.

(c) OBLIGATION OF FUNDS.—For the purposes of this subtitle, State Interagency Agreements are considered valid obligations for the purpose of obligating Federal funds allotted to the State under this subtitle.

(d) COOPERATIVE EFFORTS BETWEEN STATES.—If a State plan approved in accordance with section 124 provides for cooperative or joint effort between or among States or agencies, public or private, in more than 1 State, portions of funds allotted to 1 or more States described in this subsection may be combined in accordance with the agreements between the States or agencies involved.

(e) REALLOTMENTS.—

(1) IN GENERAL.—If the Secretary determines that an amount of an allotment to a State for a period (of a fiscal year or longer) will not be required by the State during the period for the purpose for which the allotment was made, the Secretary may reallot the amount.

(2) TIMING.—The Secretary may make such a reallotment from time to time, on such date as the Secretary may fix, but not earlier than 30 days after the Secretary has published notice of the intention of the Secretary to make the reallotment in the Federal Register.

(3) AMOUNTS.—The Secretary shall reallot the amount to other States with respect to which the Secretary has not made that determination. The Secretary shall reallot the amount in

proportion to the original allotments of the other States for such fiscal year, but shall reduce such proportionate amount for any of the other States to the extent the proportionate amount exceeds the sum that the Secretary estimates the State needs and will be able to use during such period.

(4) REALLOTMENT OF REDUCTIONS.—The Secretary shall similarly reallot the total of the reductions among the States whose proportionate amounts were not so reduced.

(5) TREATMENT.—Any amount reallotted to a State under this subsection for a fiscal year shall be deemed to be a part of the allotment of the State under subsection (a) for such fiscal year.

**SEC. 123. [15023] PAYMENTS TO THE STATES FOR PLANNING, ADMINISTRATION, AND SERVICES.**

(a) STATE PLAN EXPENDITURES.—From each State's allotments for a fiscal year under section 122, the Secretary shall pay to the State the Federal share of the cost, other than the cost for construction, incurred during such year for activities carried out under the State plan approved under section 124. The Secretary shall make such payments from time to time in advance on the basis of estimates by the Secretary of the sums the State will expend for the cost under the State plan. The Secretary shall make such adjustments as may be necessary to the payments on account of previously made underpayments or overpayments under this section.

(b) DESIGNATED STATE AGENCY EXPENDITURES.—The Secretary may make payments to a State for the portion described in section 124(c)(5)(B)(vi) in advance or by way of reimbursement, and in such installments as the Secretary may determine.

**SEC. 124. [15024] STATE PLAN.**

(a) IN GENERAL.—Any State desiring to receive assistance under this subtitle shall submit to the Secretary, and obtain approval of, a 5-year strategic State plan under this section.

(b) PLANNING CYCLE.—The plan described in subsection (a) shall be updated as appropriate during the 5-year period.

(c) STATE PLAN REQUIREMENTS.—In order to be approved by the Secretary under this section, a State plan shall meet each of the following requirements:

(1) STATE COUNCIL.—The plan shall provide for the establishment and maintenance of a Council in accordance with section 125 and describe the membership of such Council.

(2) DESIGNATED STATE AGENCY.—The plan shall identify the agency or office within the State designated to support the Council in accordance with this section and section 125(d) (referred to in this subtitle as a "designated State agency").

(3) COMPREHENSIVE REVIEW AND ANALYSIS.—The plan shall describe the results of a comprehensive review and analysis of the extent to which services, supports, and other assistance are available to individuals with developmental disabilities and their families, and the extent of unmet needs for services, supports, and other assistance for those individuals and their families, in the State. The results of the comprehensive review and analysis shall include—

(A) a description of the services, supports, and other assistance being provided to individuals with developmental disabilities and their families under other federally assisted State programs, plans, and policies under which the State operates and in which individuals with developmental disabilities are or may be eligible to participate, including particularly programs relating to the areas of emphasis, including—

(i) medical assistance, maternal and child health care, services for children with special health care needs, children's mental health services, comprehensive health and mental health services, and institutional care options;

(ii) job training, job placement, worksite accommodation, and vocational rehabilitation, and other work assistance programs; and

(iii) social, child welfare, aging, independent living, and rehabilitation and assistive technology services, and such other services as the Secretary may specify;

(B) a description of the extent to which agencies operating such other federally assisted State programs, including activities authorized under section 4 or 5 of the Assistive Technology Act of 1998, pursue interagency initiatives to improve and enhance community services, individualized supports, and other forms of assistance for individuals with developmental disabilities;

(C) an analysis of the extent to which community services and opportunities related to the areas of emphasis directly benefit individuals with developmental disabilities, especially with regard to their ability to access and use services provided in their communities, to participate in opportunities, activities, and events offered in their communities, and to contribute to community life, identifying particularly—

(i) the degree of support for individuals with developmental disabilities that are attributable to either physical impairment, mental impairment, or a combination of physical and mental impairments;

(ii) criteria for eligibility for services, including specialized services and special adaptation of generic services provided by agencies within the State, that may exclude individuals with developmental disabilities from receiving services described in this clause;

(iii) the barriers that impede full participation of members of unserved and underserved groups of individuals with developmental disabilities and their families;

(iv) the availability of assistive technology, assistive technology services, or rehabilitation technology, or information about assistive technology, assistive technology services, or rehabilitation technology to individuals with developmental disabilities;

(v) the numbers of individuals with developmental disabilities on waiting lists for services described in this subparagraph;

(vi) a description of the adequacy of current resources and projected availability of future resources to fund services described in this subparagraph;

(vii) a description of the adequacy of health care and other services, supports, and assistance that individuals with developmental disabilities who are in facilities receive (based in part on each independent review (pursuant to section 1902(a)(30)(C) of the Social Security Act (42 U.S.C. 1396a(a)(30)(C))) of an Intermediate Care Facility (Mental Retardation) within the State, which the State shall provide to the Council not later than 30 days after the availability of the review); and

(viii) to the extent that information is available, a description of the adequacy of health care and other services, supports, and assistance that individuals with developmental disabilities who are served through home and community-based waivers (authorized under section 1915(c) of the Social Security Act (42 U.S.C. 1396n(c))) receive;

(D) a description of how entities funded under subtitles C and D, through interagency agreements or other mechanisms, collaborated with the entity funded under this subtitle in the State, each other, and other entities to contribute to the achievement of the purpose of this subtitle; and

(E) the rationale for the goals related to advocacy, capacity building, and systemic change to be undertaken by the Council to contribute to the achievement of the purpose of this subtitle.

(4) PLAN GOALS.—The plan shall focus on Council efforts to bring about the purpose of this subtitle, by—

(A) specifying 5-year goals, as developed through data driven strategic planning, for advocacy, capacity building, and systemic change related to the areas of emphasis, to be undertaken by the Council, that—

(i) are derived from the unmet needs of individuals with developmental disabilities and their families identified under paragraph (3); and

(ii) include a goal, for each year of the grant, to—

(I) establish or strengthen a program for the direct funding of a State self-advocacy organization led by individuals with developmental disabilities;

(II) support opportunities for individuals with developmental disabilities who are considered leaders to provide leadership training to individuals with developmental disabilities who may become leaders; and

(III) support and expand participation of individuals with developmental disabilities in cross-

disability and culturally diverse leadership coalitions; and

(B) for each year of the grant, describing—

(i) the goals to be achieved through the grant, which, beginning in fiscal year 2002, shall be consistent with applicable indicators of progress described in section 104(a)(3);

(ii) the strategies to be used in achieving each goal; and

(iii) the method to be used to determine if each goal has been achieved.

(5) ASSURANCES.—

(A) IN GENERAL.—The plan shall contain or be supported by assurances and information described in subparagraphs (B) through (N) that are satisfactory to the Secretary.

(B) USE OF FUNDS.—With respect to the funds paid to the State under section 122, the plan shall provide assurances that—

(i) not less than 70 percent of such funds will be expended for activities related to the goals described in paragraph (4);

(ii) such funds will contribute to the achievement of the purpose of this subtitle in various political subdivisions of the State;

(iii) such funds will be used to supplement, and not supplant, the non-Federal funds that would otherwise be made available for the purposes for which the funds paid under section 122 are provided;

(iv) such funds will be used to complement and augment rather than duplicate or replace services for individuals with developmental disabilities and their families who are eligible for Federal assistance under other State programs;

(v) part of such funds will be made available by the State to public or private entities;

(vi) at the request of any State, a portion of such funds provided to such State under this subtitle for any fiscal year shall be available to pay up to ½ (or the entire amount if the Council is the designated State agency) of the expenditures found to be necessary by the Secretary for the proper and efficient exercise of the functions of the designated State agency, except that not more than 5 percent of such funds provided to such State for any fiscal year, or $50,000, whichever is less, shall be made available for total expenditures for such purpose by the designated State agency; and

(vii) not more than 20 percent of such funds will be allocated to the designated State agency for service demonstrations by such agency that—

(I) contribute to the achievement of the purpose of this subtitle; and

(II) are explicitly authorized by the Council.

(C) STATE FINANCIAL PARTICIPATION.—The plan shall provide assurances that there will be reasonable State financial participation in the cost of carrying out the plan.

(D) CONFLICT OF INTEREST.—The plan shall provide an assurance that no member of such Council will cast a vote on any matter that would provide direct financial benefit to the member or otherwise give the appearance of a conflict of interest.

(E) URBAN AND RURAL POVERTY AREAS.—The plan shall provide assurances that special financial and technical assistance will be given to organizations that provide community services, individualized supports, and other forms of assistance to individuals with developmental disabilities who live in areas designated as urban or rural poverty areas.

(F) PROGRAM ACCESSIBILITY STANDARDS.—The plan shall provide assurances that programs, projects, and activities funded under the plan, and the buildings in which such programs, projects, and activities are operated, will meet standards prescribed by the Secretary in regulations and all applicable Federal and State accessibility standards, including accessibility requirements of the Americans with Disabilities Act of 1990 (42 U.S.C. 12101 et seq.), section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), and the Fair Housing Act (42 U.S.C. 3601 et seq.).

(G) INDIVIDUALIZED SERVICES.—The plan shall provide assurances that any direct services provided to individuals with developmental disabilities and funded under the plan will be provided in an individualized manner, consistent with the unique strengths, resources, priorities, concerns, abilities, and capabilities of such individual.

(H) HUMAN RIGHTS.—The plan shall provide assurances that the human rights of the individuals with developmental disabilities (especially individuals without familial protection) who are receiving services under programs assisted under this subtitle will be protected consistent with section 109 (relating to rights of individuals with developmental disabilities).

(I) MINORITY PARTICIPATION.—The plan shall provide assurances that the State has taken affirmative steps to assure that participation in programs funded under this subtitle is geographically representative of the State, and reflects the diversity of the State with respect to race and ethnicity.

(J) EMPLOYEE PROTECTIONS.—The plan shall provide assurances that fair and equitable arrangements (as determined by the Secretary after consultation with the Secretary of Labor) will be provided to protect the interests of employees affected by actions taken under the plan to provide community living activities, including arrangements designed to preserve employee rights and benefits and provide training and retraining of such employees where necessary, and arrangements under which maximum efforts

will be made to guarantee the employment of such employees.

(K) STAFF ASSIGNMENTS.—The plan shall provide assurances that the staff and other personnel of the Council, while working for the Council, will be responsible solely for assisting the Council in carrying out the duties of the Council under this subtitle and will not be assigned duties by the designated State agency, or any other agency, office, or entity of the State.

(L) NONINTERFERENCE.—The plan shall provide assurances that the designated State agency, and any other agency, office, or entity of the State, will not interfere with the advocacy, capacity building, and systemic change activities, budget, personnel, State plan development, or plan implementation of the Council, except that the designated State agency shall have the authority necessary to carry out the responsibilities described in section 125(d)(3).

(M) STATE QUALITY ASSURANCE.—The plan shall provide assurances that the Council will participate in the planning, design or redesign, and monitoring of State quality assurance systems that affect individuals with developmental disabilities.

(N) OTHER ASSURANCES.—The plan shall contain such additional information and assurances as the Secretary may find necessary to carry out the provisions (including the purpose) of this subtitle.

(d) PUBLIC INPUT AND REVIEW, SUBMISSION, AND APPROVAL.—

(1) PUBLIC INPUT AND REVIEW.—The plan shall be based on public input. The Council shall make the plan available for public review and comment, after providing appropriate and sufficient notice in accessible formats of the opportunity for such review and comment. The Council shall revise the plan to take into account and respond to significant comments.

(2) CONSULTATION WITH THE DESIGNATED STATE AGENCY.—Before the plan is submitted to the Secretary, the Council shall consult with the designated State agency to ensure that the State plan is consistent with State law and to obtain appropriate State plan assurances.

(3) PLAN APPROVAL.—The Secretary shall approve any State plan and, as appropriate, amendments of such plan that comply with the provisions of subsections (a), (b), and (c) and this subsection. The Secretary may take final action to disapprove a State plan after providing reasonable notice and an opportunity for a hearing to the State.

**SEC. 125. [15025] STATE COUNCILS ON DEVELOPMENTAL DISABILITIES AND DESIGNATED STATE AGENCIES.**

(a) IN GENERAL.—Each State that receives assistance under this subtitle shall establish and maintain a Council to undertake advocacy, capacity building, and systemic change activities (consistent with subsections (b) and (c) of section 101) that contribute to a coordinated, consumer- and family-centered, consumer- and family-directed, comprehensive system of community services, individualized supports, and other forms of assistance that contribute to the achievement of the purpose of this subtitle. The Council

shall have the authority to fulfill the responsibilities described in subsection (c).

(b) COUNCIL MEMBERSHIP.—

(1) COUNCIL APPOINTMENTS.—

(A) IN GENERAL.—The members of the Council of a State shall be appointed by the Governor of the State from among the residents of that State.

(B) RECOMMENDATIONS.—The Governor shall select members of the Council, at the discretion of the Governor, after soliciting recommendations from organizations representing a broad range of individuals with developmental disabilities and individuals interested in individuals with developmental disabilities, including the non-State agency members of the Council. The Council may, at the initiative of the Council, or on the request of the Governor, coordinate Council and public input to the Governor regarding all recommendations.

(C) REPRESENTATION.—The membership of the Council shall be geographically representative of the State and reflect the diversity of the State with respect to race and ethnicity.

(2) MEMBERSHIP ROTATION.—The Governor shall make appropriate provisions to rotate the membership of the Council. Such provisions shall allow members to continue to serve on the Council until such members' successors are appointed. The Council shall notify the Governor regarding membership requirements of the Council, and shall notify the Governor when vacancies on the Council remain unfilled for a significant period of time.

(3) REPRESENTATION OF INDIVIDUALS WITH DEVELOPMENTAL DISABILITIES.—Not less than 60 percent of the membership of each Council shall consist of individuals who are—

(A)(i) individuals with developmental disabilities;

(ii) parents or guardians of children with developmental disabilities; or

(iii) immediate relatives or guardians of adults with mentally impairing developmental disabilities who cannot advocate for themselves; and

(B) not employees of a State agency that receives funds or provides services under this subtitle, and who are not managing employees (as defined in section 1126(b) of the Social Security Act (42 U.S.C. 1320a–5(b)) of any other entity that receives funds or provides services under this subtitle.

(4) REPRESENTATION OF AGENCIES AND ORGANIZATIONS.—

(A) IN GENERAL.—Each Council shall include—

(i) representatives of relevant State entities, including—

(I) State entities that administer funds provided under Federal laws related to individuals with disabilities, including the Rehabilitation Act of 1973 (29 U.S.C. 701 et seq.), the Individuals with Disabilities Education Act (20 U.S.C. 1400 et seq.), the Older Americans Act of 1965 (42 U.S.C.

3001 et seq.), and titles V and XIX of the Social Security Act (42 U.S.C. 701 et seq. and 1396 et seq.);

(II) Centers in the State; and

(III) the State protection and advocacy system; and

(ii) representatives, at all times, of local and nongovernmental agencies, and private nonprofit groups concerned with services for individuals with developmental disabilities in the State in which such agencies and groups are located.

(B) AUTHORITY AND LIMITATIONS.—The representatives described in subparagraph (A) shall—

(i) have sufficient authority to engage in policy planning and implementation on behalf of the department, agency, or program such representatives represent; and

(ii) recuse themselves from any discussion of grants or contracts for which such representatives' departments, agencies, or programs are grantees, contractors, or applicants and comply with the conflict of interest assurance requirement under section 124(c)(5)(D).

(5) COMPOSITION OF MEMBERSHIP WITH DEVELOPMENTAL DISABILITIES.—Of the members of the Council described in paragraph (3)—

(A) ⅓ shall be individuals with developmental disabilities described in paragraph (3)(A)(i);

(B) ⅓ shall be parents or guardians of children with developmental disabilities described in paragraph (3)(A)(ii), or immediate relatives or guardians of adults with developmental disabilities described in paragraph (3)(A)(iii); and

(C) ⅓ shall be a combination of individuals described in paragraph (3)(A).

(6) INSTITUTIONALIZED INDIVIDUALS.—

(A) IN GENERAL.—Of the members of the Council described in paragraph (5), at least 1 shall be an immediate relative or guardian of an individual with a developmental disability who resides or previously resided in an institution or shall be an individual with a developmental disability who resides or previously resided in an institution.

(B) LIMITATION.—Subparagraph (A) shall not apply with respect to a State if such an individual does not reside in that State.

(c) COUNCIL RESPONSIBILITIES.—

(1) IN GENERAL.—A Council, through Council members, staff, consultants, contractors, or subgrantees, shall have the responsibilities described in paragraphs (2) through (10).

(2) ADVOCACY, CAPACITY BUILDING, AND SYSTEMIC CHANGE ACTIVITIES.—The Council shall serve as an advocate for individuals with developmental disabilities and conduct or support programs, projects, and activities that carry out the purpose of this subtitle.

(3) EXAMINATION OF GOALS.—At the end of each grant year, each Council shall—

(A) determine the extent to which each goal of the Council was achieved for that year;

(B) determine to the extent that each goal was not achieved, the factors that impeded the achievement;

(C) determine needs that require amendment of the 5-year strategic State plan required under section 124;

(D) separately determine the information on the self-advocacy goal described in section 124(c)(4)(A)(ii); and

(E) determine customer satisfaction with Council supported or conducted activities.

(4) STATE PLAN DEVELOPMENT.—The Council shall develop the State plan and submit the State plan to the Secretary after consultation with the designated State agency under the State plan. Such consultation shall be solely for the purposes of obtaining State assurances and ensuring consistency of the plan with State law.

(5) STATE PLAN IMPLEMENTATION.—

(A) IN GENERAL.—The Council shall implement the State plan by conducting and supporting advocacy, capacity building, and systemic change activities such as those described in subparagraphs (B) through (L).

(B) OUTREACH.—The Council may support and conduct outreach activities to identify individuals with developmental disabilities and their families who otherwise might not come to the attention of the Council and assist and enable the individuals and families to obtain services, individualized supports, and other forms of assistance, including access to special adaptation of generic community services or specialized services.

(C) TRAINING.—The Council may support and conduct training for persons who are individuals with developmental disabilities, their families, and personnel (including professionals, paraprofessionals, students, volunteers, and other community members) to enable such persons to obtain access to, or to provide, community services, individualized supports, and other forms of assistance, including special adaptation of generic community services or specialized services for individuals with developmental disabilities and their families. To the extent that the Council supports or conducts training activities under this subparagraph, such activities shall contribute to the achievement of the purpose of this subtitle.

(D) TECHNICAL ASSISTANCE.—The Council may support and conduct technical assistance activities to assist public and private entities to contribute to the achievement of the purpose of this subtitle.

(E) SUPPORTING AND EDUCATING COMMUNITIES.—The Council may support and conduct activities to assist neighborhoods and communities to respond positively to individuals with developmental disabilities and their families—

(i) by encouraging local networks to provide informal and formal supports;

(ii) through education; and

(iii) by enabling neighborhoods and communities to offer such individuals and their families access to and use of services, resources, and opportunities.

(F) INTERAGENCY COLLABORATION AND COORDINATION.—The Council may support and conduct activities to promote interagency collaboration and coordination to better serve, support, assist, or advocate for individuals with developmental disabilities and their families.

(G) COORDINATION WITH RELATED COUNCILS, COMMITTEES, AND PROGRAMS.—The Council may support and conduct activities to enhance coordination of services with—

(i) other councils, entities, or committees, authorized by Federal or State law, concerning individuals with disabilities (such as the State interagency coordinating council established under part C of the Individuals with Disabilities Education Act (20 U.S.C. 1431 et seq.), the State Rehabilitation Council and the Statewide Independent Living Council established under the Rehabilitation Act of 1973 (29 U.S.C. 701 et seq.), the State mental health planning council established under subtitle B of title XIX of the Public Health Service Act (42 U.S.C. 300x–1 et seq.), and the activities authorized under section 4 or 5 of the Assistive Technology Act of 1998, and entities carrying out other similar councils, entities, or committees);

(ii) parent training and information centers under part D of the Individuals with Disabilities Education Act (20 U.S.C. 1451 et seq.) and other entities carrying out federally funded projects that assist parents of children with disabilities; and

(iii) other groups interested in advocacy, capacity building, and systemic change activities to benefit individuals with disabilities.

(H) BARRIER ELIMINATION, SYSTEMS DESIGN AND REDESIGN.—The Council may support and conduct activities to eliminate barriers to access and use of community services by individuals with developmental disabilities, enhance systems design and redesign, and enhance citizen participation to address issues identified in the State plan.

(I) COALITION DEVELOPMENT AND CITIZEN PARTICIPATION.—The Council may support and conduct activities to educate the public about the capabilities, preferences, and needs of individuals with developmental disabilities and their families and to develop and support coalitions that support the policy agenda of the Council, including training in self-advocacy, education of policymakers, and citizen leadership skills.

(J) INFORMING POLICYMAKERS.—The Council may support and conduct activities to provide information to policymakers by supporting and conducting studies and analyses, gathering information, and developing and disseminating model policies and procedures, information, approaches, strategies, findings, conclusions, and rec-

ommendations. The Council may provide the information directly to Federal, State, and local policymakers, including Congress, the Federal executive branch, the Governors, State legislatures, and State agencies, in order to increase the ability of such policymakers to offer opportunities and to enhance or adapt generic services to meet the needs of, or provide specialized services to, individuals with developmental disabilities and their families.

(K) DEMONSTRATION OF NEW APPROACHES TO SERVICES AND SUPPORTS.—

(i) IN GENERAL.—The Council may support and conduct, on a time-limited basis, activities to demonstrate new approaches to serving individuals with developmental disabilities that are a part of an overall strategy for systemic change. The strategy may involve the education of policymakers and the public about how to deliver effectively, to individuals with developmental disabilities and their families, services, supports, and assistance that contribute to the achievement of the purpose of this subtitle.

(ii) SOURCES OF FUNDING.—The Council may carry out this subparagraph by supporting and conducting demonstration activities through sources of funding other than funding provided under this subtitle, and by assisting entities conducting demonstration activities to develop strategies for securing funding from other sources.

(L) OTHER ACTIVITIES.—The Council may support and conduct other advocacy, capacity building, and systemic change activities to promote the development of a coordinated, consumer- and family-centered, consumer- and family-directed, comprehensive system of community services, individualized supports, and other forms of assistance that contribute to the achievement of the purpose of this subtitle.

(6) REVIEW OF DESIGNATED STATE AGENCY.—The Council shall periodically review the designated State agency and activities carried out under this subtitle by the designated State agency and make any recommendations for change to the Governor.

(7) REPORTS.—Beginning in fiscal year 2002, the Council shall annually prepare and transmit to the Secretary a report. Each report shall be in a form prescribed by the Secretary by regulation under section 104(b). Each report shall contain information about the progress made by the Council in achieving the goals of the Council (as specified in section 124(c)(4)), including—

(A) a description of the extent to which the goals were achieved;

(B) a description of the strategies that contributed to achieving the goals;

(C) to the extent to which the goals were not achieved, a description of factors that impeded the achievement;

(D) separate information on the self-advocacy goal described in section 124(c)(4)(A)(ii);

(E)(i) as appropriate, an update on the results of the comprehensive review and analysis described in section 124(c)(3); and

(ii) information on consumer satisfaction with Council supported or conducted activities;

(F)(i) a description of the adequacy of health care and other services, supports, and assistance that individuals with developmental disabilities in Intermediate Care Facilities (Mental Retardation) receive; and

(ii) a description of the adequacy of health care and other services, supports, and assistance that individuals with developmental disabilities served through home and community-based waivers (authorized under section 1915(c) of the Social Security Act (42 U.S.C. 1396n(c)) receive;

(G) an accounting of the manner in which funds paid to the State under this subtitle for a fiscal year were expended;

(H) a description of—

(i) resources made available to carry out activities to assist individuals with developmental disabilities that are directly attributable to Council actions; and

(ii) resources made available for such activities that are undertaken by the Council in collaboration with other entities; and

(I) a description of the method by which the Council will widely disseminate the annual report to affected constituencies and the general public and will assure that the report is available in accessible formats.

(8) BUDGET.—Each Council shall prepare, approve, and implement a budget using amounts paid to the State under this subtitle to fund and implement all programs, projects, and activities carried out under this subtitle, including—

(A)(i) conducting such hearings and forums as the Council may determine to be necessary to carry out the duties of the Council; and

(ii) as determined in Council policy—

(I) reimbursing members of the Council for reasonable and necessary expenses (including expenses for child care and personal assistance services) for attending Council meetings and performing Council duties;

(II) paying a stipend to a member of the Council, if such member is not employed or must forfeit wages from other employment, to attend Council meetings and perform other Council duties;

(III) supporting Council member and staff travel to authorized training and technical assistance activities including in-service training and leadership development activities; and

(IV) carrying out appropriate subcontracting activities;

(B) hiring and maintaining such numbers and types of staff (qualified by training and experience) and obtaining the services of such professional, consulting, technical, and clerical staff (qualified by training and experience), consistent with State law, as the Council determines to be necessary to carry out the functions of the Council under this subtitle, except that such State shall not apply hiring freezes, reductions in force, prohibitions on travel, or other policies to the staff of the Council, to the extent that such policies would impact the staff or functions funded with Federal funds, or would prevent the Council from carrying out the functions of the Council under this subtitle; and

(C) directing the expenditure of funds for grants, contracts, interagency agreements that are binding contracts, and other activities authorized by the State plan approved under section 124.

(9) STAFF HIRING AND SUPERVISION.—The Council shall, consistent with State law, recruit and hire a Director of the Council, should the position of Director become vacant, and supervise and annually evaluate the Director. The Director shall hire, supervise, and annually evaluate the staff of the Council. Council recruitment, hiring, and dismissal of staff shall be conducted in a manner consistent with Federal and State nondiscrimination laws. Dismissal of personnel shall be conducted in a manner consistent with State law and personnel policies.

(10) STAFF ASSIGNMENTS.—The staff of the Council, while working for the Council, shall be responsible solely for assisting the Council in carrying out the duties of the Council under this subtitle and shall not be assigned duties by the designated State agency or any other agency or entity of the State.

(11) CONSTRUCTION.—Nothing in this title shall be construed to authorize a Council to direct, control, or exercise any policymaking authority or administrative authority over any program assisted under the Rehabilitation Act of 1973 (29 U.S.C. 701 et seq.) or the Individuals with Disabilities Education Act (20 U.S.C. 1400 et seq.).

(d) DESIGNATED STATE AGENCY.—

(1) IN GENERAL.—Each State that receives assistance under this subtitle shall designate a State agency that shall, on behalf of the State, provide support to the Council. After the date of enactment of the Developmental Disabilities Assistance and Bill of Rights Act Amendments of 1994 (Public Law 103–230), any designation of a State agency under this paragraph shall be made in accordance with the requirements of this subsection.

(2) DESIGNATION.—

(A) TYPE OF AGENCY.—Except as provided in this subsection, the designated State agency shall be—

(i) the Council if such Council may be the designated State agency under the laws of the State;

(ii) a State agency that does not provide or pay for services for individuals with developmental disabilities; or

(iii) a State office, including the immediate office of the Governor of the State or a State planning office.

(B) CONDITIONS FOR CONTINUATION OF STATE SERVICE AGENCY DESIGNATION.—

(i) DESIGNATION BEFORE ENACTMENT.—If a State agency that provides or pays for services for individuals with developmental disabilities was a designated State agency for purposes of part B of the Developmental Disabilities Assistance and Bill of Rights Act on the date of enactment of the Developmental Disabilities Assistance and Bill of Rights Act Amendments of 1994, and the Governor of the State (or the legislature, where appropriate and in accordance with State law) determines prior to June 30, 1994, not to change the designation of such agency, such agency may continue to be a designated State agency for purposes of this subtitle.

(ii) CRITERIA FOR CONTINUED DESIGNATION.—The determination, at the discretion of the Governor (or the legislature, as the case may be), shall be made after—

(I) the Governor has considered the comments and recommendations of the general public and a majority of the non-State agency members of the Council with respect to the designation of such State agency; and

(II) the Governor (or the legislature, as the case may be) has made an independent assessment that the designation of such agency will not interfere with the budget, personnel, priorities, or other action of the Council, and the ability of the Council to serve as an independent advocate for individuals with developmental disabilities.

(C) REVIEW OF DESIGNATION.—The Council may request a review of and change in the designation of the designated State agency by the Governor (or the legislature, as the case may be). The Council shall provide documentation concerning the reason the Council desires a change to be made and make a recommendation to the Governor (or the legislature, as the case may be) regarding a preferred designated State agency.

(D) APPEAL OF DESIGNATION.—After the review is completed under subparagraph (C), a majority of the non-State agency members of the Council may appeal to the Secretary for a review of and change in the designation of the designated State agency if the ability of the Council to serve as an independent advocate is not assured because of the actions or inactions of the designated State agency.

(3) RESPONSIBILITIES.—

(A) IN GENERAL.—The designated State agency shall, on behalf of the State, have the responsibilities described in subparagraphs (B) through (G).

(B) SUPPORT SERVICES.—The designated State agency shall provide required assurances and support services as requested by and negotiated with the Council.

(C) FISCAL RESPONSIBILITIES.—The designated State agency shall—

(i) receive, account for, and disburse funds under this subtitle based on the State plan required in section 124; and

(ii) provide for such fiscal control and fund accounting procedures as may be necessary to assure the proper disbursement of, and accounting for, funds paid to the State under this subtitle.

(D) RECORDS, ACCESS, AND FINANCIAL REPORTS.—The designated State agency shall keep and provide access to such records as the Secretary and the Council may determine to be necessary. The designated State agency, if other than the Council, shall provide timely financial reports at the request of the Council regarding the status of expenditures, obligations, and liquidation by the agency or the Council, and the use of the Federal and non-Federal shares described in section 126, by the agency or the Council.

(E) NON-FEDERAL SHARE.—The designated State agency, if other than the Council, shall provide the required non-Federal share described in section 126(c).

(F) ASSURANCES.—The designated State agency shall assist the Council in obtaining the appropriate State plan assurances and in ensuring that the plan is consistent with State law.

(G) MEMORANDUM OF UNDERSTANDING.—On the request of the Council, the designated State agency shall enter into a memorandum of understanding with the Council delineating the roles and responsibilities of the designated State agency.

(4) USE OF FUNDS FOR DESIGNATED STATE AGENCY RESPONSIBILITIES.—

(A) CONDITION FOR FEDERAL FUNDING.—

(i) IN GENERAL.—The Secretary shall provide amounts to a State under section 124(c)(5)(B)(vi) for a fiscal year only if the State expends an amount from State sources for carrying out the responsibilities of the designated State agency under paragraph (3) for the fiscal year that is not less than the total amount the State expended from such sources for carrying out similar responsibilities for the previous fiscal year.

(ii) EXCEPTION.—Clause (i) shall not apply in a year in which the Council is the designated State agency.

(B) SUPPORT SERVICES PROVIDED BY OTHER AGENCIES.—With the agreement of the designated State agency, the Council may use or contract with agencies other than the designated State agency to perform the functions of the designated State agency.

**SEC. 126. [15026] FEDERAL AND NON-FEDERAL SHARE.**

(a) AGGREGATE COST.—

(1) IN GENERAL.—Except as provided in paragraphs (2) and (3), the Federal share of the cost of all projects in a State supported by an allotment to the State under this subtitle may not be more than 75 percent of the aggregate necessary cost of such projects, as determined by the Secretary.

(2) URBAN OR RURAL POVERTY AREAS.—In the case of projects whose activities or products target individuals with developmental disabilities who live in urban or rural poverty areas, as determined by the Secretary, the Federal share of the cost of all such projects may not be more than 90 percent of the aggregate necessary cost of such projects, as determined by the Secretary.

(3) STATE PLAN ACTIVITIES.—In the case of projects undertaken by the Council or Council staff to implement State plan activities, the Federal share of the cost of all such projects may be not more than 100 percent of the aggregate necessary cost of such activities.

(b) NONDUPLICATION.—In determining the amount of any State's Federal share of the cost of such projects incurred by such State under a State plan approved under section 124, the Secretary shall not consider—

(1) any portion of such cost that is financed by Federal funds provided under any provision of law other than section 122; and

(2) the amount of any non-Federal funds required to be expended as a condition of receipt of the Federal funds described in paragraph (1).

(c) NON-FEDERAL SHARE.—

(1) IN-KIND CONTRIBUTIONS.—The non-Federal share of the cost of any project supported by an allotment under this subtitle may be provided in cash or in kind, fairly evaluated, including plant, equipment, or services.

(2) CONTRIBUTIONS OF POLITICAL SUBDIVISIONS AND PUBLIC OR PRIVATE ENTITIES.—

(A) IN GENERAL.—Contributions to projects by a political subdivision of a State or by a public or private entity under an agreement with the State shall, subject to such limitations and conditions as the Secretary may by regulation prescribe under section 104(b), be considered to be contributions by such State, in the case of a project supported under this subtitle.

(B) STATE CONTRIBUTIONS.—State contributions, including contributions by the designated State agency to provide support services to the Council pursuant to section 125(d)(4), may be counted as part of such State's non-Federal share of the cost of projects supported under this subtitle.

(3) VARIATIONS OF THE NON-FEDERAL SHARE.—The non-Federal share required of each recipient of a grant from a Council under this subtitle may vary.

**SEC. 127. [15027] WITHHOLDING OF PAYMENTS FOR PLANNING, ADMINISTRATION, AND SERVICES.**

Whenever the Secretary, after providing reasonable notice and an opportunity for a hearing to the Council and the designated State agency, finds that—

(1) the Council or agency has failed to comply substantially with any of the provisions required by section 124 to be included in the State plan, particularly provisions required by paragraphs (4)(A) and (5)(B)(vii) of section 124(c), or with any of the provisions required by section 125(b)(3); or

(2) the Council or agency has failed to comply substantially with any regulations of the Secretary that are applicable to this subtitle,

the Secretary shall notify such Council and agency that the Secretary will not make further payments to the State under section 122 (or, in the discretion of the Secretary, that further payments to the State under section 122 for activities for which there is such failure), until the Secretary is satisfied that there will no longer be such failure. Until the Secretary is so satisfied, the Secretary shall make no further payments to the State under section 122, or shall limit further payments under section 122 to such State to activities for which there is no such failure.

**SEC. 128. [15028] APPEALS BY STATES.**

(a) APPEAL.—If any State is dissatisfied with the Secretary's action under section 124(d)(3) or 127, 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 not later than 60 days after such action.

(b) FILING.—The clerk of the court shall transmit promptly a copy of the petition to the Secretary, or any officer designated by the Secretary for that purpose. The Secretary shall file promptly with the court the record of the proceedings on which the Secretary based the action, as provided in section 2112 of title 28, United States Code.

(c) JURISDICTION.—Upon the filing of the petition, the court shall have jurisdiction to affirm the action of the Secretary or to set the action aside, in whole or in part, temporarily or permanently. Until the filing of the record, the Secretary may modify or set aside the order of the Secretary relating to the action.

(d) FINDINGS AND REMAND.—The findings of the Secretary about the facts, if supported by substantial evidence, shall be conclusive, but the court, for good cause shown, may remand the case involved to the Secretary for further proceedings to take further evidence. On remand, the Secretary may make new or modified findings of fact and may modify the previous action of the Secretary, and shall file with the court the record of the further proceedings. Such new or modified findings of fact shall likewise be conclusive if supported by substantial evidence.

(e) FINALITY.—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.

(f) EFFECT.—The commencement of proceedings under this section shall not, unless so specifically ordered by a court, operate as a stay of the Secretary's action.

**SEC. 129. [15029] AUTHORIZATION OF APPROPRIATIONS.**

(a) FUNDING FOR STATE ALLOTMENTS.—Except as described in subsection (b), there are authorized to be appropriated for allotments under section 122 $76,000,000 for fiscal year 2001 and such sums as may be necessary for each of fiscal years 2002 through 2007.

(b) RESERVATION FOR TECHNICAL ASSISTANCE.—

(1) LOWER APPROPRIATION YEARS.—For any fiscal year for which the amount appropriated under subsection (a) is less than $76,000,000, the Secretary shall reserve funds in accordance with section 163(c) to provide technical assistance to entities funded under this subtitle.

(2) HIGHER APPROPRIATION YEARS.—For any fiscal year for which the amount appropriated under subsection (a) is not less than $76,000,000, the Secretary shall reserve not less than $300,000 and not more than 1 percent of the amount appropriated under subsection (a) to provide technical assistance to entities funded under this subtitle.

# Subtitle C—Protection and Advocacy of Individual Rights

**SEC. 141. [15041] PURPOSE.**

The purpose of this subtitle is to provide for allotments to support a protection and advocacy system (referred to in this subtitle as a "system") in each State to protect the legal and human rights of individuals with developmental disabilities in accordance with this subtitle.

**SEC. 142. [15042] ALLOTMENTS AND PAYMENTS.**

(a) ALLOTMENTS.—

(1) IN GENERAL.—To assist States in meeting the requirements of section 143(a), the Secretary shall allot to the States the amounts appropriated under section 145 and not reserved under paragraph (6). Allotments and reallotments of such sums shall be made on the same basis as the allotments and reallotments are made under subsections (a)(1)(A) and (e) of section 122, except as provided in paragraph (2).

(2) MINIMUM ALLOTMENTS.—In any case in which—

(A) the total amount appropriated under section 145 for a fiscal year is not less than $20,000,000, the allotment under paragraph (1) for such fiscal year—

(i) to each of American Samoa, Guam, the United States Virgin Islands, and the Commonwealth of the Northern Mariana Islands may not be less than $107,000; and

(ii) to any State not described in clause (i) may not be less than $200,000; or

(B) the total amount appropriated under section 145 for a fiscal year is less than $20,000,000, the allotment under paragraph (1) for such fiscal year—

(i) to each of American Samoa, Guam, the United States Virgin Islands, and the Commonwealth of the Northern Mariana Islands may not be less than $80,000; and

(ii) to any State not described in clause (i) may not be less than $150,000.

(3) REDUCTION OF ALLOTMENT.—Notwithstanding paragraphs (1) and (2), if the aggregate of the amounts to be allotted to the States pursuant to such paragraphs for any fiscal year exceeds the total amount appropriated for such allotments under section 145 for such fiscal year, the amount to be allotted to each State for such fiscal year shall be proportionately reduced.

(4) INCREASE IN ALLOTMENTS.—In any year in which the total amount appropriated under section 145 for a fiscal year exceeds the total amount appropriated under such section (or a corresponding provision) for the preceding fiscal year by a percentage greater than the most recent percentage change in the Consumer Price Index published by the Secretary of Labor under section 100(c)(1) of the Rehabilitation Act of 1973 (29 U.S.C. 720(c)(1)) (if the percentage change indicates an increase), the Secretary shall increase each of the minimum allotments described in subparagraphs (A) and (B) of paragraph (2). The Secretary shall increase each minimum allotment by an amount that bears the same ratio to the amount of such minimum allotment (including any increases in such minimum allotment under this paragraph (or a corresponding provision) for prior fiscal years) as the amount that is equal to the difference between—

(A) the total amount appropriated under section 145 for the fiscal year for which the increase in the minimum allotment is being made; minus

(B) the total amount appropriated under section 145 (or a corresponding provision) for the immediately preceding fiscal year,

bears to the total amount appropriated under section 145 (or a corresponding provision) for such preceding fiscal year.

(5) MONITORING THE ADMINISTRATION OF THE SYSTEM.—In a State in which the system is housed in a State agency, the State may use not more than 5 percent of any allotment under this subsection for the costs of monitoring the administration of the system required under section 143(a).

(6) TECHNICAL ASSISTANCE AND AMERICAN INDIAN CONSORTIUM.—In any case in which the total amount appropriated under section 145 for a fiscal year is more than $24,500,000, the Secretary shall—

(A) use not more than 2 percent of the amount appropriated to provide technical assistance to eligible systems with respect to activities carried out under this subtitle (consistent with requests by such systems for such assistance for the year); and

(B) provide a grant in accordance with section 143(b), and in an amount described in paragraph (2)(A)(i), to an American Indian consortium to provide protection and advocacy services.

(b) PAYMENT TO SYSTEMS.—Notwithstanding any other provision of law, the Secretary shall pay directly to any system in a State that complies with the provisions of this subtitle the amount of the allotment made for the State under this section, unless the system specifies otherwise.

(c) UNOBLIGATED FUNDS.—Any amount paid to a system under this subtitle for a fiscal year and remaining unobligated at the end of such year shall remain available to such system for the next fiscal year, for the purposes for which such amount was paid.

**SEC. 143. [15043] SYSTEM REQUIRED.**

(a) SYSTEM REQUIRED.—In order for a State to receive an allotment under subtitle B or this subtitle—

(1) the State shall have in effect a system to protect and advocate the rights of individuals with developmental disabilities;

(2) such system shall—

(A) have the authority to—

(i) pursue legal, administrative, and other appropriate remedies or approaches to ensure the protection of, and advocacy for, the rights of such individuals within the State who are or who may be eligible for treatment, services, or habilitation, or who are being considered for a change in living arrangements, with particular attention to members of ethnic and racial minority groups; and

(ii) provide information on and referral to programs and services addressing the needs of individuals with developmental disabilities;

(B) have the authority to investigate incidents of abuse and neglect of individuals with developmental disabilities if the incidents are reported to the system or if there is probable cause to believe that the incidents occurred;

(C) on an annual basis, develop, submit to the Secretary, and take action with regard to goals (each of which is related to 1 or more areas of emphasis) and priorities, developed through data driven strategic planning, for the system's activities;

(D) on an annual basis, provide to the public, including individuals with developmental disabilities attributable to either physical impairment, mental impairment, or a combination of physical and mental impairment, and their representatives, and as appropriate, non-State agency representatives of the State Councils on Developmental Disabilities, and Centers, in the State, an opportunity to comment on—

(i) the goals and priorities established by the system and the rationale for the establishment of such goals; and

(ii) the activities of the system, including the coordination of services with the entities carrying out advocacy programs under the Rehabilitation Act of 1973 (29 U.S.C. 701 et seq.), the Older Americans Act of 1965 (42 U.S.C. 3001 et seq.), and the Protection and Advocacy for Mentally Ill Individuals Act of 1986 (42 U.S.C. 10801 et seq.), and with entities carrying out other related programs, including the parent training and information centers funded under the Individuals with Disabilities Education Act (20 U.S.C. 1400 et seq.), and activities authorized under section 4 or 5 of the Assistive Technology Act of 1998;

(E) establish a grievance procedure for clients or prospective clients of the system to ensure that individuals with developmental disabilities have full access to services of the system;

(F) not be administered by the State Council on Developmental Disabilities;

(G) be independent of any agency that provides treatment, services, or habilitation to individuals with developmental disabilities;

(H) have access at reasonable times to any individual with a developmental disability in a location in which services, supports, and other assistance are provided to such an individual, in order to carry out the purpose of this subtitle;

(I) have access to all records of—

(i) any individual with a developmental disability who is a client of the system if such individual, or the legal guardian, conservator, or other legal representative of such individual, has authorized the system to have such access;

(ii) any individual with a developmental disability, in a situation in which—

(I) the individual, by reason of such individual's mental or physical condition, is unable to authorize the system to have such access;

(II) the individual does not have a legal guardian, conservator, or other legal representative, or the legal guardian of the individual is the State; and

(III) a complaint has been received by the system about the individual with regard to the status or treatment of the individual or, as a result of monitoring or other activities, there is probable cause to believe that such individual has been subject to abuse or neglect; and

(iii) any individual with a developmental disability, in a situation in which—

(I) the individual has a legal guardian, conservator, or other legal representative;

(II) a complaint has been received by the system about the individual with regard to the status or treatment of the individual or, as a result of

monitoring or other activities, there is probable cause to believe that such individual has been subject to abuse or neglect;

(III) such representative has been contacted by such system, upon receipt of the name and address of such representative;

(IV) such system has offered assistance to such representative to resolve the situation; and

(V) such representative has failed or refused to act on behalf of the individual;

(J)(i) have access to the records of individuals described in subparagraphs (B) and (I), and other records that are relevant to conducting an investigation, under the circumstances described in those subparagraphs, not later than 3 business days after the system makes a written request for the records involved; and

(ii) have immediate access, not later than 24 hours after the system makes such a request, to the records without consent from another party, in a situation in which services, supports, and other assistance are provided to an individual with a developmental disability—

(I) if the system determines there is probable cause to believe that the health or safety of the individual is in serious and immediate jeopardy; or

(II) in any case of death of an individual with a developmental disability;

(K) hire and maintain sufficient numbers and types of staff (qualified by training and experience) to carry out such system's functions, except that the State involved shall not apply hiring freezes, reductions in force, prohibitions on travel, or other policies to the staff of the system, to the extent that such policies would impact the staff or functions of the system funded with Federal funds or would prevent the system from carrying out the functions of the system under this subtitle;

(L) have the authority to educate policymakers; and

(M) provide assurances to the Secretary that funds allotted to the State under section 142 will be used to supplement, and not supplant, the non-Federal funds that would otherwise be made available for the purposes for which the allotted funds are provided;

(3) to the extent that information is available, the State shall provide to the system—

(A) a copy of each independent review, pursuant to section 1902(a)(30)(C) of the Social Security Act (42 U.S.C. 1396a(a)(30)(C)), of an Intermediate Care Facility (Mental Retardation) within the State, not later than 30 days after the availability of such a review; and

(B) information about the adequacy of health care and other services, supports, and assistance that individuals with developmental disabilities who are served through home and community-based waivers (authorized under section 1915(c) of the Social Security Act (42 U.S.C. 1396n(c))) receive; and

(4) the agency implementing the system shall not be redesignated unless—

(A) there is good cause for the redesignation;

(B) the State has given the agency notice of the intention to make such redesignation, including notice regarding the good cause for such redesignation, and given the agency an opportunity to respond to the assertion that good cause has been shown;

(C) the State has given timely notice and an opportunity for public comment in an accessible format to individuals with developmental disabilities or their representatives; and

(D) the system has an opportunity to appeal the redesignation to the Secretary, on the basis that the redesignation was not for good cause.

(b) AMERICAN INDIAN CONSORTIUM.—Upon application to the Secretary, an American Indian consortium established to provide protection and advocacy services under this subtitle, shall receive funding pursuant to section 142(a)(6) to provide the services. Such consortium shall be considered to be a system for purposes of this subtitle and shall coordinate the services with other systems serving the same geographic area. The tribal council that designates the consortium shall carry out the responsibilities and exercise the authorities specified for a State in this subtitle, with regard to the consortium.

(c) RECORD.—In this section, the term "record" includes—

(1) a report prepared or received by any staff at any location at which services, supports, or other assistance is provided to individuals with developmental disabilities;

(2) a report prepared by an agency or staff person charged with investigating reports of incidents of abuse or neglect, injury, or death occurring at such location, that describes such incidents and the steps taken to investigate such incidents; and

(3) a discharge planning record.

**SEC. 144. [15044] ADMINISTRATION.**

(a) GOVERNING BOARD.—In a State in which the system described in section 143 is organized as a private nonprofit entity with a multimember governing board, or a public system with a multimember governing board, such governing board shall be selected according to the policies and procedures of the system, except that—

(1)(A) the governing board shall be composed of members who broadly represent or are knowledgeable about the needs of the individuals served by the system;

(B) a majority of the members of the board shall be—

(i) individuals with disabilities, including individuals with developmental disabilities, who are eligible for services, or have received or are receiving services through the system; or

(ii) parents, family members, guardians, advocates, or authorized representatives of individuals referred to in clause (i); and

(C) the board may include a representative of the State Council on Developmental Disabilities, the Centers in the State, and the self-advocacy organization described in section 124(c)(4)(A)(ii)(I);

(2) not more than ⅓ of the members of the governing board may be appointed by the chief executive officer of the State involved, in the case of any State in which such officer has the authority to appoint members of the board;

(3) the membership of the governing board shall be subject to term limits set by the system to ensure rotating membership;

(4) any vacancy in the board shall be filled not later than 60 days after the date on which the vacancy occurs; and

(5) in a State in which the system is organized as a public system without a multimember governing or advisory board, the system shall establish an advisory council—

(A) that shall advise the system on policies and priorities to be carried out in protecting and advocating the rights of individuals with developmental disabilities; and

(B) on which a majority of the members shall be—

(i) individuals with developmental disabilities who are eligible for services, or have received or are receiving services, through the system; or

(ii) parents, family members, guardians, advocates, or authorized representatives of individuals referred to in clause (i).

(b) LEGAL ACTION.—

(1) IN GENERAL.—Nothing in this title shall preclude a system from bringing a suit on behalf of individuals with developmental disabilities against a State, or an agency or instrumentality of a State.

(2) USE OF AMOUNTS FROM JUDGMENT.—An amount received pursuant to a suit described in paragraph (1) through a court judgment may only be used by the system to further the purpose of this subtitle and shall not be used to augment payments to legal contractors or to award personal bonuses.

(3) LIMITATION.—The system shall use assistance provided under this subtitle in a manner consistent with section 5 of the Assisted Suicide Funding Restriction Act of 1997 (42 U.S.C. 14404).

(c) DISCLOSURE OF INFORMATION.—For purposes of any periodic audit, report, or evaluation required under this subtitle, the Secretary shall not require an entity carrying out a program to disclose the identity of, or any other personally identifiable information related to, any individual requesting assistance under such program.

(d) PUBLIC NOTICE OF FEDERAL ONSITE REVIEW.—The Secretary shall provide advance public notice of any Federal programmatic or administrative onsite review of a system conducted under this subtitle and solicit public comment on the system through such notice. The Secretary shall prepare an onsite visit report containing the results of such review, which shall be distributed to the Governor of the State and to other interested public and private parties. The comments received in response to the pub-

lic comment solicitation notice shall be included in the onsite visit report.

(e) REPORTS.—Beginning in fiscal year 2002, each system established in a State pursuant to this subtitle shall annually prepare and transmit to the Secretary a report that describes the activities, accomplishments, and expenditures of the system during the preceding fiscal year, including a description of the system's goals, the extent to which the goals were achieved, barriers to their achievement, the process used to obtain public input, the nature of such input, and how such input was used.

**SEC. 145. [15045] AUTHORIZATION OF APPROPRIATIONS.**

For allotments under section 142, there are authorized to be appropriated $32,000,000 for fiscal year 2001 and such sums as may be necessary for each of fiscal years 2002 through 2007.

# Subtitle D—National Network of University Centers for Excellence in Developmental Disabilities Education, Research, and Service

**SEC. 151. [15061] GRANT AUTHORITY.**

(a) NATIONAL NETWORK.—From appropriations authorized under section 156(a)(1), the Secretary shall make 5-year grants to entities in each State designated as University Centers for Excellence in Developmental Disabilities Education, Research, and Service to carry out activities described in section 153(a).

(b) NATIONAL TRAINING INITIATIVES.—From appropriations authorized under section 156(a)(1) and reserved under section 156(a)(2), the Secretary shall make grants to Centers to carry out activities described in section 153(b).

(c) TECHNICAL ASSISTANCE.—From appropriations authorized under section 156(a)(1) and reserved under section 156(a)(3) (or from funds reserved under section 163, as appropriate), the Secretary shall enter into 1 or more cooperative agreements or contracts for the purpose of providing technical assistance described in section 153(c).

**SEC. 152. [15062] GRANT AWARDS.**

(a) EXISTING CENTERS.—

(1) IN GENERAL.—In awarding and distributing grant funds under section 151(a) for a fiscal year, the Secretary, subject to the availability of appropriations and the condition specified in subsection (d), shall award and distribute grant funds in equal amounts of $500,000 (adjusted in accordance with subsection (b)), to each Center that existed during the preceding fiscal year and that meets the requirements of this subtitle, prior to making grants under subsection (c) or (d).

(2) REDUCTION OF AWARD.—Notwithstanding paragraph (1), if the aggregate of the funds to be awarded to the Centers pursuant to paragraph (1) for any fiscal year exceeds the total amount appropriated under section 156 for such fiscal year, the

amount to be awarded to each Center for such fiscal year shall be proportionately reduced.

(b) ADJUSTMENTS.—Subject to the availability of appropriations, for any fiscal year following a year in which each Center described in subsection (a) received a grant award of not less than $500,000 under subsection (a) (adjusted in accordance with this subsection), the Secretary shall adjust the awards to take into account the most recent percentage change in the Consumer Price Index published by the Secretary of Labor under section 100(c)(1) of the Rehabilitation Act of 1973 (29 U.S.C. 720(c)(1)) (if the percentage change indicates an increase), prior to making grants under subsection (c) or (d).

(c) NATIONAL TRAINING INITIATIVES ON CRITICAL AND EMERGING NEEDS.—Subject to the availability of appropriations, for any fiscal year in which each Center described in subsection (a) receives a grant award of not less than $500,000, under subsection (a) (adjusted in accordance with subsection (b)), after making the grant awards, the Secretary shall make grants under section 151(b) to Centers to pay for the Federal share of the cost of training initiatives related to the unmet needs of individuals with developmental disabilities and their families, as described in section 153(b).

(d) ADDITIONAL GRANTS.—For any fiscal year in which each Center described in subsection (a) receives a grant award of not less than $500,000 under subsection (a) (adjusted in accordance with subsection (b)), after making the grant awards, the Secretary may make grants under section 151(a) for activities described in section 153(a) to additional Centers, or additional grants to Centers, for States or populations that are unserved or underserved by Centers due to such factors as—

(1) population;

(2) a high concentration of rural or urban areas; or

(3) a high concentration of unserved or underserved populations.

**SEC. 153. [15063] PURPOSE AND SCOPE OF ACTIVITIES.**

(a) NATIONAL NETWORK OF UNIVERSITY CENTERS FOR EXCELLENCE IN DEVELOPMENTAL DISABILITIES EDUCATION, RESEARCH, AND SERVICE.—

(1) IN GENERAL.—In order to provide leadership in, advise Federal, State, and community policymakers about, and promote opportunities for individuals with developmental disabilities to exercise self-determination, be independent, be productive, and be integrated and included in all facets of community life, the Secretary shall award grants to eligible entities designated as Centers in each State to pay for the Federal share of the cost of the administration and operation of the Centers. The Centers shall be interdisciplinary education, research, and public service units of universities (as defined by the Secretary) or public or not-for-profit entities associated with universities that engage in core functions, described in paragraph (2), addressing, directly or indirectly, 1 or more of the areas of emphasis.

(2) CORE FUNCTIONS.—The core functions referred to in paragraph (1) shall include the following:

(A) Provision of interdisciplinary pre-service preparation and continuing education of students and fellows, which may include the preparation and continuing education of leadership, direct service, clinical, or other personnel to strengthen and increase the capacity of States and communities to achieve the purpose of this title.

(B) Provision of community services—

(i) that provide training or technical assistance for individuals with developmental disabilities, their families, professionals, paraprofessionals, policymakers, students, and other members of the community; and

(ii) that may provide services, supports, and assistance for the persons described in clause (i) through demonstration and model activities.

(C) Conduct of research, which may include basic or applied research, evaluation, and the analysis of public policy in areas that affect or could affect, either positively or negatively, individuals with developmental disabilities and their families.

(D) Dissemination of information related to activities undertaken to address the purpose of this title, especially dissemination of information that demonstrates that the network authorized under this subtitle is a national and international resource that includes specific substantive areas of expertise that may be accessed and applied in diverse settings and circumstances.

(b) NATIONAL TRAINING INITIATIVES ON CRITICAL AND EMERGING NEEDS.—

(1) SUPPLEMENTAL GRANTS.—After consultation with relevant, informed sources, including individuals with developmental disabilities and their families, the Secretary shall award, under section 151(b), supplemental grants to Centers to pay for the Federal share of the cost of training initiatives related to the unmet needs of individuals with developmental disabilities and their families. The Secretary shall make the grants on a competitive basis, and for periods of not more than 5 years.

(2) ESTABLISHMENT OF CONSULTATION PROCESS BY THE SECRETARY.—Not later than 1 year after the date of enactment of this Act, the Secretary shall establish a consultation process that, on an ongoing basis, allows the Secretary to identify and address, through supplemental grants authorized under paragraph (1), training initiatives related to the unmet needs of individuals with developmental disabilities and their families.

(c) TECHNICAL ASSISTANCE.—In order to strengthen and support the national network of Centers, the Secretary may enter into 1 or more cooperative agreements or contracts to—

(1) assist in national and international dissemination of specific information from multiple Centers and, in appropriate cases, other entities whose work affects the lives of individuals with developmental disabilities;

(2) compile, analyze, and disseminate state-of-the-art training, research, and demonstration results policies, and practices from multiple Centers and, in appropriate cases,

other entities whose work affects the lives of persons with developmental disabilities;

(3) convene experts from multiple Centers to discuss and make recommendations with regard to national emerging needs of individuals with developmental disabilities;

(4)(A) develop portals that link users with every Center's website; and

(B) facilitate electronic information sharing using state-of-the-art Internet technologies such as real-time online discussions, multipoint video conferencing, and web-based audio/video broadcasts, on emerging topics that impact individuals with disabilities and their families;

(5) serve as a research-based resource for Federal and State policymakers on information concerning and issues impacting individuals with developmental disabilities and entities that assist or serve those individuals; or

(6) undertake any other functions that the Secretary determines to be appropriate;

to promote the viability and use of the resources and expertise of the Centers nationally and internationally.

**SEC. 154. [15064] APPLICATIONS.**

(a) APPLICATIONS FOR CORE CENTER GRANTS.—

(1) IN GENERAL.—To be eligible to receive a grant under section 151(a) for a Center, 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 may require.

(2) APPLICATION CONTENTS.—Each application described in paragraph (1) shall describe a 5-year plan, including a projected goal related to 1 or more areas of emphasis for each of the core functions described in section 153(a).

(3) ASSURANCES.—The application shall be approved by the Secretary only if the application contains or is supported by reasonable assurances that the entity designated as the Center will—

(A) meet regulatory standards as established by the Secretary for Centers;

(B) address the projected goals, and carry out goal-related activities, based on data driven strategic planning and in a manner consistent with the objectives of this subtitle, that—

(i) are developed in collaboration with the consumer advisory committee established pursuant to subparagraph (E);

(ii) are consistent with, and to the extent feasible complement and further, the Council goals contained in the State plan submitted under section 124 and the system goals established under section 143; and

(iii) will be reviewed and revised annually as necessary to address emerging trends and needs;

(C) use the funds made available through the grant to supplement, and not supplant, the funds that would other-

wise be made available for activities described in section 153(a);

(D) protect, consistent with the policy specified in section 101(c) (relating to rights of individuals with developmental disabilities), the legal and human rights of all individuals with developmental disabilities (especially those individuals under State guardianship) who are involved in activities carried out under programs assisted under this subtitle;

(E) establish a consumer advisory committee—

(i) of which a majority of the members shall be individuals with developmental disabilities and family members of such individuals;

(ii) that is comprised of—

(I) individuals with developmental disabilities and related disabilities;

(II) family members of individuals with developmental disabilities;

(III) a representative of the State protection and advocacy system;

(IV) a representative of the State Council on Developmental Disabilities;

(V) a representative of a self-advocacy organization described in section 124(c)(4)(A)(ii)(I); and

(VI) representatives of organizations that may include parent training and information centers assisted under section 671 or 672 of the Individuals with Disabilities Education Act, entities carrying out activities authorized under section 4 or 5 of the Assistive Technology Act of 1998, relevant State agencies, and other community groups concerned with the welfare of individuals with developmental disabilities and their families;

(iii) that reflects the racial and ethnic diversity of the State; and

(iv) that shall—

(I) consult with the Director of the Center regarding the development of the 5-year plan, and shall participate in an annual review of, and comment on, the progress of the Center in meeting the projected goals contained in the plan, and shall make recommendations to the Director of the Center regarding any proposed revisions of the plan that might be necessary; and

(II) meet as often as necessary to carry out the role of the committee, but at a minimum twice during each grant year;

(F) to the extent possible, utilize the infrastructure and resources obtained through funds made available under the grant to leverage additional public and private funds to successfully achieve the projected goals developed in the 5-year plan;

(G)(i) have a director with appropriate academic credentials, demonstrated leadership, expertise regarding

developmental disabilities, significant experience in managing grants and contracts, and the ability to leverage public and private funds; and

(ii) allocate adequate staff time to carry out activities related to each of the core functions described in section 153(a); and

(H) educate, and disseminate information related to the purpose of this title to, the legislature of the State in which the Center is located, and to Members of Congress from such State.

(b) SUPPLEMENTAL GRANT APPLICATIONS PERTAINING TO NATIONAL TRAINING INITIATIVES IN CRITICAL AND EMERGING NEEDS.—To be eligible to receive a supplemental grant under section 151(b), a Center may submit a supplemental application to the Secretary at such time, in such manner, and containing such information as the Secretary may require, pursuant to the terms and conditions set by the Secretary consistent with section 153(b).

(c) PEER REVIEW.—

(1) IN GENERAL.—The Secretary shall require that all applications submitted under this subtitle be subject to technical and qualitative review by peer review groups established under paragraph (2). The Secretary may approve an application under this subtitle only if such application has been recommended by a peer review group that has conducted the peer review required under this paragraph. In conducting the review, the group may conduct onsite visits or inspections of related activities as necessary.

(2) ESTABLISHMENT OF PEER REVIEW GROUPS.—

(A) IN GENERAL.—The Secretary, acting through the Commissioner of the Administration on Developmental Disabilities, may, notwithstanding—

(i) the provisions of title 5, United States Code, concerning appointments to the competitive service; and

(ii) the provisions of chapter 51, and subchapter III of chapter 53 of title 5, United States Code, concerning classification and General Schedule pay rates; establish such peer review groups and appoint and set the rates of pay of members of such groups.

(B) COMPOSITION.—Each peer review group shall include such individuals with disabilities and parents, guardians, or advocates of or for individuals with developmental disabilities, as are necessary to carry out this subsection.

(3) WAIVERS OF APPROVAL.—The Secretary may waive the provisions of paragraph (1) with respect to review and approval of an application if the Secretary determines that exceptional circumstances warrant such a waiver.

(d) FEDERAL SHARE.—

(1) IN GENERAL.—The Federal share of the cost of administration or operation of a Center, or the cost of carrying out a training initiative, supported by a grant made under this subtitle may not be more than 75 percent of the necessary cost of such project, as determined by the Secretary.

(2) URBAN OR RURAL POVERTY AREAS.—In the case of a project whose activities or products target individuals with developmental disabilities who live in an urban or rural poverty area, as determined by the Secretary, the Federal share of the cost of the project may not be more than 90 percent of the necessary costs of the project, as determined by the Secretary.

(3) GRANT EXPENDITURES.—For the purpose of determining the Federal share with respect to the project, expenditures on that project by a political subdivision of a State or by a public or private entity shall, subject to such limitations and conditions as the Secretary may by regulation prescribe under section 104(b), be considered to be expenditures made by a Center under this subtitle.

(e) ANNUAL REPORT.—Each Center shall annually prepare and transmit to the Secretary a report containing—

(1) information on progress made in achieving the projected goals of the Center for the previous year, including—

(A) the extent to which the goals were achieved;

(B) a description of the strategies that contributed to achieving the goals;

(C) to the extent to which the goals were not achieved, a description of factors that impeded the achievement; and

(D) an accounting of the manner in which funds paid to the Center under this subtitle for a fiscal year were expended;

(2) information on proposed revisions to the goals; and

(3) a description of successful efforts to leverage funds, other than funds made available under this subtitle, to pursue goals consistent with this subtitle.

**SEC. 155. [15065] DEFINITION.**

In this subtitle, the term "State" means each of the several States of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the United States Virgin Islands, and Guam.

**SEC. 156. [15066] AUTHORIZATION OF APPROPRIATIONS.**

(a) AUTHORIZATION AND RESERVATIONS.—

(1) AUTHORIZATION.—There are authorized to be appropriated to carry out this subtitle (other than section 153(c)(4)) $30,000,000 for fiscal year 2001 and such sums as may be necessary for each of fiscal years 2002 through 2007.

(2) RESERVATION FOR TRAINING INITIATIVES.—From any amount appropriated for a fiscal year under paragraph (1) and remaining after each Center described in section 152(a) has received a grant award of not less than $500,000, as described in section 152, the Secretary shall reserve funds for the training initiatives authorized under section 153(b).

(3) RESERVATION FOR TECHNICAL ASSISTANCE.—

(A) YEARS BEFORE APPROPRIATION TRIGGER.—For any covered year, the Secretary shall reserve funds in accordance with section 163(c) to fund technical assistance activities under section 153(c) (other than section 153(c)(4)).

(B) YEARS AFTER APPROPRIATION TRIGGER.—For any fiscal year that is not a covered year, the Secretary shall

reserve not less than $300,000 and not more than 2 percent of the amount appropriated under paragraph (1) to fund technical assistance activities under section 153(c) (other than section 153(c)(4)).

(C) COVERED YEAR.—In this paragraph, the term "covered year" means a fiscal year prior to the first fiscal year for which the amount appropriated under paragraph (1) is not less than $20,000,000.

(b) LIMITATION.—The Secretary may not use, for peer review or other activities directly related to peer review conducted under this subtitle—

(1) for fiscal year 2001, more than $300,000 of the funds made available under subsection (a); and

(2) for any succeeding fiscal year, more than the amount of funds used for the peer review and related activities in fiscal year 2001, adjusted to take into account the most recent percentage change in the Consumer Price Index published by the Secretary of Labor under section 100(c)(1) of the Rehabilitation Act of 1973 (29 U.S.C. 720(c)(1)) (if the percentage change indicates an increase).

# Subtitle E—Projects of National Significance

**SEC. 161. [15081] PURPOSE.**

The purpose of this subtitle is to provide grants, contracts, or cooperative agreements for projects of national significance that—

(1) create opportunities for individuals with developmental disabilities to directly and fully contribute to, and participate in, all facets of community life; and

(2) support the development of national and State policies that reinforce and promote, with the support of families, guardians, advocates, and communities, of individuals with developmental disabilities, the self-determination, independence, productivity, and integration and inclusion in all facets of community life of such individuals through—

(A) family support activities;

(B) data collection and analysis;

(C) technical assistance to entities funded under subtitles B and D, subject to the limitations described in sections 129(b), 156(a)(3), and 163(c); and

(D) other projects of sufficient size and scope that hold promise to expand or improve opportunities for such individuals, including—

(i) projects that provide technical assistance for the development of information and referral systems;

(ii) projects that provide technical assistance to self-advocacy organizations of individuals with developmental disabilities;

(iii) projects that provide education for policymakers;

(iv) Federal interagency initiatives;

(v) projects that enhance the participation of racial and ethnic minorities in public and private sector initiatives in developmental disabilities;

(vi) projects that provide aid to transition youth with developmental disabilities from school to adult life, especially in finding employment and postsecondary education opportunities and in upgrading and changing any assistive technology devices that may be needed as a youth matures;

(vii) initiatives that address the development of community quality assurance systems and the training related to the development, implementation, and evaluation of such systems, including training of individuals with developmental disabilities and their families;

(viii) initiatives that address the needs of aging individuals with developmental disabilities and aging caregivers of adults with developmental disabilities in the community;

(ix) initiatives that create greater access to and use of generic services systems, community organizations, and associations, and initiatives that assist in community economic development;

(x) initiatives that create access to increased living options;

(xi) initiatives that address the challenging behaviors of individuals with developmental disabilities, including initiatives that promote positive alternatives to the use of restraints and seclusion; and

(xii) initiatives that address other areas of emerging need.

**SEC. 162. [15082] GRANT AUTHORITY.**

(a) IN GENERAL.—The Secretary shall award grants, contracts, or cooperative agreements to public or private nonprofit entities for projects of national significance relating to individuals with developmental disabilities to carry out activities described in section 161(2).

(b) FEDERAL INTERAGENCY INITIATIVES.—

(1) IN GENERAL.—

(A) AUTHORITY.—The Secretary may—

(i) enter into agreements with Federal agencies to jointly carry out activities described in section 161(2) or to jointly carry out activities of common interest related to the objectives of such section; and

(ii) transfer to such agencies for such purposes funds appropriated under this subtitle, and receive and use funds from such agencies for such purposes.

(B) RELATION TO PROGRAM PURPOSES.—Funds transferred or received pursuant to this paragraph shall be used only in accordance with statutes authorizing the appropriation of such funds. Such funds shall be made available through grants, contracts, or cooperative agreements only

to recipients eligible to receive such funds under such statutes.

(C) PROCEDURES AND CRITERIA.—If the Secretary enters into an agreement under this subsection for the administration of a jointly funded project—

(i) the agreement shall specify which agency's procedures shall be used to award grants, contracts, or cooperative agreements and to administer such awards;

(ii) the participating agencies may develop a single set of criteria for the jointly funded project, and may require applicants to submit a single application for joint review by such agencies; and

(iii) unless the heads of the participating agencies develop joint eligibility requirements, an applicant for an award for the project shall meet the eligibility requirements of each program involved.

(2) LIMITATION.—The Secretary may not construe the provisions of this subsection to take precedence over a limitation on joint funding contained in an applicable statute.

**SEC. 163. [15083] AUTHORIZATION OF APPROPRIATIONS.**

(a) IN GENERAL.—There are authorized to be appropriated to carry out the projects specified in this section $16,000,000 for fiscal year 2001, and such sums as may be necessary for each of fiscal years 2002 through 2007.

(b) USE OF FUNDS.—

(1) GRANTS, CONTRACTS, AND AGREEMENTS.—Except as provided in paragraph (2), the amount appropriated under subsection (a) for each fiscal year shall be used to award grants, or enter into contracts, cooperative agreements, or other agreements, under section 162.

(2) ADMINISTRATIVE COSTS.—Not more than 1 percent of the amount appropriated under subsection (a) for each fiscal year may be used to provide for the administrative costs (other than compensation of Federal employees) of the Administration on Developmental Disabilities for administering this subtitle and subtitles B, C, and D, including monitoring the performance of and providing technical assistance to, entities that receive funds under this title.

(c) TECHNICAL ASSISTANCE FOR COUNCILS AND CENTERS.—

(1) IN GENERAL.—For each covered year, the Secretary shall expend, to provide technical assistance for entities funded under subtitle B or D, an amount from funds appropriated under subsection (a) that is not less than the amount the Secretary expended on technical assistance for entities funded under that subtitle (or a corresponding provision) in the previous fiscal year.

(2) COVERED YEAR.—In this subsection, the term "covered year" means—

(A) in the case of an expenditure for entities funded under subtitle B, a fiscal year for which the amount appropriated under section 129(a) is less than $76,000,000; and

(B) in the case of an expenditure for entities funded under subtitle D, a fiscal year prior to the first fiscal year

for which the amount appropriated under section 156(a)(1) is not less than $20,000,000.

(3) REFERENCES.—References in this subsection to subtitle D shall not be considered to include section 153(c)(4).

(d) TECHNICAL ASSISTANCE ON ELECTRONIC INFORMATION SHARING.—In addition to any funds reserved under subsection (c), the Secretary shall reserve $100,000 from the amount appropriated under subsection (a) for each fiscal year to carry out section 153(c)(4).

(e) LIMITATION.—For any fiscal year for which the amount appropriated under subsection (a) is not less than $10,000,000, not more than 50 percent of such amount shall be used for activities carried out under section 161(2)(A).

# TITLE II—FAMILY SUPPORT

**SEC. 201. [15001 note] SHORT TITLE.**

This title may be cited as the "Families of Children With Disabilities Support Act of 2000".

**SEC. 202. [15091] FINDINGS, PURPOSES, AND POLICY.**

(a) FINDINGS.—Congress makes the following findings:

(1) It is in the best interest of our Nation to preserve, strengthen, and maintain the family.

(2) Families of children with disabilities provide support, care, and training to their children that can save States millions of dollars. Without the efforts of family caregivers, many persons with disabilities would receive care through State-supported out-of-home placements.

(3) Most families of children with disabilities, especially families in unserved and underserved populations, do not have access to family-centered and family-directed services to support such families in their efforts to care for such children at home.

(4) Medical advances and improved health care have increased the life span of many people with disabilities, and the combination of the longer life spans and the aging of family caregivers places a continually increasing demand on the finite service delivery systems of the States.

(5) In 1996, 49 States provided family support initiatives in response to the needs of families of children with disabilities. Such initiatives included the provision of cash subsidies, respite care, and other forms of support. There is a need in each State, however, to strengthen, expand, and coordinate the activities of a system of family support services for families of children with disabilities that is easily accessible, avoids duplication, uses resources efficiently, and prevents gaps in services to families in all areas of the State.

(6) The goals of the Nation properly include the goal of providing to families of children with disabilities the family support services necessary—

(A) to support the family;

(B) to enable families of children with disabilities to nurture and enjoy their children at home;

(C) to enable families of children with disabilities to make informed choices and decisions regarding the nature of supports, resources, services, and other assistance made available to such families; and

(D) to support family caregivers of adults with disabilities.

(b) PURPOSES.—The purposes of this title are—

(1) to promote and strengthen the implementation of comprehensive State systems of family support services, for families with children with disabilities, that are family-centered and family-directed, and that provide families with the greatest possible decisionmaking authority and control regarding the nature and use of services and support;

(2) to promote leadership by families in planning, policy development, implementation, and evaluation of family support services for families of children with disabilities;

(3) to promote and develop interagency coordination and collaboration between agencies responsible for providing the services; and

(4) to increase the availability of, funding for, access to, and provision of family support services for families of children with disabilities.

(c) POLICY.—It is the policy of the United States that all programs, projects, and activities funded under this title shall be family-centered and family-directed, and shall be provided in a manner consistent with the goal of providing families of children with disabilities with the support the families need to raise their children at home.

**SEC. 203. [15092] DEFINITIONS AND SPECIAL RULE.**

(a) DEFINITIONS.—In this title:

(1) CHILD WITH A DISABILITY.—The term "child with a disability" means an individual who—

(A) has a significant physical or mental impairment, as defined pursuant to State policy to the extent that such policy is established without regard to type of disability; or

(B) is an infant or a young child from birth through age 8 and has a substantial developmental delay or specific congenital or acquired condition that presents a high probability of resulting in a disability if services are not provided to the infant or child.

(2) FAMILY.—

(A) IN GENERAL.—Subject to subparagraph (B), for purposes of the application of this title in a State, the term "family" has the meaning given the term by the State.

(B) EXCLUSION OF EMPLOYEES.—The term does not include an employee who, acting in a paid employment capacity, provides services to a child with a disability in an out-of-home setting such as a hospital, nursing home, personal care home, board and care home, group home, or other facility.

(3) FAMILY SUPPORT FOR FAMILIES OF CHILDREN WITH DISABILITIES.—The term "family support for families of children with disabilities" means supports, resources, services, and

other assistance provided to families of children with disabilities pursuant to State policy that are designed to—

(A) support families in the efforts of such families to raise their children with disabilities in the home;

(B) strengthen the role of the family as primary caregiver for such children;

(C) prevent involuntary out-of-the-home placement of such children and maintain family unity; and

(D) reunite families with children with disabilities who have been placed out of the home, whenever possible.

(4) SECRETARY.—The term "Secretary" means the Secretary of Health and Human Services.

(5) STATE.—The term "State" means each of the 50 States of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the United States Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

(6) SYSTEMS CHANGE ACTIVITIES.—The term "systems change activities" means efforts that result in laws, regulations, policies, practices, or organizational structures—

(A) that are family-centered and family-directed;

(B) that facilitate and increase access to, provision of, and funding for, family support services for families of children with disabilities; and

(C) that otherwise accomplish the purposes of this title.

(b) SPECIAL RULE.—References in this title to a child with a disability shall be considered to include references to an individual who is not younger than age 18 who—

(1) has a significant impairment described in subsection (a)(1)(A); and

(2) is residing with and receiving assistance from a family member.

**SEC. 204. [15093] GRANTS TO STATES.**

(a) IN GENERAL.—The Secretary shall make grants to States on a competitive basis, in accordance with the provisions of this title, to support systems change activities designed to assist States to develop and implement, or expand and enhance, a statewide system of family support services for families of children with disabilities that accomplishes the purposes of this title.

(b) AWARD PERIOD AND GRANT LIMITATION.—No grant shall be awarded under this section for a period of more than 3 years. No State shall be eligible for more than 1 grant under this section.

(c) AMOUNT OF GRANTS.—

(1) GRANTS TO STATES.—

(A) FEDERAL MATCHING SHARE.—From amounts appropriated under section 212(a), the Secretary shall pay to each State that has an application approved under section 205, for each year of the grant period, an amount that is—

(i) equal to not more than 75 percent of the cost of the systems change activities to be carried out by the State; and

(ii) not less than $100,000 and not more than $500,000.

(B) NON-FEDERAL SHARE.—The non-Federal share of the cost of the systems change activities may be in cash or in kind, fairly evaluated, including plant, equipment, or services.

(2) CALCULATION OF AMOUNTS.—The Secretary shall calculate a grant amount described in paragraph (1) on the basis of—

(A) the amounts available for making grants under this section; and

(B) the child population of the State concerned.

(d) PRIORITY FOR PREVIOUSLY PARTICIPATING STATES.—For the second and third fiscal years for which amounts are appropriated to carry out this section, the Secretary, in providing payments under this section, shall give priority to States that received payments under this section during the preceding fiscal year.

(e) PRIORITIES FOR DISTRIBUTION.—To the extent practicable, the Secretary shall award grants to States under this section in a manner that—

(1) is geographically equitable;

(2) distributes the grants among States that have differing levels of development of statewide systems of family support services for families of children with disabilities; and

(3) distributes the grants among States that attempt to meet the needs of unserved and underserved populations, such as individuals from racial and ethnic minority backgrounds, disadvantaged individuals, individuals with limited English proficiency, and individuals from underserved geographic areas (rural or urban).

**SEC. 205. [15094] APPLICATION.**

To be eligible to receive a grant under this title, a State shall submit an application to the Secretary at such time, in such manner, and containing such information and assurances as the Secretary may require, including information about the designation of a lead entity, a description of available State resources, and assurances that systems change activities will be family-centered and family-directed.

**SEC. 206. [15095] DESIGNATION OF THE LEAD ENTITY.**

(a) DESIGNATION.—The Chief Executive Officer of a State that desires to receive a grant under section 204, shall designate the office or entity (referred to in this title as the "lead entity") responsible for—

(1) submitting the application described in section 205 on behalf of the State;

(2) administering and supervising the use of the amounts made available under the grant;

(3) coordinating efforts related to and supervising the preparation of the application;

(4) coordinating the planning, development, implementation (or expansion and enhancement), and evaluation of a statewide system of family support services for families of children with disabilities among public agencies and between pub-

lic agencies and private agencies, including coordinating efforts related to entering into interagency agreements;

(5) coordinating efforts related to the participation by families of children with disabilities in activities carried out under a grant made under this title; and

(6) submitting the report described in section 208 on behalf of the State.

(b) QUALIFICATIONS.—In designating the lead entity, the Chief Executive Officer may designate—

(1) an office of the Chief Executive Officer;

(2) a commission appointed by the Chief Executive Officer;

(3) a public agency;

(4) a council established under Federal or State law; or

(5) another appropriate office, agency, or entity.

**SEC. 207. [15096] AUTHORIZED ACTIVITIES.**

(a) IN GENERAL.—A State that receives a grant under section 204 shall use the funds made available through the grant to carry out systems change activities that accomplish the purposes of this title.

(b) SPECIAL RULE.—In carrying out activities authorized under this title, a State shall ensure that such activities address the needs of families of children with disabilities from unserved or underserved populations.

**SEC. 208. [15097] REPORTING.**

A State that receives a grant under this title shall prepare and submit to the Secretary, at the end of the grant period, a report containing the results of State efforts to develop and implement, or expand and enhance, a statewide system of family support services for families of children with disabilities.

**SEC. 209. [15098] TECHNICAL ASSISTANCE.**

(a) IN GENERAL.—The Secretary shall enter into contracts or cooperative agreements with appropriate public or private agencies and organizations, including institutions of higher education, with documented experience, expertise, and capacity, for the purpose of providing technical assistance and information with respect to the development and implementation, or expansion and enhancement, of a statewide system of family support services for families of children with disabilities.

(b) PURPOSE.—An agency or organization that provides technical assistance and information under this section in a State that receives a grant under this title shall provide the technical assistance and information to the lead entity of the State, family members of children with disabilities, organizations, service providers, and policymakers involved with children with disabilities and their families. Such an agency or organization may also provide technical assistance and information to a State that does not receive a grant under this title.

(c) REPORTS TO THE SECRETARY.—An entity providing technical assistance and information under this section shall prepare and submit to the Secretary periodic reports regarding Federal policies and procedures identified within the States that facilitate or impede the delivery of family support services to families of children with disabilities. The report shall include recommendations to the

Secretary regarding the delivery of services, coordination with other programs, and integration of the policies described in section 202 in Federal law, other than this title.

**SEC. 210. [15099] EVALUATION.**

(a) IN GENERAL.—The Secretary shall conduct a national evaluation of the program of grants to States authorized by this title.

(b) PURPOSE.—

(1) IN GENERAL.—The Secretary shall conduct the evaluation under subsection (a) to assess the status and effects of State efforts to develop and implement, or expand and enhance, statewide systems of family support services for families of children with disabilities in a manner consistent with the provisions of this title. In particular, the Secretary shall assess the impact of such efforts on families of children with disabilities, and recommend amendments to this title that are necessary to assist States to accomplish fully the purposes of this title.

(2) INFORMATION SYSTEMS.—The Secretary shall work with the States to develop an information system designed to compile and report, from information provided by the States, qualitative and quantitative descriptions of the impact of the program of grants to States authorized by this title on—

(A) families of children with disabilities, including families from unserved and underserved populations;

(B) access to and funding for family support services for families of children with disabilities;

(C) interagency coordination and collaboration between agencies responsible for providing the services; and

(D) the involvement of families of children with disabilities at all levels of the statewide systems.

(c) REPORT TO CONGRESS.—Not later than 2½ years after the date of enactment of this Act, the Secretary shall prepare and submit to the appropriate committees of Congress a report concerning the results of the evaluation conducted under this section.

**SEC. 211. [15100] PROJECTS OF NATIONAL SIGNIFICANCE.**

(a) STUDY BY THE SECRETARY.—The Secretary shall review Federal programs to determine the extent to which such programs facilitate or impede access to, provision of, and funding for family support services for families of children with disabilities, consistent with the policies described in section 202.

(b) PROJECTS OF NATIONAL SIGNIFICANCE.—The Secretary shall make grants or enter into contracts for projects of national significance to support the development of national and State policies and practices related to the development and implementation, or expansion and enhancement, of family-centered and family-directed systems of family support services for families of children with disabilities.

**SEC. 212. [15101] AUTHORIZATION OF APPROPRIATIONS.**

(a) IN GENERAL.—There are authorized to be appropriated to carry out this title such sums as may be necessary for each of fiscal years 2001 through 2007.

(b) RESERVATION.—

(1) IN GENERAL.—The Secretary shall reserve for each fiscal year 10 percent, or $400,000 (whichever is greater), of the amount appropriated pursuant to subsection (a) to carry out—

(A) section 209 (relating to the provision of technical assistance and information to States); and

(B) section 210 (relating to the conduct of evaluations).

(2) SPECIAL RULE.—For each year that the amount appropriated pursuant to subsection (a) is $10,000,000 or greater, the Secretary may reserve 5 percent of such amount to carry out section 211.

# TITLE III—PROGRAM FOR DIRECT SUPPORT WORKERS WHO ASSIST INDIVIDUALS WITH DEVELOPMENTAL DISABILITIES

**SEC. 301. [15111] FINDINGS.**

Congress finds that—

(1) direct support workers, especially young adults, have played essential roles in providing the support needed by individuals with developmental disabilities and expanding community options for those individuals;

(2) 4 factors have contributed to a decrease in the available pool of direct support workers, specifically—

(A) the small population of individuals who are age 18 through 25, an age group that has been attracted to direct support work in the past;

(B) the rapid expansion of the service sector, which attracts individuals who previously would have elected to pursue employment as direct support workers;

(C) the failure of wages in the human services sector to keep pace with wages in other service sectors; and

(D) the lack of quality training and career advancement opportunities available to direct support workers; and

(3) individuals with developmental disabilities benefit from assistance from direct support workers who are well trained, and benefit from receiving services from professionals who have spent time as direct support workers.

**SEC. 302. [15112] DEFINITIONS.**

In this title:

(1) DEVELOPMENTAL DISABILITY.—The term "developmental disability" has the meaning given the term in section 102.

(2) INSTITUTION OF HIGHER EDUCATION.—The term "institution of higher education" has the meaning given the term in section 1201 of the Higher Education Act of 1965 (20 U.S.C. 1141).

(3) SECRETARY.—The term "Secretary" means the Secretary of Health and Human Services.

**SEC. 303. [15113] REACHING UP SCHOLARSHIP PROGRAM.**

(a) PROGRAM AUTHORIZATION.—The Secretary may award grants to eligible entities, on a competitive basis, to enable the entities to carry out scholarship programs by providing vouchers for postsecondary education to direct support workers who assist individuals with developmental disabilities residing in diverse settings. The Secretary shall award the grants to pay for the Federal share of the cost of providing the vouchers.

(b) ELIGIBLE ENTITY.—To be eligible to receive a grant under this section, an entity shall be—

(1) an institution of higher education;

(2) a State agency; or

(3) a consortium of such institutions or agencies.

(c) APPLICATION REQUIREMENTS.—To be eligible to receive a grant under this section, an eligible entity shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require, including a description of—

(1) the basis for awarding the vouchers;

(2) the number of individuals to receive the vouchers; and

(3) the amount of funds that will be made available by the eligible entity to pay for the non-Federal share of the cost of providing the vouchers.

(d) SELECTION CRITERIA.—In awarding a grant under this section for a scholarship program, the Secretary shall give priority to an entity submitting an application that—

(1) specifies that individuals who receive vouchers through the program will be individuals—

(A) who are direct support workers who assist individuals with developmental disabilities residing in diverse settings, while pursuing postsecondary education; and

(B) each of whom verifies, prior to receiving the voucher, that the worker has completed 250 hours as a direct support worker in the past 90 days;

(2) states that the vouchers that will be provided through the program will be in amounts of not more than $2,000 per year;

(3) provides an assurance that the eligible entity (or another specified entity that is not a voucher recipient) will contribute the non-Federal share of the cost of providing the vouchers; and

(4) meets such other conditions as the Secretary may specify.

(e) FEDERAL SHARE.—The Federal share of the cost of providing the vouchers shall be not more than 80 percent.

**SEC. 304. [15114] STAFF DEVELOPMENT CURRICULUM AUTHORIZATION.**

(a) FUNDING.—

(1) IN GENERAL.—The Secretary shall award funding, on a competitive basis, through a grant, cooperative agreement, or contract, to a public or private entity or a combination of such entities, for the development, evaluation, and dissemination of a staff development curriculum, and related guidelines, for

computer-assisted, competency-based, multimedia, interactive instruction, relating to service as a direct support worker.

(2) PARTICIPANTS.—The curriculum shall be developed for individuals who—

(A) seek to become direct support workers who assist individuals with developmental disabilities or are such direct support workers; and

(B) seek to upgrade their skills and competencies related to being a direct support worker.

(b) APPLICATION REQUIREMENTS.—To be eligible to receive an award under this section, an entity shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require, including—

(1) a comprehensive analysis of the content of direct support roles;

(2) information identifying an advisory group that—

(A) is comprised of individuals with experience and expertise with regard to the support provided by direct support workers, and effective ways to provide the support, for individuals with developmental disabilities in diverse settings; and

(B) will advise the entity throughout the development, evaluation, and dissemination of the staff development curriculum and guidelines;

(3) information describing how the entity will—

(A) develop, field test, and validate a staff development curriculum that—

(i) relates to the appropriate reading level for direct service workers who assist individuals with disabilities;

(ii) allows for multiple levels of instruction;

(iii) provides instruction appropriate for direct support workers who work in diverse settings; and

(iv) is consistent with subsections (b) and (c) of section 101 and section 109;

(B) develop, field test, and validate guidelines for the organizations that use the curriculum that provide for—

(i) providing necessary technical and instructional support to trainers and mentors for the participants;

(ii) ensuring easy access to and use of such curriculum by workers that choose to participate in using, and agencies that choose to use, the curriculum;

(iii) evaluating the proficiency of the participants with respect to the content of the curriculum;

(iv) providing necessary support to the participants to assure that the participants have access to, and proficiency in using, a computer in order to participate in the development, testing, and validation process;

(v) providing necessary technical and instructional support to trainers and mentors for the participants in conjunction with the development, testing, and validation process;

(vi) addressing the satisfaction of participants, individuals with developmental disabilities and their families, providers of services for such individuals and families, and other relevant entities with the curriculum; and

(vii) developing methods to maintain a record of the instruction completed, and the content mastered, by each participant under the curriculum; and

(C) nationally disseminate the curriculum and guidelines, including dissemination through—

(i) parent training and information centers funded under part D of the Individuals with Disabilities Education Act (20 U.S.C. 1451 et seq.);

(ii) community-based organizations of and for individuals with developmental disabilities and their families;

(iii) entities funded under title I;

(iv) centers for independent living;

(v) State educational agencies and local educational agencies;

(vi) entities operating appropriate medical facilities;

(vii) postsecondary education entities; and

(viii) other appropriate entities; and

(4) such other information as the Secretary may require.

**SEC. 305. [15115] AUTHORIZATION OF APPROPRIATIONS.**

(a) SCHOLARSHIPS.—There are authorized to be appropriated to carry out section 303 $800,000 for fiscal year 2001 and such sums as may be necessary for each of fiscal years 2002 through 2007.

(b) STAFF DEVELOPMENT CURRICULUM.—There are authorized to be appropriated to carry out section 304 $800,000 for fiscal year 2001 and such sums as may be necessary for each of fiscal years 2002 and 2003.

# TITLE IV—REPEAL [1]

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[1] Title IV is not shown because it is amendatory in nature. Subsection (a) of section 401 repealed the Developmental Disabilities Assistance and Bill of Rights Act (see footnote for the beginning of this Act), and subsection (b) amended various provisions of law to strike references to such Act and insert references to this Act, which is the Developmental Disabilities Assistance and Bill of Rights Act of 2000. There are no other sections in title IV.

# MENTAL HEALTH SYSTEMS ACT

# MENTAL HEALTH SYSTEMS ACT [1]

**(References in black brackets [ ] are to title 42, United States Code)**

## SHORT TITLE AND TABLE OF CONTENTS

SECTION 1. This Act may be cited as the "Mental Health Systems Act".

TABLE OF CONTENTS

Sec. 1. Short title and table of contents.
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TITLE V—MENTAL HEALTH RIGHTS AND ADVOCACY

Sec. 501. Bill of rights.

TITLE VI—RAPE PREVENTION AND CONTROL [2]

Sec. 601. Rape prevention and control.

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TITLE VIII—MISCELLANEOUS

* * * * * * *

Sec. 802. Report on shelter and basic living needs of chronically mentally ill individuals.

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## FINDINGS

SEC. 2. [9401] The Congress finds—

(1) despite the significant progress that has been made in making community mental health services available and in improving residential mental health facilities since the original community mental health centers legislation was enacted in 1963, unserved and underserved populations remain and there are certain groups in the population, such as chronically mentally ill individuals, children and youth, elderly individuals, racial and ethnic minorities, women, poor persons, and persons in rural areas, which often lack access to adequate private and public mental health services and support services;

(2) the process of transferring or diverting chronically mentally ill individuals from unwarranted or inappropriate institutionalized settings to their home communities has frequently not been accompanied by a process of providing those

[1] Public Law 96–398. This compilation does not include provisions of such Public Law that amended other provisions of law.

[2] Section 87(d) of Public Law 99–646, and section 3(b) of Public Law 99–654, amended various provisions of this Act by striking "rape" and inserting "sex offense", but failed to conform the table of contents in the item relating to section 601.

individuals with the mental health and support services they need in community-based settings;

(3) the shift in emphasis from institutional care to community-based care has not always been accompanied by a process of affording training, retraining, and job placement for employees affected by institutional closure and conversion;

(4) the delivery of mental health and support services is typically uncoordinated within and among local, State, and Federal entities;

(5) mentally ill persons are often inadequately served by (A) programs of the Department of Health and Human Services such as medicare, medicaid, supplemental security income, and social services, and (B) programs of the Department of Housing and Urban Development, the Department of Labor, and other Federal agencies;

(6) health care systems often lack general health care personnel with adequate mental health care training and often lack mental health care personnel and consequently many individuals with some level of mental disorder do not receive appropriate mental health care;

(7) present knowledge of methods to prevent mental illness through discovery and elimination of its causes and through early detection and treatment is too limited;

(8) a comprehensive and coordinated array of appropriate private and public mental health and support services for all people in need within specific geographic areas, based upon a cooperative local-State-Federal partnership, remains the most effective and humane way to provide a majority of mentally ill individuals with mental health care and needed support; and

(9) because of the rising demand for mental health services and the wide disparity in the distribution of psychiatrists, clinical psychologists, social workers, and psychiatric nurses, there is a shortage in the medical specialty of psychiatry and there are also shortages among the other health personnel who provide mental health services.

## TITLE I—GENERAL PROVISIONS

### DEFINITIONS

SEC. 102. [9412] For purposes of this Act:

(1) The term "Secretary" means the Secretary of Health and Human Services.

(2) The term "State" includes (in addition to the fifty States) the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, the Trust Territory of the Pacific Islands, and the Northern Mariana Islands.

(3) The term "nonprofit", as applied to any entity, means an entity which 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 person.

* * * * * * *

# TITLE V—MENTAL HEALTH RIGHTS AND ADVOCACY

## BILL OF RIGHTS

SEC. 501. [9501] It is the sense of the Congress that each State should review and revise, if necessary, its laws to ensure that mental health patients receive the protection and services they require; and in making such review and revision should take into account the recommendations of the President's Commission on Mental Health and the following:

(1) A person admitted to a program or facility for the purpose of receiving mental health services should be accorded the following:

(A) The right to appropriate treatment and related services in a setting and under conditions that—

(i) are the most supportive of such person's personal liberty; and

(ii) restrict such liberty only to the extent necessary consistent with such person's treatment needs, applicable requirements of law, and applicable judicial orders.

(B) The right to an individualized, written, treatment or service plan (such plan to be developed promptly after admission of such person), the right to treatment based on such plan, the right to periodic review and reassessment of treatment and related service needs, and the right to appropriate revision of such plan, including any revision necessary to provide a description of mental health services that may be needed after such person is discharged from such program or facility.

(C) The right to ongoing participation, in a manner appropriate to such person's capabilities, in the planning of mental health services to be provided such person (including the right to participate in the development and periodic revision of the plan described in subparagraph (B)), and, in connection with such participation, the right to be provided with a reasonable explanation, in terms and language appropriate to such person's condition and ability to understand, of—

(i) such person's general mental condition and, if such program or facility has provided a physical examination, such person's general physical condition;

(ii) the objectives of treatment;

(iii) the nature and significant possible adverse effects of recommended treatments;

(iv) the reasons why a particular treatment is considered appropriate;

(v) the reasons why access to certain visitors may not be appropriate; and

(vi) any appropriate and available alternative treatments, services, and types of providers of mental health services.

(D) The right not to receive a mode or course of treatment, established pursuant to the treatment plan, in the

absence of such person's informed, voluntary, written consent to such mode or course of treatment, except treatment—

(i) during an emergency situation if such treatment is pursuant to or documented contemporaneously by the written order of a responsible mental health professional; or

(ii) as permitted under applicable law in the case of a person committed by a court to a treatment program or facility.

(E) The right not to participate in experimentation in the absence of such person's informed, voluntary, written consent, the right to appropriate protections in connection with such participation, including the right to a reasonable explanation of the procedure to be followed, the benefits to be expected, the relative advantages of alternative treatments, and the potential discomforts and risks, and the right and opportunity to revoke such consent.

(F) The right to freedom from restraint or seclusion, other than as a mode or course of treatment or restraint or seclusion during an emergency situation if such restraint or seclusion is pursuant to or documented contemporaneously by the written order of a responsible mental health professional.

(G) The right to a humane treatment environment that affords reasonable protection from harm and appropriate privacy to such person with regard to personal needs.

(H) The right to confidentiality of such person's records.

(I) The right to access, upon request, to such person's mental health care records, except such person may be refused access to—

(i) information in such records provided by a third party under assurance that such information shall remain confidential; and

(ii) specific material in such records if the health professional responsible for the mental health services concerned has made a determination in writing that such access would be detrimental to such person's health, except that such material may be made available to a similarly licensed health professional selected by such person and such health professional may, in the exercise of professional judgment, provide such person with access to any or all parts of such material or otherwise disclose the information contained in such material to such person.

(J) The right, in the case of a person admitted on a residential or inpatient care basis, to converse with others privately, to have convenient and reasonable access to the telephone and mails, and to see visitors during regularly scheduled hours, except that, if a mental health professional treating such person determines that denial of access to a particular visitor is necessary for treatment pur-

poses, such mental health professional may, for a specific, limited, and reasonable period of time, deny such access if such mental health professional has ordered such denial in writing and such order has been incorporated in the treatment plan for such person. An order denying such access should include the reasons for such denial.

(K) The right to be informed promptly at the time of admission and periodically thereafter, in language and terms appropriate to such person's condition and ability to understand, of the rights described in this section.

(L) The right to assert grievances with respect to infringement of the rights described in this section, including the right to have such grievances considered in a fair, timely, and impartial grievance procedure provided for or by the program or facility.

(M) Notwithstanding subparagraph (J), the right of access to (including the opportunities and facilities for private communication with) any available—

(i) rights protection service within the program or facility;

(ii) rights protection service within the State mental health system designed to be available to such person; and

(iii) qualified advocate;

for the purpose of receiving assistance to understand, exercise, and protect the rights described in this section and in other provisions of law.

(N) The right to exercise the rights described in this section without reprisal, including reprisal in the form of denial of any appropriate, available treatment.

(O) The right to referral as appropriate to other providers of mental health services upon discharge.

(2)(A) The rights described in this section should be in addition to and not in derogation of any other statutory or constitutional rights.

(B) The rights to confidentiality of and access to records as provided in subparagraphs (H) and (I) of paragraph (1) should remain applicable to records pertaining to a person after such person's discharge from a program or facility.

(3)(A) No otherwise eligible person should be denied admission to a program or facility for mental health services as a reprisal for the exercise of the rights described in this section.

(B) Nothing in this section should—

(i) obligate an individual mental health or health professional to administer treatment contrary to such professional's clinical judgment;

(ii) prevent any program or facility from discharging any person for whom the provision of appropriate treatment, consistent with the clinical judgment of the mental health professional primarily responsible for such person's treatment, is or has become impossible as a result of such person's refusal to consent to such treatment;

(iii) require a program or facility to admit any person who, while admitted on prior occasions to such program or facility,

has repeatedly frustrated the purposes of such admissions by withholding consent to proposed treatment; or

(iv) obligate a program or facility to provide treatment services to any person who is admitted to such program or facility solely for diagnostic or evaluative purposes.

(C) In order to assist a person admitted to a program or facility in the exercise or protection of such person's rights, such person's attorney or legal representatives should have reasonable access to—

(i) such person;

(ii) the areas of the program or facility where such person has received treatment, resided, or had access; and

(iii) pursuant to the written authorization of such person, the records and information pertaining to such person's diagnosis, treatment, and related services described in paragraph (1)(I).

(D) Each program and facility should post a notice listing and describing, in language and terms appropriate to the ability of the persons to whom such notice is addressed to understand, the rights described in this section of all persons admitted to such program or facility. Each such notice should conform to the format and content for such notices, and should be posted in all appropriate locations.

(4)(A) In the case of a person adjudicated by a court of competent jurisdiction as being incompetent to exercise the right to consent to treatment or experimentation described in subparagraph (D) or (E) of paragraph (1), or the right to confidentiality of or access to records described in subparagraph (H) or (I) of such paragraph, or to provide authorization as described in paragraph (3)(C)(iii), such right may be exercised or such authorization may be provided by the individual appointed by such court as such person's guardian or representative for the purpose of exercising such right or such authorization.

(B) In the case of a person who lacks capacity to exercise the right to consent to treatment or experimentation under subparagraph (D) or (E) of paragraph (1), or the right to confidentiality of or access to records described in subparagraph (H) or (I) of such paragraph, or to provide authorization as described in paragraph (3)(C)(iii), because such person has not attained an age considered sufficiently advanced under State law to permit the exercise of such right or such authorization to be legally binding, such right may be exercised or such authorization may be provided on behalf of such person by a parent or legal guardian of such person.

(C) Notwithstanding subparagraphs (A) and (B), in the case of a person admitted to a program or facility for the purpose of receiving mental health services, no individual employed by or receiving any remuneration from such program or facility should act as such person's guardian or representative.

## TITLE VI—SEX OFFENSE PREVENTION AND CONTROL

### SEX OFFENSE PREVENTION AND CONTROL

SEC. 601. [9511] (a) The Secretary, acting through the National Center for the Prevention and Control of Sex Offenses (here-

after in this section referred to as the "Center"), may, directly or by grant, carry out the following:

(1) A continuing study of sex offenses, including a study and investigation of—

(A) the effectiveness of existing Federal, State, and local laws dealing with sex offenses;

(B) the relationship, if any, between traditional legal and social attitudes toward sexual roles, sex offenses, and the formulation of laws dealing with sex offenses;

(C) the treatment of the victims of sex offenses by law enforcement agencies, hospitals or other medical institutions, prosecutors, and the courts;

(D) the causes of sex offenses, identifying to the degree possible—

(i) social conditions which encourage sexual attacks, and

(ii) the motives of offenders, and

(E) the impact of a sex offense on the victim and family of the victim;

(F) sexual assaults in correctional institutions;

(G) the estimated actual incidence of forcible sex offenses as compared to the reported incidence of forcible sex offenses and the reasons for any difference between the two; and

(H) the effectiveness of existing private and local and State government educational, counseling, and other programs designed to prevent and control sex offenses.

(2) The compilation, analysis, and publication of summaries of the continuing study conducted under paragraph (1) and the research and demonstration projects conducted under paragraph (5). The Secretary shall submit not later than March 30, 1983, to the Congress a summary of such study and projects together with a review of their effectiveness and recommendations where appropriate.

(3) The development and maintenance of an information clearinghouse with regard to—

(A) the prevention and control of sex offenses;

(B) the treatment and counseling of the victims of sex offenses and their families; and

(C) the rehabilitation of offenders.

(4) The compilation and publication of training materials for personnel who are engaged or intend to engage in programs designed to prevent and control rape.

(5) Assistance to qualified public and nonprofit private entities in conducting research and demonstration projects concerning the prevention and control of rape, including projects (A) for the planning, development, implementation, and evaluation of alternative methods used in the prevention and control of rape, the treatment and counseling of the victims of rape and their families, and the rehabilitation of offenders; (B) for the application of such alternative methods; and (C) for the promotion of community awareness of the specific locations in which, and the specific social and other conditions under which sexual attacks are most likely to occur.

(b) The Secretary shall appoint an advisory committee to advise, consult with, and make recommendations to the Secretary on the implementation of subsection (a). The recommendations of the committee shall be submitted directly to the Secretary without review or revision by any person without the consent of the committee. The Secretary shall appoint to such committee persons who are particularly qualified to assist in carrying out the functions of the committee. A majority of the members of the committee shall be women. Members of the advisory committee 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 committee and, while so serving away from their homes or regular places of business, each member shall be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as authorized by section 5703 of title 5, United States Code, for persons in Government service employed intermittently.

(c) No grant may be made under subsection (a) unless an application therefor is submitted to and approved by the Secretary. The application shall be submitted in such form and manner and contain such information as the Secretary may prescribe.

(d) For the purpose of carrying out subsection (a), there are authorized to be appropriated $6,000,000 for the fiscal year ending September 30, 1981, $1,500,000 for the fiscal year ending September 30, 1982, $1,500,000 for the fiscal year ending September 30, 1983.

(e) For purposes of subsection (a), the term "sex offense" includes statutory and attempted rape and any other criminal sexual assault (whether homosexual or heterosexual) which involves force or the threat of force.

(f) Part D of the Community Mental Health Centers Act is repealed.

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## TITLE VIII—MISCELLANEOUS

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### REPORT ON SHELTER AND BASIC LIVING NEEDS OF CHRONICALLY MENTALLY ILL INDIVIDUALS

SEC. 802. [9522] (a) The Secretary of Health and Human Services and the Secretary of Housing and Urban Development shall jointly submit a report to the Committees on Labor and Human Resources and Banking, Housing, and Urban Affairs of the Senate, and the Committees on Interstate and Foreign Commerce and Banking, Finance and Urban Affairs of the House of Representatives, relating to Federal efforts to respond to the shelter and basic living needs of chronically mentally ill individuals.

(b) The report required by subsection (a) shall include—

(1) an analysis of the extent to which chronically mentally ill individuals remain inappropriately housed in institutional facilities or have otherwise inadequate or inappropriate housing arrangements;

(2) an analysis of available permanent noninstitutional housing arrangements for the chronically mentally ill;

(3) an evaluation of ongoing permanent and demonstration programs, funded in whole or in part by Federal funds, which are designed to provide noninstitutional shelter and basic living services for the chronically mentally ill, including—

(A) a description of each program;

(B) the total number of individuals estimated to be eligible to participate in each program, the number of individuals served by each program, and an estimate of the total population each program expects to serve; and

(C) an assessment of the effectiveness of each program in the provision of shelter and basic living services;

(4) recommendations of measures to encourage States to coordinate and link the provisions in State health plans which relate to mental health and, in particular, the shelter and basic living needs of chronically mentally ill individuals, with local and State housing plans;

(5) recommendations for Federal legislation relating to the provision of permanent residential noninstitutional housing arrangements and basic living services for chronically mentally ill individuals, including an estimate of the cost of such recommendations; and

(6) any other recommendations for Federal initiatives which, in the judgment of the Secretary of Health and Human Services and the Secretary of Housing and Urban Development, will lead to improved shelter and basic living services for chronically mentally ill individuals.

(c) The report required by subsection (a) shall be submitted to the committees referred to in subsection (a) no later than January 1, 1981.

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# CONSUMER–PATIENT RADIATION HEALTH AND SAFETY ACT OF 1981

# CONSUMER–PATIENT RADIATION HEALTH AND SAFETY ACT OF 1981 [1]

**(References in black brackets [ ] are to title 42, United States Code)**

SHORT TITLE

SEC. 975. This subtitle may be cited as the "Consumer-Patient Radiation Health and Safety Act of 1981".

STATEMENT OF FINDINGS

SEC. 976. [10001] The Congress finds that—

(1) it is in the interest of public health and safety to minimize unnecessary exposure to potentially hazardous radiation due to medical and dental radiologic procedures;

(2) it is in the interest of public health and safety to have a continuing supply of adequately educated persons and appropriate accreditation and certification programs administered by State governments;

(3) the protection of the public health and safety from unnecessary exposure to potentially hazardous radiation due to medical and dental radiologic procedures and the assurance of efficacious procedures are the responsibility of State and Federal governments;

(4) persons who administer radiologic procedures, including procedures at Federal facilities, should be required to demonstrate competence by reason of education, training, and experience; and

(5) the administration of radiologic procedures and the effect on individuals of such procedures have a substantial and direct effect upon United States interstate commerce.

STATEMENT OF PURPOSE

SEC. 977. [10002] It is the purpose of this subtitle to—

(1) provide for the establishment of minimum standards by the Federal Government for the accreditation of education programs for persons who administer radiologic procedures and for the certification of such persons; and

(2) insure that medical and dental radiologic procedures are consistent with rigorous safety precautions and standards.

DEFINITIONS

SEC. 978. [10003] Unless otherwise expressly provided, for purposes of this subtitle, the term—

[1] Subtitle I of title IX of Public Law 97–35.

(1) "radiation" means ionizing and nonionizing radiation in amounts beyond normal background levels from sources such as medical and dental radiologic procedures;

(2) "radiologic procedure" means any procedure or article intended for use in—

(A) the diagnosis of disease or other medical or dental conditions in humans (including diagnostic X-rays or nuclear medicine procedures); or

(B) the cure, mitigation, treatment, or prevention of disease in humans;

that achieves its intended purpose through the emission of radiation;

(3) "radiologic equipment" means any radiation electronic product which emits or detects radiation and which is used or intended for use to—

(A) diagnose disease or other medical or dental conditions (including diagnostic X-ray equipment); or

(B) cure, mitigate, treat, or prevent disease in humans;

that achieves its intended purpose through the emission or detection of radiation;

(4) "practitioner" means any licensed doctor of medicine, osteopathy, dentistry, podiatry, or chiropractic, who prescribes radiologic procedures for other persons;

(5) "persons who administer radiologic procedures" means any person, other than a practitioner, who intentionally administers radiation to other persons for medical purposes, and includes medical radiologic technologists (including dental hygienists and assistants), radiation therapy technologists, and nuclear medicine technologists;

(6) "Secretary" means the Secretary of Health and Human Services; and

(7) "State" means the several States, 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.

PROMULGATION OF STANDARDS

SEC. 979. [10004] (a) Within twelve months after the date of enactment of this Act, the Secretary, in consultation with the Radiation Policy Council, the Secretary of Veterans Affairs, the Administrator of the Environmental Protection Agency, appropriate agencies of the States, and appropriate professional organizations, shall by regulation promulgate minimum standards for the accreditation of educational programs to train individuals to perform radiologic procedures. Such standards shall distinguish between programs for the education of (1) medical radiologic technologists (including radiographers), (2) dental auxiliaries (including dental hygienists and assistants), (3) radiation therapy technologists, (4) nuclear medicine technologists, and (5) such other kinds of health auxiliaries who administer radiologic procedures as the Secretary deter-

mines appropriate. Such standards shall not be applicable to educational programs for practitioners.

(b) Within twelve months after the date of enactment of this Act, the Secretary, in consultation with the Radiation Policy Council, the Secretary of Veterans Affairs, the Administrator of the Environmental Protection Agency, interested agencies of the States, and appropriate professional organizations, shall by regulation promulgate minimum standards for the certification of persons who administer radiologic procedures. Such standards shall distinguish between certification of (1) medical radiologic technologists (including radiographers), (2) dental auxiliaries (including dental hygienists and assistants), (3) radiation therapy technologists, (4) nuclear medicine technologists, and (5) such other kinds of health auxiliaries who administer radiologic procedures as the Secretary determines appropriate. Such standards shall include minimum certification criteria for individuals with regard to accredited education, practical experience, successful passage of required examinations, and such other criteria as the Secretary shall deem necessary for the adequate qualification of individuals to administer radiologic procedures. Such standards shall not apply to practitioners.

MODEL STATUTE

SEC. 980. [10005] In order to encourage the administration of accreditation and certification programs by the States, the Secretary shall prepare and transmit to the States a model statute for radiologic procedure safety. Such model statute shall provide that—

(1) it shall be unlawful in a State for individuals to perform radiologic procedures unless such individuals are certified by the State to perform such procedures; and

(2) Any educational requirements for certification of individuals to perform radiologic procedures shall be limited to educational programs accredited by the State.

COMPLIANCE

SEC. 981. [10006] (a) The Secretary shall take all actions consistent with law to effectuate the purposes of this subtitle.

(b) A State may utilize an accreditation or certification program administered by a private entity if—

(1) such State delegates the administration of the State accreditation or certification program to such private entity;

(2) such program is approved by the State; and

(3) such program is consistent with the minimum Federal standards promulgated under this subtitle for such program.

(c) Absent compliance by the States with the provisions of this subtitle within three years after the date of enactment of this Act, the Secretary shall report to the Congress recommendations for legislative changes considered necessary to assure the State's compliance with this subtitle.

(e)[1] Notwithstanding any other provision of this section, in the case of a State which has, prior to the effective date of standards and guidelines promulgated pursuant to this subtitle, established standards for the accreditation of educational programs and certification of radiologic technologists, such State shall be deemed to be in compliance with the conditions of this section unless the Secretary determines, after notice and hearing, that such State standards do not meet the minimum standards prescribed by the Secretary or are inconsistent with the purposes of this subtitle.

FEDERAL RADIATION GUIDELINES

SEC. 982. [10007] The Secretary shall, in conjunction with the Radiation Policy Council, the Secretary of Veterans Affairs, the Administrator of the Environmental Protection Agency, appropriate agencies of the States, and appropriate professional organizations, promulgate Federal radiation guidelines with respect to radiologic procedures. Such guidelines shall—

(1) determine the level of radiation exposure due to radiologic procedures which is unnecessary and specify the techniques, procedures, and methods to minimize such unnecessary exposure;

(2) provide for the elimination of the need for retakes of diagnostic radiologic procedures;

(3) provide for the elimination of unproductive screening programs;

(4) provide for the optimum diagnostic information with minimum radiologic exposure; and

(5) include the therapeutic application of radiation to individuals in the treatment of disease, including nuclear medicine applications.

APPLICABILITY TO FEDERAL AGENCIES

SEC. 983. [10008] (a) Except as provided in subsection (b), each department, agency, and instrumentality of the executive branch of the Federal Government shall comply with standards promulgated pursuant to this subtitle.

(b) The Secretary of Veterans Affairs, through the Chief Medical Director of the Department of Veterans Affairs, shall, to the maximum extent feasible consistent with the responsibilities of such Secretary and Chief Medical Director under title 38, United States Code, prescribe regulations making the standards promulgated pursuant to this subtitle applicable to the provision of radiologic procedures in facilities over which that Secretary has jurisdiction. In prescribing and implementing regulations pursuant to this subsection, the Secretary of Veterans Affairs shall consult with the Secretary in order to achieve the maximum possible coordination of the regulations, standards, and guidelines, and the implementation thereof, which the Secretary and the Secretary of Veterans Affairs prescribe under this subtitle.

[1] Subsection (d) was repealed by section 1061(b) of Public Law 104–66 (109 Stat. 719).

# DRUG ABUSE PREVENTION, TREATMENT, AND REHABILITATION ACT

# DRUG ABUSE PREVENTION, TREATMENT, AND REHABILITATION ACT [1]

**(References in brackets [ ] are to title 21, United States Code)**

## § 1. Short title.

This Act may be cited as the "Drug Abuse Prevention, Treatment, and Rehabilitation Act".

## TITLE I—FINDINGS AND DECLARATION OF POLICY; DEFINITIONS; TERMINATION [2]

Sec.
101. Congressional findings.
102. Declaration of national policy.
103. Definitions.
104. Termination.

## § 101. [1101] Congressional findings.

The Congress makes the following findings:

(1) Drug abuse is rapidly increasing in the United States and now afflicts urban, suburban, and rural areas of the Nation.

(2) Drug abuse seriously impairs individual, as well as societal, health and well-being.

(3) Drug abuse, especially heroin addiction, substantially contributes to crime.

(4) The adverse impact of drug abuse inflicts increasing pain and hardship on individuals, families, and communities and undermines our institutions.

(5) Too little is known about drug abuse, especially the causes, and ways to treat and prevent drug abuse.

(6) The success of Federal drug abuse programs and activities requires a recognition that education, treatment, rehabilitation, research, training, and law enforcement efforts are interrelated.

(7) The effectiveness of efforts by State and local governments and by the Federal Government to control and treat drug abuse in the United States has been hampered by a lack of coordination among the States, between States and localities, among the Federal Government, States and localities, and throughout the Federal establishment.

(8) Control of drug abuse requires the development of a comprehensive, coordinated long-term Federal strategy that encompasses both effective law enforcement against illegal

[1] Public Law 92–255.
[2] Section 1007(c)(1) of Public Law 100–690 repealed section 103 without making a conforming amendment to the table of sections.

drug traffic and effective health programs to rehabilitate victims of drug abuse.

(9) The increasing rate of drug abuse constitutes a serious and continuing threat to national health and welfare, requiring an immediate and effective response on the part of the Federal Government.

(10) Although the Congress observed a significant apparent reduction in the rate of increase of drug abuse during the three-year period subsequent to the date of enactment of this Act, and in certain areas of the country apparent temporary reductions in its incidence, the increase and spread of heroin consumption since 1974, and the continuing abuse of other dangerous drugs, clearly indicate the need for effective, ongoing, and highly visible Federal leadership in the formation and execution of a comprehensive, coordinated drug abuse policy.

(11) Shifts in the usage of various drugs and in the Nation's demographic composition require a Federal strategy to adjust the focus of drug abuse programs to meet new needs and priorities on a cost-effective basis.

(12) The growing extent of drug abuse indicates an urgent need for prevention and intervention programs designed to reach the general population and members of high risk populations such as youth, women, and the elderly.

(13) Effective control of drug abuse requires high-level coordination of Federal international and domestic activities relating to both supply of, and demand for, commonly abused drugs.

(14) Local governments with high concentrations of drug abuse should be actively involved in the planning and coordination of efforts to combat drug abuse.

**§102. [1102] Declaration of national policy.**

The Congress declares that it is the policy of the United States and the purpose of this Act to focus the comprehensive resources of the Federal Government and bring them to bear on drug abuse with the objective of significantly reducing the incidence, as well as the social and personal costs, of drug abuse in the United States, and to develop and assure the implementation of a comprehensive, coordinated, long-term Federal strategy to combat drug abuse. To reach these goals, the Congress further declares that it is the policy of the United States and the purpose of this Act to meet the problems of drug abuse through—

(1) comprehensive Federal, State, and local planning for, and effective use of, Federal assistance to States and to community-based programs to meet the urgent needs of special populations, in coordination with all other governmental and nongovernmental sources of assistance;

(2) the development and support of community-based prevention programs;

(3) the development and encouragement of effective occupational prevention and treatment programs within the Government and in cooperation with the private sector; and

(4) increased Federal commitment to research into the behavioral and biomedical etiology of, the treatment of, and the

mental and physical health and social and economic consequences of, drug abuse.

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## TITLE II—OFFICE OF DRUG ABUSE POLICY

Sec.
201. Concentration of Federal effort. [1]
202. Designated drug representative.
203. Officers and employees.
204. Acceptance of uncompensated services.
205. Notice relating to the control of dangerous drugs. [1]
206. Statutory authority unaffected.

### § 201. [1115] Notice relating to the control of dangerous drugs.

Whenever the Attorney General determines that there is evidence that—

(1) a drug or other substance, which is not a controlled substance (as defined in section 102(6) of the Controlled Substances Act), has a potential for abuse, or

(2) a controlled substance should be transferred or removed from a schedule under section 202 of such Act,

he shall, prior to initiating any proceeding under section 201(a) of such Act, give the President timely notice of such determination. Information forwarded to the Attorney General pursuant to section 201(f) of such Act shall also be forwarded by the Secretary of Health and Human Services to the President.

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## TITLE IV—OTHER FEDERAL PROGRAMS [2]

Sec.
401. Community mental health centers.
402. Public Health Service facilities.
403. State plan requirements.
404. Drug abuse prevention function appropriations.
405. Special reports by the Secretary of Health and Human Services.
406. Additional drug abuse prevention functions of the Secretary of Health and Human Services.
407. Admission of drug abusers to private and public hospitals.
408. Confidentiality of patient records.
409. Repealed.
410. Grants and contracts for the demonstration of new and more effective prevention, treatment, and rehabilitation programs.
411. Records and audit.
412. National Drug Abuse Training Center.
413. Drug abuse among government and other employees.
414. Contract authority.

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[1] Section 1007(c)(1) of Public Law 100–690 repealed sections 201, 202, 203, 204, and 206, and redesignated section 205 as section 201, without making conforming amendments to the table of sections.

[2] Various public laws have amended title IV without conforming the table of sections.

**§ 404. [1171] Drug abuse prevention function appropriations.**

Any request for appropriations by a department or agency of the Government submitted after the date of enactment of this Act shall specify (1) on a line item basis, that part of the appropriations which the department or agency is requesting to carry out its drug abuse prevention functions, and (2) the authorization of the appropriations requested to carry out each of its drug abuse prevention functions.

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**§ 406. [1173] Additional drug abuse prevention functions of the Secretary of Health and Human Services.**

(b) After December 31, 1974, the Secretary shall carry out his functions under subsection (a) through the National Institute on Drug Abuse.

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**§ 410. [1177] Grants and contracts for the demonstration of new and more effective prevention, treatment, and rehabilitation programs.**

(a) The Secretary[1] acting through the National Institute on Drug Abuse, may make grants to and enter into contracts with individuals and public and private nonprofit entities—

(1) to provide training seminars, educational programs, and technical assistance for the development, demonstration, and evaluation of drug abuse prevention, treatment, and rehabilitation programs; and

(2) to conduct demonstration and evaluation projects, with a high priority on prevention and early intervention projects and on identifying new and more effective drug abuse prevention, treatment, and rehabilitation programs.

In the implementation of his authority under this section, the Secretary shall accord a high priority to applications for grants or contracts for primary prevention programs. For purposes of the preceding sentence, primary prevention programs include programs designed to discourage persons from beginning drug abuse. To the extent that appropriations authorized under this section are used to fund treatment services, the Secretary shall not limit such funding to treatment for opiate abuse, but shall also provide support for treatment for nonopiate drug abuse including polydrug abuse. Furthermore, nothing shall prevent the use of funds provided under this section for programs and projects aimed at the prevention, treatment, and rehabilitation of alcohol abuse and alcoholism as well as drug abuse.

(b) There are authorized to be appropriated $25,000,000 for the fiscal year ending June 30, 1972; $65,000,000 for the fiscal year ending June 30, 1973; $100,000,000 for the fiscal year ending June 30, 1974; $160,000,000 for each of the fiscal years ending June 30, 1975 and June 30, 1976; $40,000,000 for the period July 1, 1976,

[1] So in law. "Secretary" probably should be followed by a comma.

through September 30, 1976; and $160,000,000 for each of the fiscal years ending September 30, 1977, and September 30, 1978, to carry out this section. For the fiscal year ending September 30, 1979, there is authorized to be appropriated (1) $153,000,000 for grants and contracts under paragraphs (3) and (6) of subsection (a) for drug abuse treatment programs, and (2) $24,000,000 for grants and contracts under such subsection for other programs and activities. For grants and contracts under paragraphs (3) and (6) of subsection (a) for drug abuse treatment programs there is authorized to be appropriated $149,000,000 for the fiscal year ending September 30, 1980, and $155,000,000 for the fiscal year ending September 30, 1981; and for grants and contracts under such subsection for other programs and activities there is authorized to be appropriated $20,000,000 for the fiscal year ending September 30, 1980, and $30,000,000 for the fiscal year ending September 30, 1981. Of the funds appropriated under the preceding sentence for the fiscal year ending September 30, 1980, at least 7 percent of the funds shall be obligated for grants and contracts for primary prevention and intervention programs designed to discourage individuals, particularly those in high risk populations, from abusing drugs; and of the funds appropriated under the preceding sentence for the next fiscal year, at least 10 percent of the funds shall be obligated for such grants and contracts. For carrying out the purposes of this section, there are authorized to be appropriated $15,000,000 for the fiscal year ending September 30, 1982. Of the funds appropriated under the preceding sentence, at least 25 per centum of the funds shall be obligated for grants and contracts for primary prevention and intervention programs designed to discourage individuals, particularly individuals in high risk populations, from abusing drugs.

(c)(1) In carrying out this section, the Secretary shall require coordination of all applications for programs in a State and shall not give precedence to public agencies over private agencies, institutions, and organizations, or to State agencies over local agencies.

(2) Each applicant within a State, upon filing its application with the Secretary for a grant or contract under this section, shall submit a copy of its application for review by the State agency (if any) responsible for the administration of drug abuse prevention activities. Such State agency shall be given not more than thirty days from the date of receipt of the application to submit to the Secretary, in writing, an evaluation of the project set forth in the application. Such evaluation shall include comments on the relationship of the project to other projects pending and approved and to any State comprehensive plan for treatment and prevention of drug abuse. The State shall furnish the applicant a copy of any such evaluation. A State if it so desires may, in writing, waive its rights under this paragraph.

(3) Approval of any application for a grant or contract under this section by the Secretary, including the earmarking of financial assistance for a program or project, may be granted only if the application substantially meets a set of criteria that

(A) provide that the activities and services for which assistance under this section is sought will be substantially administered by or under the supervision of the applicant;

(B) provide for such methods of administration as are necessary for the proper and efficient operation of such programs or projects; and

(C) provide for such fiscal control and fund accounting procedures as may be necessary to assure proper disbursement of and accounting for Federal funds paid to the applicant.

(4) Each applicant within a State, upon filing its application with the Secretary for a grant or contract to provide treatment or rehabilitation services shall provide a proposed performance standard or standards, to measure, or research protocol to determine, the effectiveness of such treatment or rehabilitation program or project.

(d) The Secretary shall encourage the submission of and give special consideration to applications under this section to programs and projects aimed at underserved populations such as racial and ethnic minorities, Native Americans (including Native Hawaiians and Native American Pacific Islanders, youth, the elderly, women, handicapped individuals, and families of drug abusers.

(e) Payment under grants or contracts under this section may be made in advance or by way of reimbursement and in such installments as the Secretary may determine.

(f) Projects and programs for which grants and contracts are made or entered into under this section shall, in the case of prevention and treatment services, seek to (1) be responsive to special requirements of handicapped individuals in receiving such services; (2) whenever possible, be community based, insure care of good quality in general community care facilities and under health insurance plans, and be integrated with, and provide for the active participation of, a wide range of public and nongovernmental agencies, organizations, institutions, and individuals; (3) where a substantial number of the individuals in the population served by the project or program are of limited English-speaking ability (A) utilize the services of outreach workers fluent in the language spoken by a predominant number of such individuals and develop a plan and make 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 (B) identify an individual who is fluent both in that language and English and whose responsibilities shall include providing guidance to the individuals of limited English speaking ability and to appropriate staff members with respect to cultural sensitivities and bridging linguistic and cultural differences; and (4) where appropriate, utilize existing community resources (including community mental health centers).

(g)(1) No grant may be made under this section to a State or to any entity within the government of a State unless the grant application has been duly authorized by the chief executive officer of such State.

(2) No grant or contract may be made under this section for a period in excess of five years.

(3)(A) The amount of any grant or contract under this section may not exceed 100 per centum of the cost of carrying out the grant or contract in the first fiscal year for which the grant or contract is made under this section, 80 per centum of such cost in the

second fiscal year for which the grant or contract is made under this section, 70 per centum of such cost in the third fiscal year for which the grant or contract is made under this section, and 60 per centum of such cost in each of the fourth and fifth fiscal years for which the grant or contract is made under this section.

(B) For purposes of this paragraph, no grant or contract shall be considered to have been made under this section for a fiscal year ending before September 30, 1981.

**§ 411. [1178] Records and audit.**

(a) Each recipient of assistance under section 410 pursuant to grants or contracts entered into under other than competitive bidding procedures 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 project or undertaking in connection with which such grant or contract 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.

(b) The Secretary and 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 such grants or contracts.

**§ 412. [1179] National Drug Abuse Training Center.**

(a) The Director shall establish a National Drug Abuse Training Center (hereinafter in this section referred to as the "Center") to develop, conduct, and support a full range of training programs relating to drug abuse prevention functions. The Director shall consult with the National Advisory Council for Drug Abuse Prevention regarding the general policies of the Center. The Director may supervise the operation of the Center initially, but shall transfer the supervision of the operation of the Center to the National Institute on Drug Abuse not later than December 31, 1974.

(b) The Center shall conduct or arrange for training programs, seminars, meetings, conferences, and other related activities, including the furnishing of training and educational materials for use by others.

(c) The services and facilities of the Center shall, in accordance with regulations prescribed by the Director, be available to (1) Federal, State, and local government officials, and their respective staffs, (2) medical and paramedical personnel, and educators, and (3) other persons, including drug dependent persons, requiring training or education in drug abuse prevention.

(d)(1) For the purpose of carrying out this section, there are authorized to be appropriated $1,000,000 for the fiscal year ending June 30, 1972, $3,000,000 for the fiscal year ending June 30, 1973, $5,000,000 for the fiscal year ending June 30, 1974, and $6,000,000 for the fiscal year ending June 30, 1975.

(2) Sums appropriated under this subsection shall remain available for obligation or expenditure in the fiscal year for which appropriated and in the fiscal year next following.

**§ 414. [1181] Contract authority.**

The authority of the Secretary to enter into contracts under this title and title V shall be effective for any fiscal year only to such extent or in such amounts as are provided in advance by appropriation Acts.

# PROTECTION AND ADVOCACY FOR INDIVIDUALS WITH MENTAL ILLNESS ACT

# PROTECTION AND ADVOCACY FOR INDIVIDUALS WITH MENTAL ILLNESS ACT [1]

**(References in brackets [ ] are to title 42, United States Code)**

**SECTION 1. SHORT TITLE.**

This Act may be cited as the "Protection and Advocacy for Individuals with Mental Illness Act".

## TITLE I—PROTECTION AND ADVOCACY SYSTEMS [2]

### PART A—ESTABLISHMENT OF SYSTEMS

#### FINDINGS AND PURPOSE

SEC. 101. [10801] (a) The Congress finds that—

(1) individuals with mental illness are vulnerable to abuse and serious injury;

(2) family members of individuals with mental illness play a crucial role in being advocates for the rights of individuals with mental illness where the individuals are minors, the individuals are legally competent and choose to involve the family members, and the individuals are legally incompetent and the legal guardians, conservators, or other legal representatives are members of the family;

(3) individuals with mental illness are subject to neglect, including lack of treatment, adequate nutrition, clothing, health care, and adequate discharge planning; and

(4) State systems for monitoring compliance with respect to the rights of individuals with mental illness vary widely and are frequently inadequate.

(b) The purposes of this Act are—

(1) to ensure that the rights of individuals with mental illness are protected; and

(2) to assist States to establish and operate a protection and advocacy system for individuals with mental illness which will—

(A) protect and advocate the rights of such individuals through activities to ensure the enforcement of the Constitution and Federal and State statutes; and

(B) investigate incidents of abuse and neglect of individuals with mental illness if the incidents are reported to

[1] Public Law 99–319. (Section 3206(a) of Public Law 106–310 (114 Stat. 1193) amended the short title to read as provided above. Formerly the short title of the Act was the Protection and Advocacy for Mentally Ill Individuals Act of 1986.)

[2] References in this Act to "a individual with mental illness" probably should be "an individual with mental illness". Section 10(1) of Public Law 102–173 (105 Stat. 1219) replaced the term "mentally ill individual" with the term "individual with mental illness".

the system or if there is probable cause to believe that the incidents occurred.

DEFINITIONS

SEC. 102. [10802] For purposes of this title:

(1) The term "abuse" means any act or failure to act by an employee of a facility rendering care or treatment which was performed, or which was failed to be performed, knowingly, recklessly, or intentionally, and which caused, or may have caused, injury or death to a individual with mental illness, and includes acts such as—

(A) the rape or sexual assault of a individual with mental illness;

(B) the striking of a individual with mental illness;

(C) the use of excessive force when placing a individual with mental illness in bodily restraints; and

(D) the use of bodily or chemical restraints on a individual with mental illness which is not in compliance with Federal and State laws and regulations.

(2) The term "eligible system" means the system established in a State to protect and advocate the rights of persons with developmental disabilities under subtitle C [1] of the Developmental Disabilities Assistance and Bill of Rights Act of 2000.

(3) The term "facilities" may include, but need not be limited to, hospitals, nursing homes, community facilities for individuals with mental illness, board and care homes, homeless shelters, and jails and prisons.

(4) The term "individual with mental illness" means, except as provided in section 104(d), an individual—

(A) who has a significant mental illness or emotional impairment, as determined by a mental health professional qualified under the laws and regulations of the State; and

(B)(i)(I) who is an inpatient or resident in a facility rendering care or treatment, even if the whereabouts of such inpatient or resident are unknown;

(II) who is in the process of being admitted to a facility rendering care or treatment, including persons being transported to such a facility; or" [2];

(III) who is involuntarily confined in a municipal detention facility for reasons other than serving a sentence resulting from conviction for a criminal offense; or

(ii) who satisfies the requirements of subparagraph (A) and lives in a community setting, including their own home.

(5) The term "neglect" means a negligent act or omission by any individual responsible for providing services in a facility rendering care or treatment which caused or may have caused injury or death to a individual with mental illness or which placed a individual with mental illness at risk of injury or

[1] So in law. Probably should read "subtitle C of title I". See the amendment made by section 401(b)(13)(A) of Public Law 106–402 (114 Stat. 1739).

[2] So in law. See section 3(2)(C) of Public Law 100–509.

death, and includes an act or omission such as the failure to establish or carry out an appropriate individual program plan or treatment plan for a individual with mental illness, the failure to provide adequate nutrition, clothing, or health care to a individual with mental illness, or the failure to provide a safe environment for a individual with mental illness, including the failure to maintain adequate numbers of appropriately trained staff.

(6) The term "Secretary" means the Secretary of Health and Human Services.

(7) The term "State" means each of the several States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Commonwealth of the Northern Mariana Islands, American Samoa, the Virgin Islands, and the Trust Territory of the Pacific Islands.

(8) The term "American Indian consortium" means a consortium established under part C of the Developmental Disabilities Assistance and Bill of Rights Act (42 U.S.C. 6042 et seq.).

ALLOTMENTS

SEC. 103. [10803] The Secretary shall make allotments under this title to eligible systems to establish and administer systems—

(1) which meet the requirements of section 105; and

(2) which are designed to—

(A) protect and advocate the rights of individuals with mental illness; and

(B) investigate incidents of abuse and neglect of individuals with mental illness if the incidents are reported to the system or if there is probable cause to believe that the incidents occurred.

USE OF ALLOTMENTS

SEC. 104. [10804] (a)(1) An eligible system may use its allotment under this title to enter into contracts with State agencies and nonprofit organizations which operate throughout the State. In order to be eligible for a contract under this paragraph—

(A) such an agency shall be independent of any agency which provides treatment or services (other than advocacy services) to individuals with mental illness; and

(B) such an agency or organization shall have the capacity to protect and advocate the rights of individuals with mental illness.

(2) In carrying out paragraph (1), an eligible system should consider entering into contracts with organizations including, in particular, groups run by individuals who have received or are receiving mental health services, or the family members of such individuals, which, provide protection or advocacy services to individuals with mental illness.

(b)(1) If an eligible system is a public entity, the government of the State in which the system is located may not require the system to obligate more than 5 percent of its allotment under this title in any fiscal year for administrative expenses.

(2) An eligible system may not use more than 10 percent of any allotment under this title for any fiscal year for the costs of providing technical assistance and training to carry out this title.

(c) An eligible system may use its allotment under this title to provide representation to individuals with mental illness in Federal facilities who request representation by the eligible system. Representatives of such individuals from such system shall be accorded all the rights and authority accorded to other representatives of residents of such facilities pursuant to State law and other Federal laws.

(d) The definition of "individual with a mental illness" contained in section 102(4)(B)(iii) shall apply, and thus an eligible system may use its allotment under this title to provide representation to such individuals, only if the total allotment under this title for any fiscal year is $30,000,000 or more, and in such case, an eligible system must give priority to representing persons with mental illness as defined in subparagraphs (A) and (B)(i) of section 102(4).

SYSTEM REQUIREMENTS

SEC. 105. [10805] (a) A system established in a State under section 103 to protect and advocate the rights of individuals with mental illness shall—

(1) have the authority to—

(A) investigate incidents of abuse and neglect of individuals with mental illness if the incidents are reported to the system or if there is probable cause to believe that the incidents occurred;

(B) pursue administrative, legal, and other appropriate remedies to ensure the protection of individuals with mental illness who are receiving care or treatment in the State; and

(C) pursue administrative, legal, and other remedies on behalf of an individual who—

(i) was a individual with mental illness; and

(ii) is a resident of the State,

but only with respect to matters which occur within 90 days after the date of the discharge of such individual from a facility providing care or treatment;

(2) be independent of any agency in the State which provides treatment or services (other than advocacy services) to individuals with mental illness;

(3) have access to facilities in the State providing care or treatment;

(4) in accordance with section 106, have access to all records of—

(A) any individual who is a client of the system if such individual, or the legal guardian, conservator, or other legal representative of such individual, has authorized the system to have such access;

(B) any individual (including an individual who has died or whose whereabouts are unknown)—

(i) who by reason of the mental or physical condition of such individual is unable to authorize the system to have such access;

(ii) who does not have a legal guardian, conservator, or other legal representative, or for whom the legal guardian is the State; and

(iii) with respect to whom a complaint has been received by the system or with respect to whom as a result of monitoring or other activities (either of which result from a complaint or other evidence) there is probable cause to believe that such individual has been subject to abuse or neglect; and

(C) any individual with a mental illness, who has a legal guardian, conservator, or other legal representative, with respect to whom a complaint has been received by the system or with respect to whom there is probable cause to believe the health or safety of the individual is in serious and immediate jeopardy, whenever—

(i) such representative has been contacted by such system upon receipt of the name and address of such representative;

(ii) such system has offered assistance to such representative to resolve the situation; and

(iii) such representative has failed or refused to act on behalf of the individual;

(5) have an arrangement with the Secretary and the agency of the State which administers the State plan under title XIX of the Social Security Act for the furnishing of the information required by subsection (b);

(6) establish an advisory council—

(A) which will advise the system on policies and priorities to be carried out in protecting and advocating the rights of individuals with mental illness;

(B) which shall include attorneys, mental health professionals, individuals from the public who are knowledgeable about mental illness, a provider of mental health services, individuals who have received or are receiving mental health services, and family members of such individuals, and at least 60 percent the membership of which shall be comprised of individuals who have received or are receiving mental health services or who are family members of such individuals; and

(C) which shall be chaired by an individual who has received or is receiving mental health services or who is a family member of such an individual;

(7) on January 1, 1987, and January 1 of each succeeding year, prepare and transmit to the Secretary and the head of the State mental health agency of the State in which the system is located a report describing the activities, accomplishments, and expenditures of the system during the most recently completed fiscal year, including a section prepared by the advisory council that describes the activities of the council and its assessment of the operations of the system;

(8) on an annual basis, provide the public with an opportunity to comment on the priorities established by, and the activities of, the system;

(9) establish a grievance procedure for clients or prospective clients of the system to assure that individuals with mental illness have full access to the services of the system and for individuals who have received or are receiving mental health services, family members of such individuals with mental illness, or representatives of such individuals or family members to assure that the eligible system is operating in compliance with the provisions of this title and title III; and

(10) not use allotments provided to a system in a manner inconsistent with section 5 of the Assisted Suicide Funding Restriction Act of 1997.

(b) The Secretary and the agency of a State which administers its State plan under title XIX of the Social Security Act shall provide the eligible system of the State with a copy of each annual survey report and plan of corrections for cited deficiencies made pursuant to titles XVIII and XIX of the Social Security Act with respect to any facility rendering care or treatment to individuals with mental illness in the State in which such system is located. A report or plan shall be made available within 30 days after the completion of the report or plan.

(c)(1)(A) Each system established in a State, through allotments received under section 103, to protect and advocate the rights of individuals with mental illness shall have a governing authority.

(B) In States in which the governing authority is organized as a private non-profit entity with a multi-member governing board, or a public system with a multi-member governing board, such governing board shall be selected according to the policies and procedures of the system. The governing board shall be composed of—

(i) members (to be selected no later than October 1, 1990) who broadly represent or are knowledgeable about the needs of the clients served by the system; and

(ii) in the case of a governing authority organized as a private non-profit entity, members who broadly represent or are knowledgeable about the needs of the clients served by the system including the chairperson of the advisory council of such system. As used in this subparagraph, the term "members who broadly represent or are knowledgeable about the needs of the clients served by the system" shall be construed to include individuals who have received or are receiving mental health services and family members of such individuals.[1]

(2) The governing authority established under paragraph (1) shall—

(A) be responsible for the planning, design, implementation, and functioning of the system; and

(B) consistent with subparagraph (A), jointly develop the annual priorities of the system with the advisory council.

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[1] So in law. Section 6(d) of Public Law 102–173 (105 Stat. 1218) amended subparagraph (B) by adding the above sentence at the end.

ACCESS TO RECORDS

SEC. 106. [10806] (a) An eligible system which, pursuant to section 105(a)(4), has access to records which, under Federal or State law, are required to be maintained in a confidential manner by a provider of mental health services, shall, except as provided in subsection (b), maintain the confidentiality of such records to the same extent as is required of the provider of such services.

(b)(1) Except as provided in paragraph (2), an eligible system which has access to records pursuant to section 105(a)(4) may not disclose information from such records to the individual who is the subject of the information if the mental health professional responsible for supervising the provision of mental health services to such individual has provided the system with a written determination that disclosure of such information to such individual would be detrimental to such individual's health.

(2)(A) If disclosure of information has been denied under paragraph (1) to an individual—

(i) such individual;

(ii) the legal guardian, conservator, or other legal representative of such individual; or

(iii) an eligible system, acting on behalf of an individual described in subparagraph (B),

may select another mental health professional to review such information and to determine if disclosure of such information would be detrimental to such individual's health. If such mental health professional determines, based on professional judgment, that disclosure of such information would not be detrimental to the health of such individual, the system may disclose such information to such individual.

(B) An eligible system may select a mental health professional under subparagraph (A)(iii) on behalf of—

(i) an individual whose legal guardian is the State; or

(ii) an individual who has a legal guardian, conservator, or other legal representative other than the State if such guardian, conservator, or representative does not, within a reasonable time after such individual is denied access to information under paragraph (1), select a mental health professional under subparagraph (A) to review such information.

(C) If the laws of a State prohibit an eligible system from obtaining access to the records of individuals with mental illness in accordance with section 105(a)(4) and this section, section 105(a)(4) and this section shall not apply to such system before—

(i) the date such system is no longer subject to such a prohibition; or

(ii) the expiration of the 2-year period beginning on the date of the enactment of this Act,

whichever occurs first.

(3)(A) As used in this section, the term "records" includes reports prepared by any staff of a facility rendering care and treatment or reports prepared by an agency charged with investigating reports of incidents of abuse, neglect, and injury occurring at such facility that describe incidents of abuse, neglect, and injury occur-

ring at such facility and the steps taken to investigate such incidents, and discharge planning records.

(B) An eligible system shall have access to the type of records described in subparagraph (A) in accordance with the provisions of subsection (a) and paragraphs (1) and (2) of subsection (b).

LEGAL ACTIONS

SEC. 107. [10807] (a) Prior to instituting any legal action in a Federal or State court on behalf of a individual with mental illness, an eligible system, or a State agency or nonprofit organization which entered into a contract with an eligible system under section 104(a), shall exhaust in a timely manner all administrative remedies where appropriate. If, in pursuing administrative remedies, the system, agency, or organization determines that any matter with respect to such individual will not be resolved within a reasonable time, the system, agency, or organization may pursue alternative remedies, including the initiation of a legal action.

(b) Subsection (a) does not apply to any legal action instituted to prevent or eliminate imminent serious harm to a individual with mental illness.

## PART B—ADMINISTRATIVE PROVISIONS

APPLICATIONS

SEC. 111. [10821] (a) No allotment may be made under this title to an eligible system unless an application therefor is submitted to the Secretary. Each such application shall contain—

(1) assurances that amounts paid to such system from an allotment under this title will be used to supplement and not to supplant the level of non-Federal funds available in the State in which such system is established to protect and advocate the rights of individuals with mental illness;

(2) assurances that such system will have a staff which is trained or being trained to provide advocacy services to individuals with mental illness and to work with family members of clients served by the system where the individuals with mental illness are minors, legally competent and do not object, and legally incompetent and the legal guardians, conservators, or other legal representatives are family members;

(3) assurances that such system, and any State agency or nonprofit organization with which such system may enter into a contract under section 104(a), will not, in the case of any individual who has a legal guardian, conservator, or representative other than the State, take actions which are duplicative of actions taken on behalf of such individual by such guardian, conservator, or representative unless such guardian, conservator, or representative requests the assistance of such system; and

(4) such other information as the Secretary may by regulation prescribe.

(b) The assurance required under subsection (a)(2) regarding trained staff may be satisfied through the provision of training by individuals who have received or are receiving mental health services and family members of such individuals.

(c) Applications submitted under this section shall remain in effect for a 4-year period, and the assurances required under this section shall be for the same 4-year period.

ALLOTMENT FORMULA AND REALLOTMENTS

SEC. 112. [10822] (a)(1)(A) Except as provided in paragraph (2) and subject to the availability of appropriations under section 117, the Secretary shall make allotments under section 103 from amounts appropriated under section 117 for a fiscal year to eligible systems on the basis of a formula prescribed by the Secretary which is based equally—

(i) on the population of each State in which there is an eligible system; and

(ii) on the population of each such State weighted by its relative per capita income.

(B) For purposes of subparagraph (A)(ii), the term "relative per capita income" means the quotient of the per capita income of the United States and the per capita income of the State, except that if the State is Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, the Marshall Islands, the Federated States of Micronesia, the Republic of Palau, or the Virgin Islands, the quotient shall be considered to be one.

(2)(A) The minimum amount of the allotment of an eligible system shall be the product (rounded to the nearest $100) of the appropriate base amount determined under subparagraph (B) and the factor specified in subparagraph (C).

(B) For purposes of subparagraph (A), the appropriate base amount—

(i) for American Samoa, Guam, the Marshall Islands, the Federated States of Micronesia, the Commonwealth of the Northern Mariana Islands, the Republic of Palau, and the Virgin Islands, is $139,300; and

(ii) for any other State, is $260,000.

(C) The factor specified in this subparagraph is the ratio of the amount appropriated under section 117 for the fiscal year for which the allotment is being made to the amount appropriated under such section for fiscal year 1995.

(D) If the total amount appropriated for a fiscal year is at least $25,000,000, the Secretary shall make an allotment in accordance with subparagraph (A) to the eligible system serving the American Indian consortium.

(b)(1) To the extent that all the amounts appropriated under section 117 for a fiscal year are not allotted to eligible systems because—

(A) one or more eligible systems have not submitted an application for an allotment for such fiscal year; or

(B) one or more eligible systems have notified the Secretary that they do not intend to use the full amount of their allotment,

the amount which is not so allotted shall be reallotted among the remaining eligible systems.

(2) The amount of an allotment to an eligible system for a fiscal year which the Secretary determines will not be required by the system during the period for which it is available shall be available

for reallotment by the Secretary to other eligible systems with respect to which such a determination has not been made.

(3) The Secretary shall make reallotments under paragraphs (1) and (2) on such date or dates as the Secretary may fix (but not earlier than 30 days after the Secretary has published notice of the intention of the Secretary to make such reallotment in the Federal Register). A reallotment to an eligible system shall be made in proportion to the original allotment of such system for such fiscal year, but with such proportionate amount for such system being reduced to the extent it exceeds the sum the Secretary estimates such system needs and will be able to use during such period. The total of such reductions shall be similarly reallotted among eligible systems whose proportionate amounts were not so reduced. Any amount so reallotted to an eligible system for a fiscal year shall be deemed to be a part of its allotment under subsection (a) for such fiscal year.

PAYMENTS UNDER ALLOTMENTS

SEC. 113. [10823] For each fiscal year, the Secretary shall make payments to each eligible system from its allotment under this title. Any amount paid to an eligible system for a fiscal year and remaining unobligated at the end of such year shall remain available to such system for the next fiscal year for the purposes for which it was made.

REPORTS BY THE SECRETARY

SEC. 114. [10824] (a) The Secretary shall include in each report required under section 105 of the Developmental Disabilities Assistance and Bill of Rights Act of 2000 a separate statement which contains—

(1) a description of the activities, accomplishments, and expenditures of systems to protect and advocate the rights of individuals with mental illness supported with payments from allotments under this title, including—

(A) a specification of the total number of individuals with mental illness served by such systems;

(B) a description of the types of activities undertaken by such systems;

(C) a description of the types of facilities providing care or treatment with respect to which such activities are undertaken;

(D) a description of the manner in which such activities are initiated; and

(E) a description of the accomplishments resulting from such activities;

(2) a description of—

(A) systems to protect and advocate the rights of individuals with mental illness supported with payments from allotments under this title;

(B) activities conducted by States to protect and advocate such rights;

(C) mechanisms established by residential facilities for individuals with mental illness to protect and advocate such rights; and

(D) the coordination among such systems, activities, and mechanisms;

(3) a specification of the number of systems established with allotments under this title and of whether each such system was established by a public or nonprofit private entity; and

(4) recommendations for activities and services to improve the protection and advocacy of the rights of individuals with mental illness and a description of needs for such activities and services which have not been met by systems established under this title.

(b) In preparing each statement required by subsection (a), the Secretary shall use and include information submitted to the Secretary in the reports required under section 105(a)(7).

TECHNICAL ASSISTANCE

SEC. 115.[1] [10825] The Secretary shall use not more than 2 percent of the amounts appropriated under section 117 to provide technical assistance to eligible systems with respect to activities carried out under this title, consistent with requests by such systems for such assistance.

ADMINISTRATION

SEC. 116. [10826] (a) IN GENERAL.—The Secretary shall carry out this title through the Administrator of the Substance Abuse and Mental Health Services Administration.

(b) REGULATIONS.—Not later than 6 months after the date of enactment of this subsection, the Secretary shall promulgate final regulations to carry out this title and title III.

**SEC. 117. [10827] AUTHORIZATION OF APPROPRIATIONS.**

There are authorized to be appropriated for allotments under this title, $19,500,000 for fiscal year 1992, and such sums as may be necessary for each of the fiscal years 1993 through 2003.

## TITLE II—RESTATEMENT OF BILL OF RIGHTS FOR MENTAL HEALTH PATIENTS

RESTATEMENT OF BILL OF RIGHTS

SEC. 201. [10841] It is the sense of the Congress that, as previously stated in title V of the Mental Health Systems Act, each State should review and revise, if necessary, its laws to ensure that mental health patients receive the protection and services they require, and that in making such review and revision, States should take into account the recommendations of the President's Commission on Mental Health and the following:

(1) A person admitted to a program or facility for the purpose of receiving mental health services should be accorded the following:

[1] Section 7(b)(2) of Public Law 100–509 provided that "[s]ection 10 (42 U.S.C. 10825) is amended to read as follows". The Act does not contain a section 10; however, the citation provided for the United States Code was the correct citation for section 115, and the language added by the amendment designated the language as section "115". The amendment has been executed to reflect the probable intent of the Congress.

(A) The right to appropriate treatment and related services in a setting and under conditions that—

(i) are the most supportive of such person's personal liberty; and

(ii) restrict such liberty only to the extent necessary consistent with such person's treatment needs, applicable requirements of law, and applicable judicial orders.

(B) The right to an individualized, written, treatment or service plan (such plan to be developed promptly after admission of such person), the right to treatment based on such plan, the right to periodic review and reassessment of treatment and related service needs, and the right to appropriate revision of such plan, including any revision necessary to provide a description of mental health services that may be needed after such person is discharged from such program or facility.

(C) The right to ongoing participation, in a manner appropriate to such person's capabilities, in the planning of mental health services to be provided such person (including the right to participate in the development and periodic revision of the plan described in subparagraph (B)), and, in connection with such participation, the right to be provided with a reasonable explanation, in terms and language appropriate to such person's condition and ability to understand, of—

(i) such person's general mental condition and, if such program or facility has provided a physical examination, such person's general physical condition;

(ii) the objectives of treatment;

(iii) the nature and significant possible adverse effects of recommended treatments;

(iv) the reasons why a particular treatment is considered appropriate;

(v) the reasons why access to certain visitors may not be appropriate; and

(vi) any appropriate and available alternative treatments, services, and types of providers of mental health services.

(D) The right not to receive a mode or course of treatment, established pursuant to the treatment plan, in the absence of such person's informed, voluntary, written consent to such mode or course of treatment, except treatment—

(i) during an emergency situation if such treatment is pursuant to or documented contemporaneously by the written order of a responsible mental health professional; or

(ii) as permitted under applicable law in the case of a person committed by a court to a treatment program or facility.

(E) The right not to participate in experimentation in the absence of such person's informed, voluntary, written consent, the right to appropriate protections in connection

with such participation, including the right to a reasonable explanation of the procedure to be followed, the benefits to be expected, the relative advantages of alternative treatments, and the potential discomforts and risks, and the right and opportunity to revoke such consent.

(F) The right to freedom from restraint or seclusion, other than as a mode or course of treatment or restraint or seclusion during an emergency situation if such restraint or seclusion is pursuant to or documented contemporaneously by the written order of a responsible mental health professional.

(G) The right to a humane treatment environment that affords reasonable protection from harm and appropriate privacy to such person with regard to personal needs.

(H) The right to confidentiality of such person's records.

(I) The right to access, upon request, to such person's mental health care records, except such person may be refused access to—

(i) information in such records provided by a third party under assurance that such information shall remain confidential; and

(ii) specific material in such records if the health professional responsible for the mental health services concerned has made a determination in writing that such access would be detrimental to such person's health, except that such material may be made available to a similarly licensed health professional selected by such person and such health professional may, in the exercise of professional judgment, provide such person with access to any or all parts of such material or otherwise disclose the information contained in such material to such person.

(J) The right, in the case of a person admitted on a residential or inpatient care basis, to converse with others privately, to have convenient and reasonable access to the telephone and mails, and to see visitors during regularly scheduled hours, except that, if a mental health professional treating such person determines that denial of access to a particular visitor is necessary for treatment purposes, such mental health professional may, for a specific, limited, and reasonable period of time, deny such access if such mental health professional has ordered such denial in writing and such order has been incorporated in the treatment plan for such person. An order denying such access should include the reasons for such denial.

(K) The right to be informed promptly at the time of admission and periodically thereafter, in language and terms appropriate to such person's condition and ability to understand, of the rights described in this section.

(L) The right to assert grievances with respect to infringement of the rights described in this section, including the right to have such grievances considered in a fair,

timely, and impartial grievance procedure provided for or by the program or facility.

(M) Notwithstanding subparagraph (J), the right of access to (including the opportunities and facilities for private communication with) any available—

(i) rights protection service within the program or facility;

(ii) rights protection service within the State mental health system designed to be available to such person;

(iii) system established under title I to protect and advocate the rights of individuals with mental illness; and

(iv) qualified advocate;

for the purpose of receiving assistance to understand, exercise, and protect the rights described in this section and in other provisions of law.

(N) The right to exercise the rights described in this section without reprisal, including reprisal in the form of denial of any appropriate, available treatment.

(O) The right to referral as appropriate to other providers of mental health services upon discharge.

(2)(A) The rights described in this section should be in addition to and not in derogation of any other statutory or constitutional rights.

(B) The rights to confidentiality of and access to records as provided in subparagraphs (H) and (I) of paragraph (1) should remain applicable to records pertaining to a person after such person's discharge from a program or facility.

(3)(A) No otherwise eligible person should be denied admission to a program or facility for mental health services as a reprisal for the exercise of the rights described in this section.

(B) Nothing in this section should—

(i) obligate an individual mental health or health professional to administer treatment contrary to such professional's clinical judgment;

(ii) prevent any program or facility from discharging any person for whom the provision of appropriate treatment, consistent with the clinical judgment of the mental health professional primarily responsible for such person's treatment, is or has become impossible as a result of such person's refusal to consent to such treatment;

(iii) require a program or facility to admit any person who, while admitted on prior occasions to such program or facility, has repeatedly frustrated the purposes of such admissions by withholding consent to proposed treatment; or

(iv) obligate a program or facility to provide treatment services to any person who is admitted to such program or facility solely for diagnostic or evaluative purposes.

(C) In order to assist a person admitted to a program or facility in the exercise or protection of such person's rights,

such person's attorney or legal representatives should have reasonable access to—

(i) such person;

(ii) the areas of the program or facility where such person has received treatment, resided, or had access; and

(iii) pursuant to the written authorization of such person, the records and information pertaining to such person's diagnosis, treatment, and related services described in paragraph (1)(I).

(D) Each program and facility should post a notice listing and describing, in language and terms appropriate to the ability of the persons to whom such notice is addressed to understand, the rights described in this section of all persons admitted to such program or facility. Each such notice should conform to the format and content for such notices, and should be posted in all appropriate locations.

(4)(A) In the case of a person adjudicated by a court of competent jurisdiction as being incompetent to exercise the right to consent to treatment or experimentation described in subparagraph (D) or (E) of paragraph (1), or the right to confidentiality of or access to records described in subparagraph (H) or (I) of such paragraph, or to provide authorization as described in paragraph (3)(C)(iii), such right may be exercised or such authorization may be provided by the individual appointed by such court as such person's guardian or representative for the purpose of exercising such right or such authorization.

(B) In the case of a person who lacks capacity to exercise the right to consent to treatment or experimentation under subparagraph (D) or (E) of paragraph (1), or the right to confidentiality of or access to records described in subparagraph (H) or (I) of such paragraph, or to provide authorization as described in paragraph (3)(C)(iii), because such person has not attained an age considered sufficiently advanced under State law to permit the exercise of such right or such authorization to be legally binding, such right may be exercised or such authorization may be provided on behalf of such person by a parent or legal guardian of such person.

(C) Notwithstanding subparagraphs (A) and (B), in the case of a person admitted to a program or facility for the purpose of receiving mental health services, no individual employed by or receiving any remuneration from such program or facility should act as such person's guardian or representative.

## TITLE III—CONSTRUCTION

### CONSTRUCTION

SEC. 301. [10851] (a) Titles I and II shall not be construed as establishing any new rights for individuals with mental illness.

(b) For purposes of this section, the term "individual with mental illness" has the same meaning as in section 102(3). [1]

[1] So in law. Probably should be "section 102(4)". See the redesignations made by section 4(1) of Public Law 102–173 (105 Stat. 1217).

## TITLE IV—OTHER PROGRAMS [1]

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### BALANCED BUDGET PROVISION

SEC. 402. [10801 note] This Act shall not be construed as superseding any of the balanced budget provisions set forth in section 3(7) of the Congressional Budget and Impoundment Control Act of 1974.

[1] The Act contains a section 401. The section amended part B of title III of the Public Health Service Act to add a new section 316 regarding family support groups for Alzheimer's disease patients.

# HEALTH CARE QUALITY IMPROVEMENT ACT OF 1986

# HEALTH CARE QUALITY IMPROVEMENT ACT OF 1986 [1]

**(References in brackets [ ] are to title 42, United States Code)**

**SEC. 401. [11101 note] SHORT TITLE.**

This title may be cited as the "Health Care Quality Improvement Act of 1986".

**SEC. 402. [11101] FINDINGS.**

The Congress finds the following:

(1) The increasing occurrence of medical malpractice and the need to improve the quality of medical care have become nationwide problems that warrant greater efforts than those that can be undertaken by any individual State.

(2) There is a national need to restrict the ability of incompetent physicians to move from State to State without disclosure or discovery of the physician's previous damaging or incompetent performance.

(3) This nationwide problem can be remedied through effective professional peer review.

(4) The threat of private money damage liability under Federal laws, including treble damage liability under Federal antitrust law, unreasonably discourages physicians from participating in effective professional peer review.

(5) There is an overriding national need to provide incentive and protection for physicians engaging in effective professional peer review.

## PART A—PROMOTION OF PROFESSIONAL REVIEW ACTIVITIES

**SEC. 411. [11111] PROFESSIONAL REVIEW.**

(a) IN GENERAL.—

(1) LIMITATION ON DAMAGES FOR PROFESSIONAL REVIEW ACTIONS.—If a professional review action (as defined in section 431(9)) of a professional review body meets all the standards specified in section 412(a), except as provided in subsection (b)—

(A) the professional review body,

(B) any person acting as a member or staff to the body,

(C) any person under a contract or other formal agreement with the body, and

(D) any person who participates with or assists the body with respect to the action,

shall not be liable in damages under any law of the United States or of any State (or political subdivision thereof) with re-

[1] Title IV of Public Law 99–660.

spect to the action. The preceding sentence shall not apply to damages under any law of the United States or any State relating to the civil rights of any person or persons, including the Civil Rights Act of 1964, 42 U.S.C. 2000e, et seq. and the Civil Rights Acts, 42 U.S.C. 1981, et seq. Nothing in this paragraph shall prevent the United States or any Attorney General of a State from bringing an action, including an action under section 4C of the Clayton Act, 15 U.S.C. 15C, where such an action is otherwise authorized.

(2) PROTECTION FOR THOSE PROVIDING INFORMATION TO PROFESSIONAL REVIEW BODIES.—Notwithstanding any other provision of law, no person (whether as a witness or otherwise) providing information to a professional review body regarding the competence or professional conduct of a physician shall be held, by reason of having provided such information, to be liable in damages under any law of the United States or of any State (or political subdivision thereof) unless such information is false and the person providing it knew that such information was false.

(b) EXCEPTION.—If the Secretary has reason to believe that a health care entity has failed to report information in accordance with section 423(a), the Secretary shall conduct an investigation. If, after providing notice of noncompliance, an opportunity to correct the noncompliance, and an opportunity for a hearing, the Secretary determines that a health care entity has failed substantially to report information in accordance with section 423(a), the Secretary shall publish the name of the entity in the Federal Register. The protections of subsection (a)(1) shall not apply to an entity the name of which is published in the Federal Register under the previous sentence with respect to professional review actions of the entity commenced during the 3-year period beginning 30 days after the date of publication of the name.

(c) TREATMENT UNDER STATE LAWS.—

(1) PROFESSIONAL REVIEW ACTIONS TAKEN ON OR AFTER OCTOBER 14, 1989.—Except as provided in paragraph (2), subsection (a) shall apply to State laws in a State only for professional review actions commenced on or after October 14, 1989.

(2) EXCEPTIONS.—

(A) STATE EARLY OPT-IN.—Subsection (a) shall apply to State laws in a State for actions commenced before October 14, 1989, if the State by legislation elects such treatment.

(B) EFFECTIVE DATE OF ELECTION.—An election under State law is not effective, for purposes of, [1] for actions commenced before the effective date of the State law, which may not be earlier than the date of the enactment of that law.

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[1] So in law. Probably should be "for purposes of subparagraph (A)". The provision formerly made a reference to "subparagraphs (A) and (B)". Section 6103(e)(6) of Public Law 101–239 struck out this reference, after having struck former subparagraph (B). (Former subparagraph (C) was redesignated as subparagraph (B).)

**SEC. 412. [11112] STANDARDS FOR PROFESSIONAL REVIEW ACTIONS.**

(a) IN GENERAL.—For purposes of the protection set forth in section 411(a), a professional review action must be taken—

(1) in the reasonable belief that the action was in the furtherance of quality health care,

(2) after a reasonable effort to obtain the facts of the matter,

(3) after adequate notice and hearing procedures are afforded to the physician involved or after such other procedures as are fair to the physician under the circumstances, and

(4) in the reasonable belief that the action was warranted by the facts known after such reasonable effort to obtain facts and after meeting the requirement of paragraph (3).

A professional review action shall be presumed to have met the preceding standards necessary for the protection set out in section 411(a) unless the presumption is rebutted by a preponderance of the evidence.

(b) ADEQUATE NOTICE AND HEARING.—A health care entity is deemed to have met the adequate notice and hearing requirement of subsection (a)(3) with respect to a physician if the following conditions are met (or are waived voluntarily by the physician):

(1) NOTICE OF PROPOSED ACTION.—The physician has been given notice stating—

(A)(i) that a professional review action has been proposed to be taken against the physician,

(ii) reasons for the proposed action,

(B)(i) that the physician has the right to request a hearing on the proposed action,

(ii) any time limit (of not less than 30 days) within which to request such a hearing, and

(C) a summary of the rights in the hearing under paragraph (3).

(2) NOTICE OF HEARING.—If a hearing is requested on a timely basis under paragraph (1)(B), the physician involved must be given notice stating—

(A) the place, time, and date, of the hearing, which date shall not be less than 30 days after the date of the notice, and

(B) a list of the witnesses (if any) expected to testify at the hearing on behalf of the professional review body.

(3) CONDUCT OF HEARING AND NOTICE.—If a hearing is requested on a timely basis under paragraph (1)(B)—

(A) subject to subparagraph (B), the hearing shall be held (as determined by the health care entity)—

(i) before an arbitrator mutually acceptable to the physician and the health care entity,

(ii) before a hearing officer who is appointed by the entity and who is not in direct economic competition with the physician involved, or

(iii) before a panel of individuals who are appointed by the entity and are not in direct economic competition with the physician involved;

(B) the right to the hearing may be forfeited if the physician fails, without good cause, to appear;

(C) in the hearing the physician involved has the right—

(i) to representation by an attorney or other person of the physician's choice,

(ii) to have a record made of the proceedings, copies of which may be obtained by the physician upon payment of any reasonable charges associated with the preparation thereof,

(iii) to call, examine, and cross-examine witnesses,

(iv) to present evidence determined to be relevant by the hearing officer, regardless of its admissibility in a court of law, and

(v) to submit a written statement at the close of the hearing; and

(D) upon completion of the hearing, the physician involved has the right—

(i) to receive the written recommendation of the arbitrator, officer, or panel, including a statement of the basis for the recommendations, and

(ii) to receive a written decision of the health care entity, including a statement of the basis for the decision.

A professional review body's failure to meet the conditions described in this subsection shall not, in itself, constitute failure to meet the standards of subsection (a)(3).

(c) ADEQUATE PROCEDURES IN INVESTIGATIONS OR HEALTH EMERGENCIES.—For purposes of section 411(a), nothing in this section shall be construed as—

(1) requiring the procedures referred to in subsection (a)(3)—

(A) where there is no adverse professional review action taken, or

(B) in the case of a suspension or restriction of clinical privileges, for a period of not longer than 14 days, during which an investigation is being conducted to determine the need for a professional review action; or

(2) precluding an immediate suspension or restriction of clinical privileges, subject to subsequent notice and hearing or other adequate procedures, where the failure to take such an action may result in an imminent danger to the health of any individual.

**SEC. 413. [11113] PAYMENT OF REASONABLE ATTORNEYS' FEES AND COSTS IN DEFENSE OF SUIT.**

In any suit brought against a defendant, to the extent that a defendant has met the standards set forth under section 412(a) and the defendant substantially prevails, the court shall, at the conclusion of the action, award to a substantially prevailing party defending against any such claim the cost of the suit attributable to such claim, including a reasonable attorney's fee, if the claim, or the claimant's conduct during the litigation of the claim, was frivolous, unreasonable, without foundation, or in bad faith. For the purposes of this section, a defendant shall not be considered to have substantially prevailed when the plaintiff obtains an award for damages or permanent injunctive or declaratory relief.

**SEC. 414. [11114] GUIDELINES OF THE SECRETARY.**

The Secretary may establish, after notice and opportunity for comment, such voluntary guidelines as may assist the professional review bodies in meeting the standards described in section 412(a).

**SEC. 415. [11115] CONSTRUCTION.**

(a) IN GENERAL.—Except as specifically provided in this part, nothing in this part shall be construed as changing the liabilities or immunities under law or as preempting or overriding any State law which provides incentives, immunities, or protection for those engaged in a professional review action that is in addition to or greater than that provided by this part.

(b) SCOPE OF CLINICAL PRIVILEGES.—Nothing in this part shall be construed as requiring health care entities to provide clinical privileges to any or all classes or types of physicians or other licensed health care practitioners.

(c) TREATMENT OF NURSES AND OTHER PRACTITIONERS.—Nothing in this part shall be construed as affecting, or modifying any provision of Federal or State law, with respect to activities of professional review bodies regarding nurses, other licensed health care practitioners, or other health professionals who are not physicians.

(d) TREATMENT OF PATIENT MALPRACTICE CLAIMS.—Nothing in this title shall be construed as affecting in any manner the rights and remedies afforded patients under any provision of Federal or State law to seek redress for any harm or injury suffered as a result of negligent treatment or care by any physician, health care practitioner, or health care entity, or as limiting any defenses or immunities available to any physician, health care practitioner, or health care entity.

**SEC. 416. [11111 note] EFFECTIVE DATE.**

This part shall apply to professional review actions commenced on or after the date of the enactment of this Act.

## PART B—REPORTING OF INFORMATION

**SEC. 421. [11131] REQUIRING REPORTS ON MEDICAL MALPRACTICE PAYMENTS.**

(a) IN GENERAL.—Each entity (including an insurance company) which makes payment under a policy of insurance, self-insurance, or otherwise in settlement (or partial settlement) of, or in satisfaction of a judgment in, a medical malpractice action or claim shall report, in accordance with section 424, information respecting the payment and circumstances thereof.

(b) INFORMATION TO BE REPORTED.—The information to be reported under subsection (a) includes—

(1) the name of any physician or licensed health care practitioner for whose benefit the payment is made,

(2) the amount of the payment,

(3) the name (if known) of any hospital with which the physician or practitioner is affiliated or associated,

(4) a description of the acts or omissions and injuries or illnesses upon which the action or claim was based, and

(5) such other information as the Secretary determines is required for appropriate interpretation of information reported under this section.

(c) SANCTIONS FOR FAILURE TO REPORT.—Any entity that fails to report information on a payment required to be reported under this section shall be subject to a civil money penalty of not more than $10,000 for each such payment 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 under that section.

(d) REPORT ON TREATMENT OF SMALL PAYMENTS.—The Secretary shall study and report to Congress, not later than two years after the date of the enactment of this Act, on whether information respecting small payments should continue to be required to be reported under subsection (a) and whether information respecting all claims made concerning a medical malpractice action should be required to be reported under such subsection.

**SEC. 422. [11132] REPORTING OF SANCTIONS TAKEN BY BOARDS OF MEDICAL EXAMINERS.**

(a) IN GENERAL.—

(1) ACTIONS SUBJECT TO REPORTING.—Each Board of Medical Examiners—

(A) which revokes or suspends (or otherwise restricts) a physician's license or censures, reprimands, or places on probation a physician, for reasons relating to the physician's professional competence or professional conduct, or

(B) to which a physician's license is surrendered,

shall report, in accordance with section 424, the information described in paragraph (2).

(2) INFORMATION TO BE REPORTED.—The information to be reported under paragraph (1) is—

(A) the name of the physician involved,

(B) a description of the acts or omissions or other reasons (if known) for the revocation, suspension, or surrender of license, and

(C) such other information respecting the circumstances of the action or surrender as the Secretary deems appropriate.

(b) FAILURE TO REPORT.—If, after notice of noncompliance and providing opportunity to correct noncompliance, the Secretary determines that a Board of Medical Examiners has failed to report information in accordance with subsection (a), the Secretary shall designate another qualified entity for the reporting of information under section 423.

**SEC. 423. [11133] REPORTING OF CERTAIN PROFESSIONAL REVIEW ACTIONS TAKEN BY HEALTH CARE ENTITIES.**

(a) REPORTING BY HEALTH CARE ENTITIES.—

(1) ON PHYSICIANS.—Each health care entity which—

(A) takes a professional review action that adversely affects the clinical privileges of a physician for a period longer than 30 days;

(B) accepts the surrender of clinical privileges of a physician—

(i) while the physician is under an investigation by the entity relating to possible incompetence or improper professional conduct, or

(ii) in return for not conducting such an investigation or proceeding; or

(C) in the case of such an entity which is a professional society, takes a professional review action which adversely affects the membership of a physician in the society,

shall report to the Board of Medical Examiners, in accordance with section 424(a), the information described in paragraph (3).

(2) PERMISSIVE REPORTING ON OTHER LICENSED HEALTH CARE PRACTITIONERS.—A health care entity may report to the Board of Medical Examiners, in accordance with section 424(a), the information described in paragraph (3) in the case of a licensed health care practitioner who is not a physician, if the entity would be required to report such information under paragraph (1) with respect to the practitioner if the practitioner were a physician.

(3) INFORMATION TO BE REPORTED.—The information to be reported under this subsection is—

(A) the name of the physician or practitioner involved,

(B) a description of the acts or omissions or other reasons for the action or, if known, for the surrender, and

(C) such other information respecting the circumstances of the action or surrender as the Secretary deems appropriate.

(b) REPORTING BY BOARD OF MEDICAL EXAMINERS.—Each Board of Medical Examiners shall report, in accordance with section 424, the information reported to it under subsection (a) and known instances of a health care entity's failure to report information under subsection (a)(1).

(c) SANCTIONS.—

(1) HEALTH CARE ENTITIES.—A health care entity that fails substantially to meet the requirement of subsection (a)(1) shall lose the protections of section 411(a)(1) if the Secretary publishes the name of the entity under section 411(b).

(2) BOARD OF MEDICAL EXAMINERS.—If, after notice of noncompliance and providing an opportunity to correct noncompliance, the Secretary determines that a Board of Medical Examiners has failed to report information in accordance with subsection (b), the Secretary shall designate another qualified entity for the reporting of information under subsection (b).

(d) REFERENCES TO BOARD OF MEDICAL EXAMINERS.—Any reference in this part to a Board of Medical Examiners includes, in the case of a Board in a State that fails to meet the reporting requirements of section 422(a) or subsection (b), a reference to such other qualified entity as the Secretary designates.

**SEC. 424. [11134] FORM OF REPORTING.**

(a) TIMING AND FORM.—The information required to be reported under sections 421, 422(a), and 423 shall be reported regularly (but not less often than monthly) and in such form and manner as the Secretary prescribes. Such information shall first be required to be reported on a date (not later than one year after the date of the enactment of this Act) specified by the Secretary.

(b) TO WHOM REPORTED.—The information required to be reported under sections 421, 422(a), and 423(b) shall be reported to the Secretary, or, in the Secretary's discretion, to an appropriate private or public agency which has made suitable arrangements with the Secretary with respect to receipt, storage, protection of confidentiality, and dissemination of the information under this part.

(c) REPORTING TO STATE LICENSING BOARDS.—

(1) MALPRACTICE PAYMENTS.—Information required to be reported under section 421 shall also be reported to the appropriate State licensing board (or boards) in the State in which the medical malpractice claim arose.

(2) REPORTING TO OTHER LICENSING BOARDS.—Information required to be reported under section 423(b) shall also be reported to the appropriate State licensing board in the State in which the health care entity is located if it is not otherwise reported to such board under subsection (b).

**SEC. 425. [11135] DUTY OF HOSPITALS TO OBTAIN INFORMATION.**

(a) IN GENERAL.—It is the duty of each hospital to request from the Secretary (or the agency designated under section 424(b)), on and after the date information is first required to be reported under section 424(a))—

(1) at the time a physician or licensed health care practitioner applies to be on the medical staff (courtesy or otherwise) of, or for clinical privileges at, the hospital, information reported under this part concerning the physician or practitioner, and

(2) once every 2 years information reported under this part concerning any physician or such practitioner who is on the medical staff (courtesy or otherwise) of, or has been granted clinical privileges at, the hospital.

A hospital may request such information at other times.

(b) FAILURE TO OBTAIN INFORMATION.—With respect to a medical malpractice action, a hospital which does not request information respecting a physician or practitioner as required under subsection (a) is presumed to have knowledge of any information reported under this part to the Secretary with respect to the physician or practitioner.

(c) RELIANCE ON INFORMATION PROVIDED.—Each hospital may rely upon information provided to the hospital under this title and shall not be held liable for such reliance in the absence of the hospital's knowledge that the information provided was false.

**SEC. 426. [11136] DISCLOSURE AND CORRECTION OF INFORMATION.**

With respect to the information reported to the Secretary (or the agency designated under section 424(b)) under this part respecting a physician or other licensed health care practitioner, the Secretary shall, by regulation, provide for—

(1) disclosure of the information, upon request, to the physician or practitioner, and

(2) procedures in the case of disputed accuracy of the information.

**SEC. 427. [11137] MISCELLANEOUS PROVISIONS.**

(a) PROVIDING LICENSING BOARDS AND OTHER HEALTH CARE ENTITIES WITH ACCESS TO INFORMATION.—The Secretary (or the agency designated under section 424(b)) shall, upon request, provide information reported under this part with respect to a physician or other licensed health care practitioner to State licensing boards, to hospitals, and to other health care entities (including health maintenance organizations) that have entered (or may be entering) into an employment or affiliation relationship with the physician or practitioner or to which the physician or practitioner has applied for clinical privileges or appointment to the medical staff.

(b) CONFIDENTIALITY OF INFORMATION.—

(1) IN GENERAL.—Information reported under this part is considered confidential and shall not be disclosed (other than to the physician or practitioner involved) except with respect to professional review activity, as necessary to carry out subsections (b) and (c) of section 425 (as specified in regulations by the Secretary), or in accordance with regulations of the Secretary promulgated pursuant to subsection (a). Nothing in this subsection shall prevent the disclosure of such information by a party which is otherwise authorized, under applicable State law, to make such disclosure. Information reported under this part that is in a form that does not permit the identification of any particular health care entity, physician, other health care practitioner, or patient shall not be considered confidential. The Secretary (or the agency designated under section 424(b)), on application by any person, shall prepare such information in such form and shall disclose such information in such form.

(2) PENALTY FOR VIOLATIONS.—Any person who violates paragraph (1) shall be subject to a civil money 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 under that section.

(3) USE OF INFORMATION.—Subject to paragraph (1), information provided under section 425 and subsection (a) is intended to be used solely with respect to activities in the furtherance of the quality of health care.

(4) FEES.—The Secretary may establish or approve reasonable fees for the disclosure of information under this section or section 426. The amount of such a fee may not exceed the costs of processing the requests for disclosure and of providing such information. Such fees shall be available to the Secretary (or, in the Secretary's discretion, to the agency designated under section 424(b)) to cover such costs.

(c) RELIEF FROM LIABILITY FOR REPORTING.—No person or entity (including the agency designated under section 424(b)) shall be held liable in any civil action with respect to any report made under this part (including information provided under subsection

(a)[1] without knowledge of the falsity of the information contained in the report.

(d) INTERPRETATION OF INFORMATION.—In interpreting information reported under this part, a payment in settlement of a medical malpractice action or claim shall not be construed as creating a presumption that medical malpractice has occurred.

## PART C—DEFINITIONS AND REPORTS

**SEC. 431. [11151] DEFINITIONS.**

In this title:

(1) The term "adversely affecting" includes reducing, restricting, suspending, revoking, denying, or failing to renew clinical privileges or membership in a health care entity.

(2) The term "Board of Medical Examiners" includes a body comparable to such a Board (as determined by the State) with responsibility for the licensing of physicians and also includes a subdivision of such a Board or body.

(3) The term "clinical privileges" includes privileges, membership on the medical staff, and the other circumstances pertaining to the furnishing of medical care under which a physician or other licensed health care practitioner is permitted to furnish such care by a health care entity.

(4)(A) The term "health care entity" means—

(i) a hospital that is licensed to provide health care services by the State in which it is located,

(ii) an entity (including a health maintenance organization or group medical practice) that provides health care services and that follows a formal peer review process for the purpose of furthering quality health care (as determined under regulations of the Secretary), and

(iii) subject to subparagraph (B), a professional society (or committee thereof) of physicians or other licensed health care practitioners that follows a formal peer review process for the purpose of furthering quality health care (as determined under regulations of the Secretary).

(B) The term "health care entity" does not include a professional society (or committee thereof) if, within the previous 5 years, the society has been found by the Federal Trade Commission or any court to have engaged in any anti-competitive practice which had the effect of restricting the practice of licensed health care practitioners.

(5) The term "hospital" means an entity described in paragraphs (1) and (7) of section 1861(e) of the Social Security Act.

(6) The terms "licensed health care practitioner" and "practitioner" mean, with respect to a State, an individual (other than a physician) who is licensed or otherwise authorized by the State to provide health care services.

(7) The term "medical malpractice action or claim" means a written claim or demand for payment based on a health care provider's furnishing (or failure to furnish) health care services, and includes the filing of a cause of action, based on the

[1] So in law. A closing parenthesis probably should follow "subsection (a)".

law of tort, brought in any court of any State or the United States seeking monetary damages.

(8) The term "physician" means a doctor of medicine or osteopathy or a doctor of dental surgery or medical dentistry legally authorized to practice medicine and surgery or dentistry by a State (or any individual who, without authority holds himself or herself out to be so authorized).

(9) The term "professional review action" means an action or recommendation of a professional review body which is taken or made in the conduct of professional review activity, which is based on the competence or professional conduct of an individual physician (which conduct affects or could affect adversely the health or welfare of a patient or patients), and which affects (or may affect) adversely the clinical privileges, or membership in a professional society, of the physician. Such term includes a formal decision of a professional review body not to take an action or make a recommendation described in the previous sentence and also includes professional review activities relating to a professional review action. In this title, an action is not considered to be based on the competence or professional conduct of a physician if the action is primarily based on—

(A) the physician's association, or lack of association, with a professional society or association,

(B) the physician's fees or the physician's advertising or engaging in other competitive acts intended to solicit or retain business,

(C) the physician's participation in prepaid group health plans, salaried employment, or any other manner of delivering health services whether on a fee-for-service or other basis,

(D) a physician's association with, supervision of, delegation of authority to, support for, training of, or participation in a private group practice with, a member or members of a particular class of health care practitioner or professional, or

(E) any other matter that does not relate to the competence or professional conduct of a physician.

(10) The term "professional review activity" means an activity of a health care entity with respect to an individual physician—

(A) to determine whether the physician may have clinical privileges with respect to, or membership in, the entity,

(B) to determine the scope or conditions of such privileges or membership, or

(C) to change or modify such privileges or membership.

(11) The term "professional review body" means a health care entity and the governing body or any committee of a health care entity which conducts professional review activity, and includes any committee of the medical staff of such an entity when assisting the governing body in a professional review activity.

(12) The term "Secretary" means the Secretary of Health and Human Services.

(13) The term "State" means the 50 States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

(14) The term "State licensing board" means, with respect to a physician or health care provider in a State, the agency of the State which is primarily responsible for the licensing of the physician or provider to furnish health care services.

**SEC. 432. [11152] REPORTS AND MEMORANDA OF UNDERSTANDING.**

(a) ANNUAL REPORTS TO CONGRESS.—The Secretary shall report to Congress, annually during the three years after the date of the enactment of this Act, on the implementation of this title.

(b) MEMORANDA OF UNDERSTANDING.—The Secretary of Health and Human Services shall seek to enter into memoranda of understanding with the Secretary of Defense and the Administrator of Veterans' Affairs to apply the provisions of part B of this title to hospitals and other facilities and health care providers under the jurisdiction of the Secretary or Administrator, respectively. The Secretary shall report to Congress, not later than two years after the date of the enactment of this Act, on any such memoranda and on the cooperation among such officials in establishing such memoranda.

(c) MEMORANDUM OF UNDERSTANDING WITH DRUG ENFORCEMENT ADMINISTRATION.—The Secretary of Health and Human Services shall seek to enter into a memorandum of understanding with the Administrator of Drug Enforcement relating to providing for the reporting by the Administrator to the Secretary of information respecting physicians and other practitioners whose registration to dispense controlled substances has been suspended or revoked under section 304 of the Controlled Substances Act. The Secretary shall report to Congress, not later than two years after the date of the enactment of this Act, on any such memorandum and on the cooperation between the Secretary and the Administrator in establishing such a memorandum.

# ALZHEIMER'S DISEASE AND RELATED DEMENTIAS RESEARCH ACT OF 1992

# ALZHEIMER'S DISEASE AND RELATED DEMENTIAS RESEARCH ACT OF 1992

**(References in brackets [ ] are to title 42, United States Code)**

# TITLE IX—ALZHEIMER'S DISEASE AND RELATED DEMENTIAS RESEARCH [1]

## PART A—GENERAL PROVISIONS

### SHORT TITLE

SEC. 901. [11201 note] This title may be cited as the "Alzheimer's Disease and Related Dementias Research Act of 1992".

### FINDINGS

SEC. 902. [11201] The Congress finds that—

(1) best estimates indicate that between 2,000,000 and 3,000,000 Americans presently have Alzheimer's disease or related dementias;

(2) estimates of the number of individuals afflicted with Alzheimer's disease and related dementias are unreliable because current diagnostic procedures lack accuracy and sensitivity and because there is a need for epidemiological data on incidence and prevalence of such disease and dementias;

(3) studies estimate that between one-half and two-thirds of patients in nursing homes meet the clinical and mental status criteria for dementia;

(4) the cost of caring for individuals with Alzheimer's disease and related dementias is great, and conservative estimates range between $38,000,000,000 and $42,000,000,000 per year solely for direct costs;

(5) progress in the neurosciences and behavioral sciences has demonstrated the interdependence and mutual reinforcement of basic science, clinical research, and services research for Alzheimer's disease and related dementias;

(6) programs initiated as part of the Decade of the Brain are likely to provide significant progress in understanding the fundamental mechanisms underlying the causes of, and treatments for, Alzheimer's disease and related dementias;

(7) although substantial progress has been made in recent years in identifying possible leads to the causes of Alzheimer's disease and related dementias, and more progress can be expected in the near future, there is little likelihood of a breakthrough in the immediate future that would eliminate or substantially reduce—

[1] Title IX of Public Law 99–660.

(A) the number of individuals with the disease and dementias; or

(B) the difficulties of caring for the individuals;

(8) the responsibility for care of individuals with Alzheimer's disease and related dementias falls primarily on their families, and the care is financially and emotionally devastating;

(9) attempts to reduce the emotional and financial burden of caring for dementia patients is impeded by a lack of knowledge about such patients, how to care for such patients, the costs associated with such care, the effectiveness of various modes of care, the quality and type of care necessary at various stages of the disease, and other appropriate services that are needed to provide quality care;

(10) the results of the little research that has been undertaken concerning dementia has been inadequate or the results have not been widely disseminated;

(11) more knowledge is needed concerning—

(A) the epidemiology of, and the identification of risk factors for, Alzheimer's disease and related dementias;

(B) the development of methods for early diagnosis, functional assessment, and psychological evaluation of individuals with Alzheimer's disease for the purpose of monitoring the course of the disease and developing strategies for improving the quality of life for such individuals;

(C) the understanding of the optimal range and cost-effectiveness of community and institutional services for individuals with Alzheimer's disease and related dementias and their families, particularly with respect to the design, delivery, staffing, and mix of such services and the coordination of such services with other services, and with respect to the relationship of formal to informal support services;

(D) the understanding of optimal methods to combine formal support services provided by health care professionals with informal support services provided by family, friends, and neighbors of individuals with Alzheimer's disease, and the identification of ways family caregivers can be sustained through interventions to reduce psychological and social problems and physical problems induced by stress;

(E) existing data that are relevant to Alzheimer's disease and related dementias; and

(F) the costs incurred in caring for individuals with Alzheimer's disease and related dementias;

(12) it is imperative to provide appropriate coordination of the efforts of the Federal Government in the provision of services for individuals with Alzheimer's disease and related dementias;

(13) it is important to increase the understanding of Alzheimer's disease and related dementias by the diverse range of personnel involved in the care of individuals with such disease and dementias; and

(14) it is imperative that the Social Security Administration be provided information pertaining to Alzheimer's disease and related dementias, particularly for personnel in such Administration involved in the establishment and updating of criteria for determining whether an individual is under a disability for purposes of titles II and XVI of the Social Security Act.

## PART B—COUNCIL ON ALZHEIMER'S DISEASE [1]

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## PART C—ADVISORY PANEL ON ALZHEIMER'S DISEASE

### ESTABLISHMENT OF PANEL

SEC. 921. [11221] (a) There is established in the Department the Advisory Panel on Alzheimer's Disease (hereinafter referred to as the "Panel"). The Panel shall be composed of—

(1) 15 voting members appointed by the Director of the Office of Technology Assessment, of which—

(A) 3 shall be individuals who are biomedical research scientists with demonstrated achievements in biomedical research relating to Alzheimer's disease, including at least one individual who is a researcher at a center supported under section 445 of the Public Health Service Act;

(B) 3 shall be individuals with demonstrated achievements in research relevant to services for the care of individuals with Alzheimer's disease and related dementias;

(C) 3 shall be individuals who are providers of services, or administrators of organizations which provide services, for individuals with Alzheimer's disease and related dementias and their families;

(D) 3 shall be individuals who are experts in the financing of health care services and long-term care services, including one individual who is a representative of private health care services insurers; and

(E) 3 shall be representatives of national voluntary organizations which are concerned with the problems of individuals with Alzheimer's disease and related dementias and their families; and

(2) the Chairman of the Council, the Director of the National Institute on Aging, the Director of the National Institute of Mental Health, the Administrator of the Agency for Health Care Policy and Research [2], and the Commissioner on Aging [3], who shall be nonvoting ex officio members.

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[1] So in law. Section 601(a)(2)(E) of Public Law 105–362 (112 Stat. 3284) struck all the sections of part B (sections 911 and 912) without striking the part heading.

[2] Section 2 of Public Law 106–129 (113 Stat. 1653) designated such Agency as the Agency for Healthcare Research and Quality.

[3] Probably should be "Assistant Secretary for Aging". See section 3(b)(3) of Public Law 103–171 (107 Stat. 1991), which provides for an amendment to each of sections 911(a)(8) and 921(a)(2) of the "Alzheimer's Disease and Related Dementias Act of 1986". The amendments cannot be executed because there no longer is any Act with that short title. See section 2(a) of Public Law 102–507 (106 Stat. 3281), which changed the short title of this Act to the "Alzheimer's Disease and Related Dementias Research Act of 1992".

(b) The Director of the Office of Technology Assessment shall appoint members to the Panel under subsection (a)(1) within 90 days after the date of enactment of this Act.

(c) The Secretary shall appoint a Chairman of the Panel from among the members appointed under subsection (a)(1).

(d)(1)(A) Except as provided in subparagraph (B), members of the Panel appointed under subsection (a)(1) shall each serve for a term of 3 years.

(B) Of the members appointed under subsection (a)(1) that are serving on the Panel on the day before the date of the enactment of this subsection—

(i) five shall serve for a term that expires on such date;

(ii) five shall serve for a term that expires 1 year after such date; and

(iii) five shall serve for a term that expires 2 years after such date.

(2) A vacancy on the Panel shall be filled in the same manner as the original appointment was made, and not later than 90 days after the date on which the vacancy first arises. A vacancy on the Panel shall not affect the powers of the Panel.

(e) A majority of the members of the Panel appointed under subsection (a)(1) shall constitute a quorum, but a lesser number may hold hearings. The Panel may establish such subcommittees as the Panel considers appropriate.

(f) The Panel shall meet at the call of the Chairman, but not less than once per year.

(g) The Executive Secretary of the Council shall serve as Executive Secretary of the Panel. The Secretary shall provide the Panel with such additional administrative staff and support as may be necessary to enable the Panel to carry out its functions.

(h) Each member of the Panel appointed under subsection (a)(1) shall receive compensation at a rate at the daily equivalent of the maximum rate specified for GS–15 of the General Schedule under section 5332 of title 5, United States Code, for each day, including travel time, that such member is engaged in duties as a member of the Panel. While away from their homes or regular places of business in the performance of duties as a member of the Panel, members of the Panel appointed under subsection (a)(1) shall be allowed travel expenses, including per diem in lieu of subsistence, at rates authorized for employees of agencies under section 5702 of title 5, United States Code.

(i) Notwithstanding section 14 of the Federal Advisory Committee Act (5 U.S.C. App.), on September 30, 1996, the Panel shall be abolished and all programs established under this part shall terminate.

FUNCTIONS OF THE PANEL

SEC. 922. [11222] (a) The Panel shall assist the Secretary and the Council in the identification of priorities and emerging issues with respect to Alzheimer's disease and related dementias and the care of individuals with such disease and dementias. The Panel shall advise the Secretary and the Council with respect to the identification of—

(1) emerging issues in, and promising areas of, biomedical research relating to Alzheimer's disease and related dementias;

(2) emerging issues in, and promising areas of, research relating to services for individuals with Alzheimer's disease and related dementias and their families;

(3) emerging issues and promising initiatives in home and community based services, and systems of such services, for individuals with Alzheimer's disease and related dementias and their families; and

(4) emerging issues in, and innovative financing mechanisms for, payment for health care services and social services for individuals with Alzheimer's disease and related dementias and their families, particularly financing mechanisms in the private sector.

(b) The Panel shall prepare and transmit to the Congress, the Secretary, and the Council, and make available to the public, an annual report. Such report shall contain such recommendations as the Panel considers appropriate for administrative and legislative actions to improve services for individuals with Alzheimer's disease and related dementias and their families and to provide for promising biomedical research relating to Alzheimer's disease and related dementias.

**SEC. 923. [11223] AUTHORIZATION OF APPROPRIATIONS.**

There are authorized to be appropriated to carry out this part such sums as may be necessary for each of the fiscal years 1992 through 1996.

## PART D—RESEARCH RELATING TO SERVICES FOR INDIVIDUALS WITH ALZHEIMER'S DISEASE AND RELATED DEMENTIAS AND THEIR FAMILIES

### Subpart 1—Responsibilities of the National Institute of Mental Health

#### RESEARCH PROGRAM AND PLAN

SEC. 931. [11251] (a) The Director of the National Institute of Mental Health shall conduct, or make grants for the conduct of, research relevant to appropriate services and specialized care for individuals with Alzheimer's disease and related dementias and their families.

(b) The Director of the National Institute of Mental Health shall—

(1) ensure that the research conducted under subsection (a) includes research concerning—

(A) mental health services and treatment modalities relevant to the mental, behavioral, and psychological problems associated with Alzheimer's disease and related dementias;

(B) the most effective methods for providing comprehensive multidimensional assessments to obtain information about the current functioning of, and needs for the care of, individuals with Alzheimer's disease and related dementias;

(C)[1] the optimal range, types, and cost-effectiveness of services and specialized care for individuals with Alzheimer's disease and related dementias and for their families, in community and residential settings (including home care, day care, and respite care), and in institutional settings, particularly with respect to—

(i) the design of the services and care;

(ii) appropriate staffing for the provision of the services and care;

(iii) the timing of the services and care during the progression of the disease or dementias; and

(iv) the appropriate mix and coordination of the services and specialized care;

(D) the efficacy of various special care units in the United States for individuals with Alzheimer's disease, including an assessment of the costs incurred in operating such units, the evaluation of best practices for the development of appropriate standards to be used by such units, and the measurement of patient outcomes in such units;

(E) methods to combine formal support services provided by health care professionals for individuals with Alzheimer's disease and related dementias with informal support services provided for such individuals by their families, friends, and neighbors, including services such as day care services, respite care services, home care services, nursing home services, and other residential services and care, and an evaluation of the services actually used for such individuals and the sources of payment for such services;

(F) methods to sustain family members who provide care for individuals with Alzheimer's disease and related dementias through interventions to reduce psychological and social problems and physical problems induced by stress; and

(G) improved methods to deliver services for individuals with Alzheimer's disease and related dementias and their families, including services such as outreach services, comprehensive assessment and care management services, outpatient treatment services, home care services, respite care services, adult day care services, partial hospitalization services, nursing home services, and other residential services and care; and

(2) ensure that the research is coordinated with, and uses, to the maximum extent feasible, resources of, other Federal programs relating to Alzheimer's disease and dementia, including centers supported under section 445 of the Public Health Service Act, 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

[1] Indentation is so in law. See paragraphs (1) and (2) of section 7(a) of Public Law 102–507 (106 Stat. 3284).

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.

DISSEMINATION

SEC. 932. [11252] The Director of the National Institute of Mental Health shall disseminate the results of research conducted under this subpart to appropriate professional entities and to the public.

**SEC. 933. [11253] AUTHORIZATION OF APPROPRIATIONS.**

There are authorized to be appropriated to carry out this subpart such sums as may be necessary for each of the fiscal years 1992 through 1996.

## Subpart 2—Responsibilities of the Agency for Health Care Policy and Research [1]

**SEC. 934. [11261] RESEARCH PROGRAM.**

(a) GRANTS FOR RESEARCH.—The Administrator of the Agency for Health Care Policy and Research [1] shall conduct, or make grants for the conduct of, research relevant to appropriate services for individuals with Alzheimer's disease and related dementias and for their families.

(b) RESEARCH SUBJECTS.—The Administrator of the Agency for Health Care Policy and Research [1] shall ensure that research conducted under subsection (a) shall include research—

(1) concerning improving the organization, delivery, and financing of services for individuals with Alzheimer's disease and related dementias and for their families, including research on—

(A) the design, staffing, and operation of special care units for the individuals in institutional settings, as well as individuals in institutional settings, as well as individuals in home care, day care, and respite care; and

(B) the exploration and enhancement of services such as home care, day care, and respite care, that provide alternatives to institutional care;

(2) concerning the costs incurred by individuals with Alzheimer's disease and related dementias and by their families in obtaining services, particularly services that are essential to the individuals and that are not generally required by other patients under long-term care programs;

(3) concerning the costs, cost-effectiveness, and effectiveness of various interventions to provide services for individuals with Alzheimer's disease and related dementias and for their families;

(4) conducted in consultation with the Director of the National Institute on Aging and the Commissioner of the Administration on Aging, concerning the role of physicians in caring for persons with Alzheimer's disease and related dementias

[1] See footnote 2 to section 921(a)(2).

and for their families, including the role of a physician in connecting such persons with appropriate health care and supportive services, including those supported through State and area agencies on aging designated under section 305(a) (1) and (2)(A) of the Older Americans Act of 1965 (42 U.S.C. 3025(a)(1) and (2)(A)); and

(5) conducted in consultation with the Director of the National Institute on Aging and the Commissioner of the Administration on Aging, concerning legal and ethical issues, including issues associated with special care units, facing individuals with Alzheimer's disease and related dementias and facing their families.

DISSEMINATION

SEC. 935. [11262] The Director of the National Center for Health Services Research and Health Care Technology Assessment[1] shall disseminate the results of research conducted under this subpart to appropriate professional entities and to the public.

**SEC. 936. [11263] AUTHORIZATION OF APPROPRIATIONS.**

There are authorized to be appropriated to carry out this subpart such sums as may be necessary for each of the fiscal years 1992 through 1996.

## Subpart 3—Responsibilities of the Centers for Medicare & Medicaid Services

RESEARCH PROGRAM AND PLAN

SEC. 937. [11271] (a) The Administrator of the Centers for Medicare & Medicaid Services shall conduct, or make grants for the conduct of, research relevant to appropriate services for individuals with Alzheimer's disease and related dementias and their families.

(b)(1) Within 6 months after the date of enactment of this Act, the Administrator of the Centers for Medicare & Medicaid Services shall prepare and transmit to the Chairman of the Council a plan for research to be conducted under (a)[2]. The plan shall—

(A) provide for a determination of the types of services required by individuals with Alzheimer's disease and related dementias and their families to allow such individuals to remain living at home or in a community-based setting;

(B) provide for a determination of the costs of providing needed services to individuals with Alzheimer's disease and related dementias and their families, including the expenditures for institutional, home, and community-based services and the source of payment for such expenditures;

(C) provide for an assessment of the adequacy of benefits provided through the Medicare and Medicaid[3] programs and through private health insurance for needed services for indi-

[1] Superseded by the Agency for Health Care Policy and Research. Section 2 of Public Law 106–129 (113 Stat. 1653) designated the Agency for Health Care Policy and Research as the Agency for Healthcare Research and Quality.

[2] So in law. Probably should be "subsection (a)".

[3] Titles XVIII and XIX of the Social Security Act.

viduals with Alzheimer's disease and related dementias and their families; and

(D) provide for a determination of the costs to the Medicare and Medicaid programs and to private health insurers (if available) of providing covered benefits to individuals with Alzheimer's disease and related dementias and their families.

(2) Within one year after transmitting the plan required under paragraph (1), and annually thereafter, the Administrator of the Centers for Medicare & Medicaid Services shall prepare and transmit to the Chairman of the Council such revisions of such plan as the Administrator considers appropriate.

(c) In preparing and revising the plan required by subsection (b), the Administrator of the Centers for Medicare & Medicaid Services shall consult with the Chairman of the Council and the heads of agencies within the Department.

DISSEMINATION

SEC. 938. [11272] The Administrator of the Centers for Medicare & Medicaid Services shall disseminate the results of research conducted under this subpart to appropriate professional entities and to the public.

AUTHORIZATIONS OF APPROPRIATIONS

SEC. 939. [11273] To carry out this subpart, there are authorized to be appropriated $2,000,000 for each of fiscal years 1988 through 1991.

## PART E—EDUCATIONAL ACTIVITIES

PROVIDING INFORMATION FOR PERSONNEL OF THE SOCIAL SECURITY ADMINISTRATION

SEC. 961. [11291] (a) The Secretary shall develop a mechanism to ensure the prompt provision of the most current information concerning Alzheimer's disease and related dementias to the Commissioner of Social Security, particularly information which will increase the understanding of personnel of the Social Security Administration concerning such disease and dementias.

(b) The Commissioner of Social Security shall ensure that information received under subsection (a) is provided to personnel of the Social Security Administration, particularly personnel involved in the process of determining, for purposes of titles II and XVI of the Social Security Act, whether an individual is under a disability.

**SEC. 962. [11292] EDUCATION OF THE PUBLIC, INDIVIDUALS WITH ALZHEIMER'S DISEASE AND THEIR FAMILIES, AND HEALTH AND LONG-TERM CARE PROVIDERS.**

(a) TRAINING MODELS GRANTS.—

(1) GRANTS.—The Director of the National Institute on Aging may award grants to eligible entities to assist the entities in developing and evaluating model training programs—

(A) for—

(i) health care professionals, including mental health professionals;

(ii) health care paraprofessionals;

(iii) personnel, including information and referral, case management, and in-home services personnel (including personnel receiving support under the Older Americans Act of 1965 (42 U.S.C. 3001 et seq.)), providing supportive services to the elderly and the families of the elderly;

(iv) family caregivers providing care and treatment for individuals with Alzheimer's disease and related disorders; and

(v) personnel of local organizations (including community groups, business and labor groups, and religious, educational, and charitable organizations) that have traditionally not been involved in planning and developing long-term care services; and

(B) with attention to such variables as—

(i) curricula development for training and continuing education programs;

(ii) care setting; and

(iii) intervention technique.

(2) ELIGIBLE ENTITY.—To be eligible to receive grants under this subsection, an entity shall be—

(A) an educational institution providing training and education in medicine, psychology, nursing, social work, gerontology, or health care administration;

(B) an educational institution providing preparatory training and education of personnel for nursing homes, hospitals, and home or community settings; or

(C) an Alzheimer's Disease Research Center described in section 445(a) of the Public Health Service Act.

(b) EDUCATIONAL GRANTS.—The Director of the National Institute on Aging is authorized to make grants to public and nonprofit private entities to assist such entities in establishing programs, for educating health care providers and the families of individuals with Alzheimer's disease or related disorders, regarding—

(1) caring for individuals with such diseases or disorders; and

(2) the availability in the community of public and private sources of assistance, including financial assistance, for caring for such individuals.

(c) AWARD OF GRANTS.—In awarding grants under this section, the Director of the National Institute on Aging shall—

(1) award the grants on the basis of merit;

(2) award the grants in a manner that will ensure access to the programs described in subsections (a) and (b) by rural, minority, and underserved populations throughout the country; and

(3) ensure that the grants are distributed among the principal geographic regions of the United States.

(d) APPLICATION.—To be eligible to receive a grant under this section, an entity shall submit an application to the Director of the National Institute on Aging at such time, in such manner, and containing or accompanied by such information, as the Director may reasonably require, including, at a minimum, an assurance that

the entity will coordinate programs provided under this section with the State agency designated under section 305(a)(1) of the Older Americans Act of 1965, in the State in which the entity will provide such programs.

(e) COORDINATION.—The Director of the National Institute on Aging shall coordinate the award of grants under this section with the heads of other appropriate agencies, including the Commissioner of the Administration on Aging.

EDUCATION PROGRAMS FOR SAFETY AND TRANSPORTATION PERSONNEL

SEC. 963. [11293] The Director of the National Institute on Aging, through centers supported under section 445 of the Public Health Service Act, training academies, and continuing education programs, shall conduct education and information dissemination activities concerning Alzheimer's disease and related dementias for personnel involved in ensuring the public safety and providing public transportation. Such activities shall be designed to enhance the ability of such personnel to respond appropriately to individuals with Alzheimer's disease and related dementias whom such personnel may encounter in the course of their employment.

AUTHORIZATION OF APPROPRIATIONS

SEC. 964. [11294] (a) To carry out sections 961 and 963, there are authorized to be appropriated $1,000,000 for each of the fiscal years 1988 through 1991.

(b) There are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1992 through 1996, to carry out section 962.

# ABANDONED INFANTS ASSISTANCE ACT OF 1988

## ABANDONED INFANTS ASSISTANCE ACT OF 1988 [1]

**SECTION 1. SHORT TITLE.**

This Act may be cited as the "Abandoned Infants Assistance Act of 1988".

**SEC. 2. FINDINGS.**

The Congress finds that—

(1) throughout the Nation, the number of infants and young children who have been exposed to drugs taken by their mothers during pregnancy has increased dramatically;

(2) the inability of parents who abuse drugs to provide adequate care for such infants and young children and a lack of suitable shelter homes for such infants and young children have led to the abandonment of such infants and young children in hospitals for extended periods;

(3) an unacceptable number of these infants and young children will be medically cleared for discharge, yet remain in hospitals as boarder babies;

(4) hospital-based child care for these infants and young children is extremely costly and deprives them of an adequate nurturing environment;

(5) training is inadequate for foster care personnel working with medically fragile infants and young children and infants and young children exposed to drugs;

(6) a particularly devastating development is the increase in the number of infants and young children who are infected with the human immunodeficiency virus (which is believed to cause acquired immune deficiency syndrome and which is commonly known as HIV) or who have been perinatally exposed to the virus or to a dangerous drug;

(7) many such infants and young children have at least one parent who is an intravenous drug abuser;

(8) such infants and young children are particularly difficult to place in foster homes, and are being abandoned in hospitals in increasing numbers by mothers dying of acquired immune deficiency syndrome, or by parents incapable of providing adequate care;

(9) there is a need for comprehensive services for such infants and young children, including foster family care services, case management services, family support services, respite and crisis intervention services, counseling services, and group residential home services;

(10) there is a need to support the families of such infants and young children through the provision of services that will prevent the abandonment of the infants and children; and

[1] 42 U.S.C. 670 note.

(11) there is a need for the development of funding strategies that coordinate and make the optimal use of all private resources, and Federal, State, and local resources, to establish and maintain such services.

# TITLE I—PROJECTS REGARDING ABANDONMENT OF INFANTS AND YOUNG CHILDREN IN HOSPITALS

**SEC. 101. ESTABLISHMENT OF PROGRAM OF DEMONSTRATION PROJECTS.**

(a) IN GENERAL.—The Secretary of Health and Human Services may make grants to public and nonprofit private entities for the purpose of developing, implementing, and operating projects to demonstrate methods—

(1) to prevent the abandonment of infants and young children, including the provision of services to members of the natural family for any condition that increases the probability of abandonment of an infant or young child;

(2) to identify and address the needs of abandoned infants and young children;

(3) to assist abandoned infants and young children to reside with their natural families or in foster care, as appropriate;

(4) to recruit, train, and retain foster families for abandoned infants and young children;

(5) to carry out residential care programs for abandoned infants and young children who are unable to reside with their families or to be placed in foster care;

(6) to carry out programs of respite care for families and foster families of infants and young children described in subsection (b);

(7) to recruit and train health and social services personnel to work with families, foster care families, and residential care programs for abandoned infants and young children; and

(8) to prevent the abandonment of infants and young children, and to care for the infants and young children who have been abandoned, through model programs providing health, educational, and social services at a single site in a geographic area in which a significant number of infants and young children described in subsection (b) reside (with special consideration given to applications from entities that will provide the services of the project through community-based organizations).

(b) PRIORITY IN PROVISION OF SERVICES.—The Secretary may not make a grant under subsection (a) unless the applicant for the grant agrees that, in carrying out the purpose described in subsection (a) (other than with respect to paragraph (6) of such subsection), the applicant will give priority to abandoned infants and young children—

(1) who are infected with the human immunodeficiency virus or who have been perinatally exposed to the virus; or

(2) who have been perinatally exposed to a dangerous drug.

(c) CASE PLAN WITH RESPECT TO FOSTER CARE.—The Secretary may not make a grant under subsection (a) unless the applicant for the grant agrees that, if the applicant expends the grant to carry out any program of providing care to infants and young children in foster homes or in other nonmedical residential settings away from their parents, the applicant will ensure that—

(1) a case plan of the type described in paragraph (1) of section 475 of the Social Security Act is developed for each such infant and young child (to the extent that such infant and young child is not otherwise covered by such a plan); and

(2) the program includes a case review system of the type described in paragraph (5) of such section (covering each such infant and young child who is not otherwise subject to such a system).

(d) ADMINISTRATION OF GRANT.—

(1) The Secretary may not make a grant under subsection (a) unless the applicant for the grant agrees—

(A) to use the funds provided under this section only for the purposes specified in the application submitted to, and approved by, the Secretary pursuant to subsection (e);

(B) to establish such fiscal control and fund accounting procedures as may be necessary to ensure proper disbursement and accounting of Federal funds paid to the applicant under this section;

(C) to report to the Secretary annually on the utilization, cost, and outcome of activities conducted, and services furnished, under this section; and

(D) that if, during the majority of the 180-day period preceding the date of the enactment of this Act, the applicant has carried out any program with respect to the care of abandoned infants and young children, the applicant will expend the grant only for the purpose of significantly expanding, in accordance with subsection (a), activities under such program above the level provided under such program during the majority of such period.

(2) Subject to the availability of amounts made available in appropriations Acts for the fiscal year involved, the duration of a grant under subsection (a) shall be for a period of 3 years, except that the Secretary—

(A) may terminate the grant if the Secretary determines that the entity involved has substantially failed to comply with the agreements required as a condition of the provision of the grant; and

(B) shall continue the grant for one additional year if the Secretary determines that the entity has satisfactorily complied with such agreements.

(e) REQUIREMENT OF APPLICATION.—The Secretary may not make a grant under subsection (a) unless—

(1) an application for the grant is submitted to the Secretary;

(2) with respect to carrying out the purpose for which the grant 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.

(f) TECHNICAL ASSISTANCE TO GRANTEES.—The Secretary may, without charge to any grantee under subsection (a), provide technical assistance (including training) with respect to the planning, development, and operation of projects described in such subsection. The Secretary may provide such technical assistance directly, through contracts, or through grants.

(g) TECHNICAL ASSISTANCE WITH RESPECT TO PROCESS OF APPLYING FOR GRANT.—The Secretary may provide technical assistance (including training) to public and nonprofit private entities with respect to the process of applying to the Secretary for a grant under subsection (a). The Secretary may provide such technical assistance directly, through contracts, or through grants.

(h) PRIORITY REQUIREMENT.—In making grants under subsection (a), the Secretary shall give priority to applicants located in States that have developed and implemented procedures for expedited termination of parental rights and placement for adoption of infants determined to be abandoned under State law.

**SEC. 102. EVALUATIONS, STUDIES, AND REPORTS BY SECRETARY.**

(a) EVALUATIONS OF DEMONSTRATION PROJECTS.—The Secretary shall, directly or through contracts with public and nonprofit private entities, provide for evaluations of projects carried out under section 101 and for the dissemination of information developed as result of such projects.

(b) DISSEMINATION OF INFORMATION TO INDIVIDUALS WITH SPECIAL NEEDS.—

(1)(A) The Secretary may enter into contracts or cooperative agreements with public or nonprofit private entities for the development and operation of model projects to disseminate the information described in subparagraph (B) to individuals who are disproportionately at risk of dysfunctional behaviors that lead to the abandonment of infants or young children.

(B) The information referred to in subparagraph (A) is information on the availability to individuals described in such subparagraph, and the families of the individuals, of financial assistance and services under Federal, State, local, and private programs providing health services, mental health services, educational services, housing services, social services, or other appropriate services.

(2) The Secretary may not provide a contract or cooperative agreement under paragraph (1) to an entity unless—

(A) the entity has demonstrated expertise in the functions with respect to which such financial assistance is to be provided; and

(B) the entity agrees that in disseminating information on programs described in such paragraph, the entity will give priority—

(i) to providing the information to individuals described in such paragraph who—

(I) engage in the abuse of alcohol or drugs, who are infected with the human immunodeficiency virus, or who have limited proficiency in speaking the English language; or

(II) have been historically underserved in the provision of the information; and

(ii) to providing information on programs that are operated in the geographic area in which the individuals involved reside and that will assist in eliminating or reducing the extent of behaviors described in such paragraph.

(3) In providing contracts and cooperative agreements under paragraph (1), the Secretary may not provide more than 1 such contract or agreement with respect to any geographic area.

(4) Subject to the availability of amounts made available in appropriations Acts for the fiscal year involved, the duration of a contract or cooperative agreement under paragraph (1) shall be for a period of 3 years, except that the Secretary may terminate such financial assistance if the Secretary determines that the entity involved has substantially failed to comply with the agreements required as a condition of the provision of the assistance.

(c) STUDY AND REPORT ON NUMBER OF ABANDONED INFANTS AND YOUNG CHILDREN.—

(1) The Secretary shall conduct a study for the purpose of determining—

(A) an estimate of the number of infants and young children abandoned in hospitals in the United States and the number of such infants and young children who are infants and young children described in section 101(b); and

(B) an estimate of the annual costs incurred by the Federal Government and by State and local governments in providing housing and care for such infants and young children.

(2) Not later than April 1, 1992, the Secretary shall complete the study required in paragraph (1) and submit to the Congress a report describing the findings made as a result of the study.

(d) STUDY AND REPORT ON EFFECTIVE CARE METHODS.—

(1) The Secretary shall conduct a study for the purpose of determining the most effective methods for responding to the needs of abandoned infants and young children.

(2) The Secretary shall, not later than April 1, 1991, complete the study required in paragraph (1) and submit to the Congress a report describing the findings made as a result of the study.

**SEC. 103. DEFINITIONS.**

For purposes of this title:

(1) The terms "abandoned" and "abandonment", with respect to infants and young children, mean that the infants and

young children are medically cleared for discharge from acute-care hospital settings, but remain hospitalized because of a lack of appropriate out-of-hospital placement alternatives.

(2) The term "dangerous drug" means a controlled substance, as defined in section 102 of the Controlled Substances Act.

(3) The term "natural family" shall be broadly interpreted to include natural parents, grandparents, family members, guardians, children residing in the household, and individuals residing in the household on a continuing basis who are in a care-giving situation with respect to infants and young children covered under this Act.

**SEC. 104. AUTHORIZATION OF APPROPRIATIONS.**

(a) IN GENERAL.—

(1) For the purpose of carrying out this title (other than section 102(b)), there are authorized to be appropriated $35,000,000 for fiscal year 1997 and such sums as may be necessary for each of the fiscal years 1998 through 2001.

(2)(A) Of the amounts appropriated under paragraph (1) for any fiscal year in excess of the amount appropriated under this subsection for fiscal year 1991, as adjusted in accordance with subparagraph (B), the Secretary shall make available not less than 50 percent for grants under section 101(a) to carry out projects described in paragraph (8) of such section.

(B) For purposes of subparagraph (A), the amount relating to fiscal year 1991 shall be adjusted for a fiscal year to a greater amount to the extent necessary to reflect the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with March of the preceding fiscal year.

(3) Not more than 5 percent of the amounts appropriate [1] under paragraph (1) for any fiscal year may be obligated for carrying out section 102(a).

(b) DISSEMINATION OF INFORMATION FOR INDIVIDUALS WITH SPECIAL NEEDS.—For the purpose of carrying out section 102(b), there is authorized to be appropriated $5,000,000 for each of the fiscal years 1992 through 1995.

(c) ADMINISTRATIVE EXPENSES.—

(1) For the purpose of the administration of this title by the Secretary, there is authorized to be appropriated for each fiscal year specified in subsection (a)(1) an amount equal to 5 percent of the amount authorized in such subsection to be appropriated for the fiscal year. With respect to the amounts appropriated under such subsection, the preceding sentence may not be construed to prohibit the expenditure of the amounts for the purpose described in such sentence.

(2) The Secretary may not obligate any of the amounts appropriated under paragraph (1) for a fiscal year unless, from the amounts appropriated under subsection (a)(1) for the fiscal year, the Secretary has obligated for the purpose described in such paragraph an amount equal to the amounts obligated by the Secretary for such purpose in fiscal year 1991.

[1] So in law. Probably should be "appropriated".

(d) AVAILABILITY OF FUNDS.—Amounts appropriated under this section shall remain available until expended.

# TITLE II—MEDICAL COSTS OF TREATMENT WITH RESPECT TO ACQUIRED IMMUNE DEFICIENCY SYNDROME

**SEC. 201. STUDY AND REPORT ON ASSISTANCE.**

(a) STUDY.—The Secretary shall conduct a study for the purpose of—

(1) determining cost-effective methods for providing assistance to individuals for the medical costs of treatment of conditions arising from infection with the etiologic agent for acquired immune deficiency syndrome, including determining the feasibility of risk-pool health insurance for individuals at risk of such infection;

(2) determining the extent to which Federal payments under title XIX of the Social Security Act are being expended for medical costs described in paragraph (1); and

(3) providing an estimate of the extent to which such Federal payments will be expended for such medical costs during the 5-year period beginning on the date of the enactment of this Act.

(b) REPORT.—The Secretary shall, not later than 12 months after the date of the enactment of this Act, complete the study required in subsection (a) 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 describing the findings made as a result of the study.

# TITLE III—GENERAL PROVISIONS

**SEC. 301. DEFINITIONS.**

For purposes of this Act:

(1) The term "acquired immune deficiency syndrome" includes infection with the etiologic agent for such syndrome, any condition indicating that an individual is infected with such etiologic agent, and any condition arising from such etiologic agent.

(2) The term "Secretary" means the Secretary of Health and Human Services.

# MISCELLANEOUS PROVISIONS

# MISCELLANEOUS PROVISION RELATING TO AVAILABILITY OF APPROPRIATIONS

## MISCELLANEOUS PROVISION RELATING TO AVAILABILITY OF APPROPRIATIONS

SECTION 601 OF PUBLIC LAW 91–296 [1]

TITLE VI—AVAILABILITY OF APPROPRIATIONS

SEC. 601. Notwithstanding any other provision of law, unless enacted after the enactment of this Act expressly in limitation of the provisions of this section, funds appropriated for any fiscal year to carry out any program for which appropriations are authorized by the Public Health Service Act (Public Law 410, Seventy-eighth Congress, as amended) or the Mental Retardation Facilities and Community Mental Health Centers Construction Act of 1963 (Public Law 88–164, as amended) shall remain available for obligation and expenditure until the end of such fiscal year.

[1] 42 U.S.C. 201 note.

# MISCELLANEOUS PROVISIONS RELATING TO ALCOHOL AND TREATMENT

# MISCELLANEOUS PROVISIONS RELATING TO ALCOHOL AND TREATMENT

## COMPREHENSIVE ALCOHOL ABUSE AND ALCOLOHISM PREVENTION, TREATMENT, AND REHABILITATION ACT OF 1974 [1]

**(References in black brackets [ ] are to title 42, United States Code)**

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## TITLE III—TECHNICAL ASSISTANCE AND FEDERAL GRANTS AND CONTRACTS

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### PART B—PROJECTS GRANTS AND CONTRACTS

#### GRANTS AND CONTRACTS FOR THE DEMONSTRATION OF NEW AND MORE EFFECTIVE ALCOHOL ABUSE AND ALCOHOLISM PREVENTION, TREATMENT, AND REHABILITATION PROGRAMS

SEC. 311. [4577] (a) The Secretary, acting through the Institute, may make grants to public and nonprofit private entities and may enter into contracts with public and private entities and with individuals—

(1) to conduct demonstration and evaluation projects, with a high priority on prevention and early intervention projects in occupational and educational settings and on modified community living and work-care arrangements such as halfway houses, recovery homes, and supervised home care, and with particular emphasis on developing new and more effective alcohol abuse and alcoholism prevention, treatment, and rehabilitation programs,

(2) to support projects of a demonstration value in developing methods for the effective coordination of all alcoholism treatment, training, prevention, and research resources available within a health service area established under section 1511 of the Public Health Service Act, and

(3) to provide education and training, which may include additional training to enable treatment personnel to meet certification requirements of public or private accreditation or licensure, or requirements of third-party payors,

for the prevention and treatment of alcohol abuse and alcoholism and for the rehabilitation of alcohol abusers and alcoholics.

(b) Projects and programs for which grants and contracts are made under this section shall (1) be responsive to special requirements of handicapped individuals in receiving such services; (2) whenever possible, be community based, seek (in the case of pre-

[1] Public Law 91–616.

vention and treatment services) to insure care of good quality in general community care facilities and under health insurance plans, and be integrated with, and provide for the active participation of, a wide range of public and nongovernmental agencies, organizations, institutions, and individuals; (3) where a substantial number of the individuals in the population served by the project or program are of limited English-speaking ability, utilize the services of outreach workers fluent in the language spoken by a predominant number of such individuals and develop a plan and make 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 identify an individual employed by the project or program, or who is available to the project or program on a full-time basis, who is fluent both in that language and English and whose responsibilities shall include providing guidance to the individuals of limited English-speaking ability and to appropriate staff members with respect to cultural sensitivities and bridging linguistic and cultural differences; and (4) where appropriate utilize existing community resources (including community mental health centers).

(c)(1) In administering this section, the Secretary shall require coordination of all applications for projects and programs in a State.

(2)(A) Each applicant from within a State, upon filing its application with the Secretary for a grant or contract under this section, shall submit a copy of its application for review by the State agency responsible for the administration of alcohol abuse and alcoholism prevention, treatment, and rehabilitation activities. Such State agency shall be given not more than thirty days from the date of receipt of the application to submit to the Secretary, in writing, an evaluation of the project or program set forth in the application. Such evaluation shall include comments on the relationship of the project to other projects and programs pending and approved and to any State comprehensive plan for treatment and prevention of alcohol abuse and alcoholism. The State shall furnish the applicant a copy of any such evaluation.

(B)(i) Except as provided in clause (ii), each application for a grant under this section shall be submitted by the Secretary to the National Advisory Council on Alcohol Abuse and Alcoholism for its review. The Secretary may approve an application for a grant under this section only if it is recommended for approval by such Council.

(ii) Clause (i) shall not apply to an application for a grant under this section for a project or program for any period of 12 consecutive months for which period payments under such grant will be less than $250,000, if an application for a grant under this section for such project or program and for a period of time which includes such 12-month period has been submitted to, and approved by, the Secretary.

(3) Approval of any application for a grant or contract by the Secretary, including the earmarking or financial assistance for a program or project, may be granted only if the application substantially meets a set of criteria established by the Secretary that—

(A) provides that the projects and programs for which assistance under this section is sought will be substantially administered by or under the supervision of the applicant;

(B) provides for such methods of administration as are necessary for the proper and efficient operation of such programs and projects; and

(C) provides for such fiscal control and fund accounting procedures as may be necessary to assure proper disbursement of and accounting for Federal funds paid to the applicant.

(4) The Secretary shall encourage the submission of and give special consideration to applications under this section for programs and projects aimed at underserved populations such as racial and ethnic minorities, Native Americans (including Native Hawaiians and Native American Pacific Islanders), youth, the elderly, women, handicapped individuals, public inebriates, and families of alcoholics.

(5)(A) No grant may be made under this section to a State or to any entity within the government of a State unless the grant application has been duly authorized by the chief executive officer of such State.

(B) No grant or contract may be made under this section for a period in excess of five years.

(C)(i) The amount of any grant or contract under this section may not exceed 100 per centum of the cost of carrying out the grant or contract in the first fiscal year for which the grant or contract is made under this section, 80 per centum of such cost in the second fiscal year for which the grant or contract is made under this section, 70 per centum of such cost in the third fiscal year for which the grant or contract is made under this section, and 60 per centum of such cost in each of the fourth and fifth fiscal years for which the grant or contract is made under this section.

(ii) For purposes of this subparagraph, no grant or contract shall be considered to have been made under this section for a fiscal year ending before September 30, 1981.

(6) Each applicant, upon filing its application with the Secretary for a grant or contract to provide prevention or treatment services, shall provide a proposed performance standard or standards to measure, or research protocol to determine, the effectiveness of such services.

(7) Nothing shall prevent the use of funds provided under this section for programs and projects aimed at the prevention, treatment, or rehabilitation of drug abuse as well as alcohol abuse and alcoholism.

AUTHORIZATIONS OF APPROPRIATIONS

SEC. 312. [4578] For purposes of section 311, there are authorized to be appropriated $85,000,000 for the fiscal year ending September 30, 1977, $91,000,000 for the fiscal year ending September 30, 1978, and $102,500,000 for the fiscal year ending September 30, 1979, $102,500,000 for the fiscal year ending September 30, 1980, $115,000,000 for the fiscal year ending September 30, 1981, and $15,000,000 for the fiscal year ending September 30, 1982. Of the funds appropriated under this section for the fiscal year ending

September 30, 1980, at least 8 percent of the funds shall be obligated for grants for projects, programs, and services to prevent (through outreach, intervention, and education) the occurrence of alcoholism and alcohol abuse; of the funds appropriated under this section for the next fiscal year at least 10 percent of the funds shall be obligated for such grants and of the funds appropriated under this section for the fiscal year ending September 30, 1982, at least 25 per centum of the funds shall be obligated for such grants.

SEC. 334. (a) Not later than June 1, 1980, the Secretary of Health, Education, and Welfare, acting through the Assistant Secretary for Health, and the Secretary of the Treasury, acting through the Assistant Secretary for Enforcement and Operations, shall jointly report to the President and the Congress—

(1) the extent and nature of birth defects associated with alcohol consumption by pregnant women,

(2) the extent and nature of other health hazards associated with alcoholic beverages, and

(3) the actions which should be taken by the Federal Government under the Federal Alcohol Administration Act and the Federal Food, Drug, and Cosmetic Act with respect to informing the general public of such health hazards.

(b) Subsection (a) shall not be construed to limit the authority of the Attorney General, the Secretary of the Treasury, or the Secretary of Health, Education, and Welfare under the Federal Alcohol Administration Act or the Federal Food, Drug, and Cosmetic Act.

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## TITLE VI—GENERAL

SEC. 601. [4591] If any section, provision, or term of this Act is adjudged invalid for any reason, such judgment shall not affect, impair, or invalidate any other section, provision, or term of this Act, and the remaining sections, provisions, and terms shall be and remain in full force and effect.

SEC. 602. [4592] (a) Each recipient of assistance under this Act pursuant to grants or contracts entered into under other than competitive bidding procedures 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 project or undertaking in connection with which such grant or contract 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.

(b) The Secretary and 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 the grants or contracts entered into under the provisions of this Act under other than competitive bidding procedures.

SEC. 603. [4593] Payments under this Act may be made in advance or by way of reimbursement and in such installments as the Secretary may determine.

SEC. 604. [4594] 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.

# MISCELLANEOUS PROVISIONS RELATING TO ADVISORY COMMITTEES

## MISCELLANEOUS PROVISIONS RELATING TO ADVISORY COMMITTEES

TITLE X OF PUBLIC LAW 94–278 [1]

### TITLE X—APPOINTMENT OF ADVISORY COMMITTEES

SEC. 1001. [42 U.S.C. 217a–1] All appointments to advisory committees established to assist in implementing the Public Health Service Act, the Mental Retardation Facilities and Community Mental Health Centers Construction Act of 1963, and the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970, shall be made without regard to political affiliation.

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FEDERAL ADVISORY COMMITTEE ACT [2]

FINDINGS AND PURPOSES

SEC. 2. (a) The Congress finds that there are numerous committees, boards, commissions, councils, and similar groups which have been established to advise officers and agencies in the executive branch of the Federal Government and that they are frequently a useful and beneficial means of furnishing expert advice, ideas, and diverse opinions to the Federal Government.

(b) The Congress further finds and declares that—

(1) the need for many existing advisory committees has not been adequately reviewed;

(2) new advisory committees should be established only when they are determined to be essential and their number should be kept to the minimum necessary;

(3) advisory committees should be terminated when they are no longer carrying out the purposes for which they were established;

(4) standards and uniform procedures should govern the establishment, operation, administration, and duration of advisory committees;

(5) the Congress and the public should be kept informed with respect to the number, purpose, membership, activities, and cost of advisory committees; and

(6) the function of advisory committees should be advisory only, and that all matters under their consideration should be determined, in accordance with law, by the official, agency, or officer involved.

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[1] 42 U.S.C. 217a–1.

[2] Public Law 92–463 (5 U.S.C. App.).

DEFINITIONS

SEC. 3. For the purpose of this Act—

(1) The term "Director" means the Director of the Office of Management and Budget.

(2) The term "advisory committee" means any committee, board, commission, council, conference, panel, task force, or other similar group, or any subcommittee or other subgroup thereof (hereafter in this paragraph referred to as "committee"), which is—

(A) established by statute or reorganization plan, or

(B) established or utilized by the President, or

(C) established or utilized by one or more agencies,

in the interest of obtaining advice or recommendations for the President or one or more agencies or officers of the Federal Government, except that such term excludes (i) any committee that is composed wholly of full-time, or permanent part-time, officers or employees of the Federal Government, and (ii) any committee that is created by the National Academy of Sciences or the National Academy of Public Administration.

(3) The term "agency" has the same meaning as in section 551(1) of title 5, United States Code.

(4) The term "Presidential advisory committee" means an advisory committee which advises the President.

APPLICABILITY

SEC. 4. (a) The provisions of this Act or of any rule, order, or regulation promulgated under this Act shall apply to each advisory committee except to the extent that any Act of Congress establishing any such advisory committee specifically provides otherwise.

(b) Nothing in this Act shall be construed to apply to any advisory committee established or utilized by—

(1) the Central Intelligence Agency; or

(2) the Federal Reserve System.

(c) Nothing in this Act shall be construed to apply to any local civic group whose primary function is that of rendering a public service with respect to a Federal program, or any State or local committee, council, board, commission, or similar group established to advise or make recommendations to State or local officials or agencies.

RESPONSIBILITIES OF CONGRESSIONAL COMMITTEES

SEC. 5. (a) In the exercise of its legislative review function, each standing committee of the Senate and the House of Representatives shall make a continuing review of the activities of each advisory committee under its jurisdiction to determine whether such advisory committee should be abolished or merged with any other advisory committee, whether the responsibilities of such advisory committee should be revised, and whether such advisory committee performs a necessary function not already being performed. Each such standing committee shall take appropriate action to obtain the enactment of legislation necessary to carry out the purpose of this subsection.

(b) In considering legislation establishing, or authorizing the establishment of any advisory committee, each standing committee of the Senate and of the House of Representatives shall determine, and report such determination to the Senate or to the House of Representatives, as the case may be, whether the functions of the proposed advisory committee are being or could be performed by one or more agencies or by an advisory committee already in existence, or by enlarging the mandate of an existing advisory committee. Any such legislation shall—

(1) contain a clearly defined purpose for the advisory committee;

(2) require the membership of the advisory committee to be fairly balanced in terms of the points of view represented and the functions to be performed by the advisory committee;

(3) contain appropriate provisions to assure that the advice and recommendations of the advisory committee will not be inappropriately influenced by the appointing authority or by any special interest, but will instead be the result of the advisory committee's independent judgment;

(4) contain provisions dealing with authorization of appropriations, the date for submission of reports (if any), the duration of the advisory committee, and the publicaiton of reports and other materials, to the extent that the standing committee determines the provisions of section 10 of this Act to be inadequate; and

(5) contain provisions which will assure that the advisory committee will have adequate staff (either supplied by an agency or employed by it), will be provided adequate quarters, and will have funds available to meet its other necessary expenses.

(c) To the extent they are applicable, the guidelines set out in subsection (b) of this section shall be followed by the President, agency, heads, or other Federal officials in creating an advisory committee.

RESPONSIBILITIES OF THE PRESIDENT

SEC. 6. (a) The President may delegate responsibility for evaluating and taking action, where appropriate, with respect to all public recommendations made to him by Presidential advisory committees.

(b) Within one year after a Presidential advisory committee has submitted a public report to the President, the President or his delegate shall make a report to the Congress stating either his proposals for action or his reasons for inaction, with respect to the recommendations contained in the public report.

(c) The President shall, not later than December 31 of each year, make an annual report to the Congress on the activities, status, and changes in the composition of advisory committees in existence during the preceding fiscal year. The report shall contain the name of every advisory committee, the date of and authority for its creation, its termination date or the date it is to make a report, its functions, a reference to the reports it has submitted, a statement of whether it is an ad hoc or continuing body, the dates of its meetings, the names and occupations of its current members,

and the total estimated annual cost to the United States to fund, service, supply, and maintain such committee. Such report shall include a list of those advisory committees abolished by the President, and in the case of advisory committees established by statute, a list of those advisory committees which the President recommends be abolished together with his reasons therefor. The President shall exclude from this report any information which, in his judgment, should be withheld for reasons of national security, and he shall include in such report a statement that such information is excluded.

RESPONSIBILITIES OF THE DIRECTOR, OFFICE OF MANAGEMENT AND BUDGET

SEC. 7. (a) The Director shall establish and maintain within the Office of Management and Budget a Committee Management Secretariat, which shall be responsible for all matters relating to advisory committees.

(b) The Director shall, immediately after the enactment of this Act, institute a comprehensive review of the activities and responsibilities of each advisory committee to determine—

(1) whether such committee is carrying out its purpose;

(2) whether, consistent with the provisions of applicable statutes, the responsibilities assigned to it should be revised;

(3) whether it should be merged with other advisory committees; or

(4) whether it should be abolished.

The Director may from time to time request such information as he deems necessary to carry out his functions under this subsection. Upon the completion of the Director's review he shall make recommendations to the President and to either the agency head or the Congress with respect to action he believes should be taken. Thereafter, the Director shall carry out a similar review annually. Agency heads shall cooperate with the Director in making the required by this subsection.

(c) The Director shall prescribe administrative guidelines and management controls applicable to advisory committees, and, to the maximum extent feasible, provide advice, assistance, and guidance to advisory committees to improve their performance. In carrying out his functions under this subsection, the Director shall consider the recommendations of each agency head with respect to means of improving the performance of advisory committees whose duties are related to such agency.

(d)(1) The Director, after study and consultation with the Civil Service Commission, shall establish guidelines with respect to uniform fair rates of pay for comparable services of members, staffs, and consultants of advisory committees in a manner which gives appropriate recognition to the responsibilities and qualifications required and other relevant factors. Such regulations shall provide that—

(A) no member of any advisory committee or of the staff of any advisory committee shall receive compensation at a rate in excess of the rate specified for GS–18 of the General Schedule under section 5332 of title 5, United States Code;

(B) such members, while engaged in the performance of their duties away from their homes or regular places of business, may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5, United States Code, for persons employed intermittently in the Government service; and

(C) such members—

(i) who are blind or deaf or who otherwise qualify as handicapped individuals (within the meaning of section 501 of the Rehabilitation Act of 1973 (29 U.S.C. 794)), and

(ii) who do not otherwise qualify for assistance under section 3102 of title 5, United States Code, by reason of being an employee of an agency (within the meaning of section 3102(a)(1) of such title 5),

may be provided services pursuant to section 3102 of such title 5 while in performance of their advisory committee duties.

(2) Nothing in this subsection shall prevent—

(A) an individual who (without regard to his service with an advisory committee) is a full-time employee of the United States, or

(B) an individual who immediately before his service with an advisory committee was such an employee,

from receiving compensation at the rate at which he otherwise would be compensated (or was compensated) as a full-time employee of the United States.

(e) The Director shall include in budget recommendations a summary of the amounts he deems necessary for the expenses of advisory committees, including the expenses for publication of reports where appropriate.

RESPONSIBILITIES OF AGENCY HEADS

SEC. 8. (a) Each agency head shall establish uniform administrative guidelines and management controls for advisory committees established by that agency, which shall be consistent with directives of the Director under section 7 and section 10. Each agency shall maintain systematic information on the nature, functions, and operations of each advisory committee within its jurisdiction.

(b) The head of each agency which has an advisory committee shall designate an Advisory Committee Management Officer who shall—

(1) exercise control and supervision over the establishment, procedures, and accomplishments of advisory committees established by that agency;

(2) assemble and maintain the reports, records, and other papers of any such committee during its existence; and

(3) carry out, on behalf of that agency, the provisions of section 552 of title 5, United States Code, with respect to such reports, records, and other papers.

ESTABLISHMENT AND PURPOSE OF ADVISORY COMMITTEES

SEC. 9. (a) No advisory committee shall be established unless such establishment is—

(1) specifically authorized by statute or by the President; or

(2) determined as a matter of formal record, by the head of the agency involved after consultation with the Director, with timely notice published in the Federal Register, to be in the public interest in connection with the performance of duties imposed on that agency by law.

(b) Unless otherwise specifically provided by statute or Presidential directive, advisory committees shall be utilized solely for advisory functions. Determinations of action to be taken and policy to be expressed with respect to matters upon which an advisory committee reports or makes recommendations shall be made solely by the President or an officer of the Federal Government.

(c) No advisory committee shall meet or take any action until an advisory committee charter has been filed with (1) the Director, in the case of Presidential advisory committees, or (2) with the head of the agency to whom any advisory committee reports and with the standing committees of the Senate and of the House of Representatives having legislative jurisdiction of such agency. Such charter shall contain the following information:

(A) the committee's official designation;

(B) the committee's objectives and the scope of its activity;

(C) the period of time necessary for the committee to carry out its purposes;

(D) the agency or official to whom the committee reports;

(E) the agency responsible for providing the necessary support for the committee;

(F) a description of the duties for which the committee is responsible, and, if such duties are not solely advisory, a specification of the authority for such functions;

(G) the estimated annual operating costs in dollars and man-years for such committee;

(H) the estimated number and frequency of committee meetings;

(I) the committee's termination date, if less than two years from the date of the committee's establishment; and

(J) the date the charter is filed.

A copy of any such charter shall also be furnished to the Library of Congress.

ADVISORY COMMITTEE PROCEDURES

SEC. 10. (a)(1) Each advisory committee meeting shall be open to the public.

(2) Except when the President determines otherwise for reasons of national security, timely notice of each such meeting shall be published in the Federal Register, and the Director shall prescribe regulations to provide for other types of public notice to insure that all interested persons are notified of such meeting prior thereto.

(3) Interested persons shall be permitted to attend, appear before, or file statements with any advisory committee, subject to such reasonable rules or regulations as the Director may prescribe.

(b) Subject to section 552 of title 5, United States Code, the records, reports, transcripts, minutes, appendixes, working papers,

drafts, studies, agenda, or other documents which were made available to or prepared for or by each advisory committee shall be available for public inspection and copying at a single location in the offices of the advisory committee or the agency to which the advisory committee reports until the advisory committee ceases to exist.

(c) Detailed minutes of each meeting of each advisory committee shall be kept and shall contain a record of the persons present, a complete and accurate description of matters discussed and conclusions reached, and copies of all reports received, issued, or approved by the advisory committee. The accuracy of all minutes shall be certified to by the chairman of the advisory committee.

(d) Subsections (a)(1) and (a)(3) of this section shall not apply to any portion of an advisory committee meeting where the President, or the head of the agency to which the advisory committee reports, determines that such portion of such meeting may be closed to the public in accordance with subsection (c) of section 552b of title 5, United States Code. Any such determination shall be in writing and shall contain the reasons for such determination. If such a determination is made, the advisory committee shall issue a report at least annually setting forth a summary of its activities and such related matters as would be informative to the public consistent with the policy of section 552(b) of title 5, United States Code.

(e) There shall be designated an officer or employee of the Federal Government to chair or attend each meeting of each advisory committee. The officer or employee so designated is authorized whenever he determines it to be in the public interest, to adjourn any such meeting. No advisory committee shall conduct any meeting in the absence of that officer or employee.

(f) Advisory committees shall not hold any meetings except at the call of, or with the advance approval of, a designated officer or employee of the Federal Government, and in the case of advisory committees (other than Presidential advisory committees), with an agenda approved by such officer or employee.

AVAILABILITY OF TRANSCRIPTS

SEC. 11. (a) Except where prohibited by contractual agreements entered into prior to the effective date of this Act, agencies and advisory committees shall make available to any person, at actual cost of duplication, copies of transcripts of agency proceedings or advisory committee meetings.

(b) As used in this section "agency proceeding" means any proceeding as defined in section 551(12) of title 5, United States Code.

FISCAL AND ADMINISTRATIVE PROVISIONS

SEC. 12. (a) Each agency shall keep records as will fully disclose the disposition of any funds which may be at the disposal of its advisory committees and the nature and extent of their activities. The General Services Administration, or such other agency as the President may designate, shall maintain financial records with respect to Presidential advisory committees. The Comptroller General of the United States, or any of his authorized representatives,

shall have access, for the purpose of audit and examination, to any such records.

(b) Each agency shall be responsible for providing support services for each advisory committee established by or reporting to it unless the establishing authority provides otherwise. Where any such advisory committee reports to more than one agency, only one agency shall be responsible for support services at any one time. In the case of Presidential advisory committees, such services may be provided by the General Services Administration.

RESPONSIBILITIES OF LIBRARY OF CONGRESS

SEC. 13. Subject to section 552 of title 5, United States Code, the Director shall provide for the filing with the Library of Congress of at least eight copies of each report made by every advisory committee and, where appropriate, background papers prepared by consultants. The Librarian of Congress shall establish a depository for such reports and papers where they shall be available to public inspection and use.

TERMINATION OF ADVISORY COMMITTEES

SEC. 14. (a)(1) Each advisory committee which is in existence on the effective date of this Act shall terminate not later than the expiration of the two-year period following such effective date unless—

(A) in the case of an advisory committee established by the President or an officer of the Federal Government, such advisory committee is renewed by the President or that officer by a appropriate action prior to the expiration of such two-year period; or

(B) in the case of an advisory committee established by an Act of Congress, its duration is otherwise provided for by law.

(2) Each advisory committee established after such effective date shall terminate not later than the expiration of the two-year period beginning on the date of its establishment unless—

(A) in the case of an advisory committee established by the President or an officer of the Federal Government such advisory committee is renewed by the President or such officer by appropriate action prior to the end of such period; or

(B) in the case of an advisory committee established by an Act of Congress, its duration is otherwise provided for by law.

(b)(1) Upon the renewal of any advisory committee, such advisory committee shall file a charter in accordance with section 9(c).

(2) Any advisory committee established by an Act of Congress shall file a charter in accordance with such section upon the expiration of each successive two-year period following the date of enactment of the Act establishing such advisory committee.

(3) No advisory committee required under this subsection to file a charter shall take any action (other than preparation and filing of such charter) prior to the date on which such charter if filed.

(c) Any advisory committee which is renewed by the President or any officer of the Federal Government may be continued only for successive two-year periods by appropriate action taken by the

President or such officer prior to the date on which such advisory committee would otherwise terminate.

REQUIREMENTS RELATING TO THE NATIONAL ACADEMY OF SCIENCES AND THE NATIONAL ACADEMY OF PUBLIC ADMINISTRATION

SEC. 15. (a) IN GENERAL.—An agency may not use any advice or recommendation provided by the National Academy of Sciences or National Academy of Public Administration that was developed by use of a committee created by that academy under an agreement with an agency, unless—

(1) the committee was not subject to any actual management or control by an agency or an officer of the Federal Government;

(2) in the case of a committee created after the date of the enactment of the Federal Advisory Committee Act Amendments of 1997, the membership of the committee was appointed in accordance with the requirements described in subsection (b)(1); and

(3) in developing the advice or recommendation, the academy complied with—

(A) subsection (b)(2) through (6), in the case of any advice or recommendation provided by the National Academy of Sciences; or

(B) subsection (b)(2) and (5), in the case of any advice or recommendation provided by the National Academy of Public Administration.

(b) REQUIREMENTS.—The requirements referred to in subsection (a) are as follows:

(1) The Academy shall determine and provide public notice of the names and brief biographies of individuals that the Academy appoints or intends to appoint to serve on the committee. The Academy shall determine and provide a reasonable opportunity for the public to comment on such appointments before they are made or, if the Academy determines such prior comment is not practicable, in the period immediately following the appointments. The Academy shall make its best efforts to ensure that (A) no individual appointed to serve on the committee has a conflict of interest that is relevant to the functions to be performed, unless such conflict is promptly and publicly disclosed and the Academy determines that the conflict is unavoidable, (B) the committee membership is fairly balanced as determined by the Academy to be appropriate for the functions to be performed, and (C) the final report of the Academy will be the result of the Academy's independent judgment. The Academy shall require that individuals that the Academy appoints or intends to appoint to serve on the committee inform the Academy of the individual's conflicts of interest that are relevant to the functions to be performed.

(2) The Academy shall determine and provide public notice of committee meetings that will be open to the public.

(3) The Academy shall ensure that meetings of the committee to gather data from individuals who are not officials, agents, or employees of the Academy are open to the public, unless the Academy determines that a meeting would disclose

matters described in section 552(b) of title 5, United States Code. The Academy shall make available to the public, at reasonable charge if appropriate, written materials presented to the committee by individuals who are not officials, agents, or employees of the Academy, unless the Academy determines that making material available would disclose matters described in that section.

(4) The Academy shall make available to the public as soon as practicable, at reasonable charge if appropriate, a brief summary of any committee meeting that is not a data gathering meeting, unless the Academy determines that the summary would disclose matters described in section 552(b) of title 5, United States Code. The summary shall identify the committee members present, the topics discussed, materials made available to the committee, and such other matters that the Academy determines should be included.

(5) The Academy shall make available to the public its final report, at reasonable charge if appropriate, unless the Academy determines that the report would disclose matters described in section 552(b) of title 5, United States Code. If the Academy determines that the report would disclose matters described in that section, the Academy shall make public an abbreviated version of the report that does not disclose those matters.

(6) After publication of the final report, the Academy shall make publicly available the names of the principal reviewers who reviewed the report in draft form and who are not officials, agents, or employees of the Academy.

(c) REGULATIONS.—The Administrator of General Services may issue regulations implementing this section.

EFFECTIVE DATE

SEC. 16. Except as provided in section 7(b), this Act shall become effective upon the expiration of ninety days following the date of enactment.

# MISCELLANEOUS PROVISIONS RELATING TO ABORTIONS (ANTI–COERCION)

## MISCELLANEOUS PROVISIONS RELATING TO ABORTIONS (ANTI–COERCION)

SECTION 401 OF PUBLIC LAW 93–45 [1]

MISCELLANEOUS

SEC. 401. [42 U.S.C. 300a–7] (a) * * *

(b) The receipt of any grant, contract, loan, or loan guarantee under the Public Health Service Act, the Community Mental Health Centers Act, or the Development Disabilities Services and Facilities Construction Act by any individual or entity does not authorize any court or any public official or other public authority to require—

(1) such individual to perform or assist in the performance of any sterilization procedure or abortion if his performance or assistance in the performance of such procedure or abortion would be contrary to his religious beliefs or moral convictions; or

(2) such entity to—

(A) make its facilities available for the performance of any sterilization procedure or abortion if the performance of such procedure or abortion in such facilities is prohibited by the entity on the basis of religious beliefs or moral convictions, or

(B) provide any personnel for the performance or assistance in the performance of any sterilization procedure or abortion if the performance or assistance in the performance of such procedure or abortion by such personnel would be contrary to the religious beliefs or moral convictions of such personnel.

(c)(1) No entity which receives a grant, contract, loan, or loan guarantee under the Public Health Service Act, the Community Mental Health Centers Act, or the Development Disabilities Services and Facilities Construction Act after the date of enactment of this Act may—

(A) discriminate in the employment, promotion, or termination of employment of any physician or other health care personnel, or

(B) discriminate in the extension of staff or other privileges to any physician or other health care personnel,

because he performed or assisted in the performance of a lawful sterilization procedure or abortion, because he refused to perform or assist in the performance of such a procedure or abortion on the grounds that his performance or assistance in the performance of the procedure or abortion would be contrary to his religious beliefs

[1] 42 U.S.C. 300a–7.

or moral convictions or because of his religious beliefs or moral convictions respecting sterilization procedures or abortions.

(2) No entity which receives after the date of enactment of this paragraph a grant or contract for biomedical or behavorial research under any program administered by the Secretary of Health, Education, and Welfare may—

(A) discriminate in the employment, promotion, or termination of employment of any physician or other health care personnel, or

(B) discriminate in the extension of staff or other privileges to any physician or other health care personnel,

because he performed or assisted in the performance of any lawful health service or research activity, because he refused to perform or assist in the performance of any such service or activity on the grounds that his performance or assistance in the performance of such service or activity would be contrary to his religious beliefs or moral convictions, or because of his religious beliefs or moral convictions respecting any such service or activity.

(d) No individual shall be required to perform or assist in the performance of any part of a health service program or research activity funded in whole or in part under a program administered by the Secretary of Health, Education, and Welfare if his performance or assistance in the performance of such part of such program or activity would be contrary to his religious beliefs or moral convictions.

(e) No entity which receives, after the date of enactment of this paragraph, any grant, contract, loan, loan guarantee, or interest subsidy under the Public Health Service Act, the Community Mental Health Centers Act, or the Developmental Disabilities Assistance and Bill of Rights Act of 2000 may deny admission or otherwise discriminate against any applicant (including applicants for internships and residencies) for training or study because of the applicant's reluctance, or willingness, to counsel, suggest, recommend, assist, or in any way participate in the performance of abortions or sterilizations contrary to or consistent with the applicant's religious beliefs or moral convictions.

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SECTION 205 OF PUBLIC LAW 94–63 [1]

SEC. 205. [42 U.S.C. 300a–8] Any—

(1) officer or employee of the United States,

(2) officer or employee of any State, political subdivision of a State, or any other entity, which administers or supervises the administration of any program receiving Federal financial assistance, or

(3) person who receives, under any program receiving Federal financial assistance, compensation for services,

who coerces or endeavors to coerce any person to undergo an abortion or sterilization procedure by threatening such person with the loss of, or disqualification for the receipt of, any benefit or service under a program receiving Federal financial assistance shall be

[1] 42 U.S.C. 300a–8.

fined not more than $1,000 or imprisoned for not more than one year, or both.

# MISCELLANEOUS PROVISIONS RELATING TO ORPHAN DRUGS

## MISCELLANEOUS PROVISIONS RELATING TO ORPHAN DRUGS

Section 5 OF THE ORPHAN DRUG ACT [1]

GRANTS AND CONTRACTS FOR DEVELOPMENT OF DRUGS FOR RARE DISEASES AND CONDITIONS

SEC. 5. [21 U.S.C. 360ee] (a) The Secretary may make grants to and enter into contracts with public and private entities and individuals to assist in (1) defraying the cost of qualified testing expenses incurred in connection with the development of drugs for rare diseases and conditions, (2) defraying the costs of developing medical devices for rare diseases or conditions, and (3) defraying the costs of developing medical foods for rare diseases or conditions.

(b) For purposes of subsection (a):

(1) The term "qualified testing" means—

(A) human clinical testing—

(i) which is carried out under an exemption for a drug for a rare disease or condition under section 505(i) of the Federal Food, Drug, and Cosmetic Act (or regulations issued under such section); and

(ii) which occurs after the date such drug is designated under section 526 of such Act and before the date on which an application with respect to such drug is submitted under section 505(b) of such Act or under section 351 of the Public Health Service Act; and

(B) preclinical testing involving a drug for a rare disease or condition which occurs after the date such drug is designated under section 526 of such Act and before the date on which an application with respect to such drug is submitted under section 505(b) of such Act or under section 351 of the Public Health Service Act.

(2) The term "rare disease or condition" means (1) in the case of a drug, any disease or condition which (A) affects less than 200,000 persons in the United States, or (B) affects more than 200,000 in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for such disease or condition will be recovered from sales in the United States of such drug, (2) in the case of a medical device, any disease or condition that occurs so infrequently in the United States that there is no reasonable expectation that a medical device for such disease or condition will be developed without assistance under subsection (a), and (3) in the case of a medical food, any dis-

[1] Public Law 97–414; 21 U.S.C. 360ee.

ease or condition that occurs so infrequently in the United States that there is no reasonable expectation that a medical food for such disease or condition will be developed without assistance under subsection (a). Determinations under the preceding sentence with respect to any drug shall be made on the basis of the facts and circumstances as of the date the request for designation of the drug under section 526 of the Federal Food, Drug, and Cosmetic Act is made.

(3) The term "medical food" means a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.

(c) For grants and contracts under subsection (a) there are authorized to be appropriated $10,000,000 for fiscal year 1988, $12,000,000 for fiscal year 1989, $14,000,000 for fiscal year 1990.

# MISCELLANEOUS PROVISIONS RELATING TO OUTCOMES OF HEALTH CARE

# MISCELLANEOUS PROVISIONS RELATING TO OUTCOMES OF HEALTH CARE

## SECTION 1142 OF THE SOCIAL SECURITY ACT [1]

### RESEARCH ON OUTCOMES OF HEALTH CARE SERVICES AND PROCEDURES

SEC. 1142. (a) ESTABLISHMENT OF PROGRAM.—

(1) IN GENERAL.—The Secretary, acting through the Administrator for Health Care Policy and Research [2], shall—

(A) conduct and support research with respect to the outcomes, effectiveness, and appropriateness of health care services and procedures in order to identify the manner in which diseases, disorders, and other health conditions can most effectively and appropriately be prevented, diagnosed, treated, and managed clinically; and

(B) assure that the needs and priorities of the program under title XVIII are appropriately reflected in the development and periodic review and updating (through the process set forth in section 913 of the Public Health Service Act) of treatment-specific or condition-specific practice guidelines for clinical treatments and conditions in forms appropriate for use in clinical practice, for use in educational programs, and for use in reviewing quality and appropriateness of medical care.

(2) EVALUATIONS OF ALTERNATIVE SERVICES AND PROCEDURES.—In carrying out paragraph (1), the Secretary shall conduct or support evaluations of the comparative effects, on health and functional capacity, of alternative services and procedures utilized in preventing, diagnosing, treating, and clinically managing diseases, disorders, and other health conditions.

(3) INITIAL GUIDELINES.—

(A) In carrying out paragraph (1)(B) of this subsection, and section 912(d) of the Public Health Service Act, the Secretary shall, by not later than January 1, 1991, assure the development of an initial set of the guidelines specified in paragraph (1)(B) that shall include not less than 3 clinical treatments or conditions that—

(i)(I) account for a significant portion of expenditures under title XVIII; and

(II) have a significant variation in the frequency or the type of treatment provided; or

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[1] 42 U.S.C. 1320b–12.

[2] Pursuant to section 2(b)(2) of Public Law 106–129 (113 Stat. 1670), the reference shall be considered to be a reference to the Director of the Agency for Healthcare Research and Quality.

(ii) otherwise meet the needs and priorities of the program under title XVIII, as set forth under subsection (b)(3).

(B)(i) The Secretary shall provide for the use of guidelines developed under subparagrah (A) to improve the quality, effectiveness, and appropriateness of care provided under title XVIII. The Secretary shall determine the impact of such use on the quality, appropriateness, effectiveness, and cost of medical care provided under such title and shall report to the Congress on such determination by not later than January 1, 1993.

(ii) For the purpose of carrying out clause (i), the Secretary shall expend, from the amounts specified in clause (iii), $1,000,000 for fiscal year 1990 and $1,500,000 for each of the fiscal years 1991 and 1992.

(iii) For each fiscal year, for purposes of expenditures required in clause (ii)—

(I) 60 percent of an amount equal to the expenditure involved is appropriated from the Federal Hospital Insurance Trust Fund (established under section 1817); and

(II) 40 percent of an amount equal to the expenditure involved is appropriated from the Federal Supplementary Medical Insurance Trust Fund (established under section 1841).

(b) PRIORITIES.—

(1) IN GENERAL.—The Secretary shall establish priorities with respect to the diseases, disorders, and other health conditions for which research and evaluations are to be conducted or supported under subsection (a). In establishing such priorities, the Secretary shall, with respect to a disease, disorder, or other health condition, consider the extent to which—

(A) improved methods of prevention, diagnosis, treatment, and clinical management can benefit a significant number of individuals;

(B) there is significant variation among physicians in the particular services and procedures utilized in making diagnoses and providing treatments or there is significant variation in the outcomes of health care services or procedures due to different patterns of diagnosis or treatment;

(C) the services and procedures utilized for diagnosis and treatment result in relatively substantial expenditures; and

(D) the data necessary for such evaluations are readily available or can readily be developed.

(2) PRELIMINARY ASSESSMENTS.—For the purpose of establishing priorities under paragraph (1), the Secretary may, with respect to services and procedures utilized in preventing, diagnosing, treating, and clinically managing diseases, disorders, and other health conditions, conduct or support assessments of the extent to which—

(A) rates of utilization vary among similar populations for particular diseases, disorders, and other health conditions;

(B) uncertainties exist on the effect of utilizing a particular service or procedure; or

(C) inappropriate services and procedures are provided.

(3) RELATIONSHIP WITH MEDICARE PROGRAM.—In establishing priorities under paragraph (1) for research and evaluation, and under section 914(a) of the Public Health Service Act for the agenda under such section, the Secretary shall assure that such priorities appropriately reflect the needs and priorities of the program under title XVIII, as set forth by the Administrator of the Health Care Financing Administration.

(c) METHODOLOGIES AND CRITERIA FOR EVALUATIONS.—For the purpose of facilitating research under subsection (a), the Secretary shall—

(1) conduct and support research with respect to the improvement of methodologies and criteria utilized in conducting research with respect to outcomes of health care services and procedures;

(2) conduct and support reviews and evaluations of existing research findings with respect to such treatment or conditions;

(3) conduct and support reviews and evaluations of the existing methodologies that use large data bases in conducting such research and shall develop new research methodologies, including data-based methods of advancing knowledge and methodologies that measure clinical and functional status of patients, with respect to such research;

(4) provide grants and contracts to research centers, and contracts to other entities, to conduct such research on such treatment or conditions, including research on the appropriate use of prescription drugs;

(5) conduct and support research and demonstrations on the use of claims data and data on clinical and functional status of patients in determining the outcomes, effectiveness, and appropriateness of such treatment; and

(6) conduct and support supplementation of existing data bases, including the collection of new information, to enhance data bases for research purposes, and the design and development of new data bases that would be used in outcomes and effectiveness research.

(d) STANDARDS FOR DATA BASES.—In carrying out this section, the Secretary shall develop—

(1) uniform definitions of data to be collected and used in describing a patient's clinical and functional status;

(2) common reporting formats and linkages for such data; and

(3) standards to assure the security, confidentiality, accuracy, and appropriate maintenance of such data.

(e) DISSEMINATION OF RESEARCH FINDINGS AND GUIDELINES.—

(1) IN GENERAL.—The Secretary shall provide for the dissemination of the findings of research and the guidelines described in subsection (a), and for the education of providers and others in the application of such research findings and guidelines.

(2) COOPERATIVE EDUCATIONAL ACTIVITIES.—In disseminating findings and guidelines under paragraph (1), and in providing for education under such paragraph, the Secretary shall work with professional associations, medical specialty and subspecialty organizations, and other relevant groups to identify and implement effective means to educate physicians, other providers, consumers, and others in using such findings and guidelines, including training for physician managers within provider organizations.

(f) EVALUATIONS.—The Secretary shall conduct and support evaluations of the activities carried out under this section to determine the extent to which such activities have had an effect on the practices of physicians in providing medical treatment, the delivery of health care, and the outcomes of health care services and procedures.

(g) RESEARCH WITH RESPECT TO DISSEMINATION.—The Secretary may conduct or support research with respect to improving methods of disseminating information on the effectiveness and appropriateness of health care services and procedures.

(h) REPORT TO CONGRESS.—Not later than February 1 of each of the years 1991 and 1992, and of each second year thereafter, the Secretary shall report to the Congress on the progress of the activities under this section during the preceding fiscal year (or preceding 2 fiscal years, as appropriate), including the impact of such activities on medical care (particularly medical care for individuals receiving benefits under title XVIII).

(i) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—There are authorized to be appropriated to carry out this section—

(A) $50,000,000 for fiscal year 1990;
(B) $75,000,000 for fiscal year 1991;
(C) $110,000,000 for fiscal year 1992;
(D) $148,000,000 for fiscal year 1993; and
(E) $185,000,000 for fiscal year 1994.

(2) SPECIFICATIONS.—For the purpose of carrying out this section, for each of the fiscal years 1990 through 1992 an amount equal to two-thirds of the amounts authorized to be appropriated under paragraph (1), and for each of the fiscal years 1993 and 1994 an amount equal to 70 percent of such amounts, are to be appropriated in the following proportions from the following trust funds:

(A) 60 percent from the Federal Hospital Insurance Trust Fund (established under section 1817).

(B) 40 percent from the Federal Supplementary Medical Insurance Trust Fund (established under section 1841).

(3) ALLOCATIONS.—

(A) For each fiscal year, of the amounts transferred or otherwise appropriated to carry out this section, the Secretary shall reserve appropriate amounts for each of the purposes specified in clauses (i) through (iv) of subparagraph (B).

(B) The purposes referred to in subparagraph (A) are—

(i) the development of guidelines, standards, performance measures, and review criteria;

(ii) research and evaluation;

(iii) data-base standards and development; and

(iv) education and information dissemination.

# MISCELLANEOUS PROVISIONS RELATING TO WAIVER REGARDING TITLE VI OF PUBLIC HEALTH SERVICE ACT

## MISCELLANEOUS PROVISIONS RELATING TO WAIVER REGARDING TITLE VI OF PUBLIC HEALTH SERVICE ACT

SUBTITLE D OF TITLE VII OF PUBLIC LAW 100–607

# Subtitle D—Waiver of Liability for Certain Sale of Facility Under Program of Construction and Modernization of Medical Facilities

**SEC. 731. ESTABLISHMENT OF WAIVER AUTHORITY.**

(a) IN GENERAL.—If, pursuant to subsection (b) of section 732, the Secretary of Health and Human Services makes a certification of compliance with the conditions described in subsection (a) of such section, section 609 of the Public Health Service Act (42 U.S.C. 291i) shall not, with respect to the transferor and transferee described in subsection (b), apply to the sale on November 26, 1986, of the medical facility—

(1) located in Blanding, in the State of Utah;

(2) known, prior to such date, as San Juan County Nursing Home; and

(3) with respect to which funds were received during the years 1967 through 1970 pursuant to title VI of the Public Health Service Act (42 U.S.C. 291 et seq.).

(b) DESCRIPTION OF PARTIES TO SALE.—In the sale described in subsection (a), the transferor is San Juan County, a political subdivision of the State of Utah, and the transferee is Auburn Manor Holding Corporation, a corporation under the laws of the State of California.

**SEC. 732. CONDITIONS OF WAIVER.**

(a) IN GENERAL.—The conditions referred to in section 731(a) are that, not later than the expiration of the 12-month period beginning on the date of the enactment of this Act [1]—

(1)(A) San Juan County establish an irrevocable trust with a res of $321,057 for the sole purpose of satisfying, with respect to the medical facility described in section 731(a), the obligation of San Juan County under regulations issued under clause (2) of section 603(e) of the Public Health Service Act (42 U.S.C. 291c(e));

(B) except to the extent inconsistent with this title [2], San Juan [3] establish such trust in accordance with regulations

[1] Enacted November 4, 1988.
[2] So in law. Probably should be "subtitle".
[3] So in law. Probably should be "San Juan County". See section 734(2).

issued under section 609(d)(1)(A) of such Act for trusts established pursuant to such section; and

(C) San Juan County agree—

(i) except to the extent inconsistent with this title [1], to administer such trust in accordance with regulations issued under such section 609(d)(1)(A) of such Act; and

(ii) with respect to the obligation described in subparagraph (A)—

(I) to carry out such obligation at the medical facility known as San Juan County Hospital and located in Monticello, in the State of Utah;

(II) to ensure that uncompensated services provided at any location other than such medical facility will not be reimbursed from the trust established pursuant to subparagraph (A); and

(III) not to seek contribution from Auburn Corporation toward the satisfaction of such obligation; and

(2) Auburn Corporation agree—

(A) to satisfy, with respect to the medical facility described in section 731(a), the obligation of San Juan County under regulations issued under clause (1) of section 603(e) of the Public Health Service Act;

(B) to satisfy such obligation at the medical facility described in section 731(a); and

(C) not to seek contribution from San Juan County toward the satisfaction of such obligation.

(b) DETERMINATION AND CERTIFICATION OF SATISFACTION OF CONDITIONS.—The Secretary shall make a determination of whether the conditions described in subsection (a) are satisfied by San Juan County and Auburn Corporation within the period described in such subsection. If the Secretary makes a determination that the conditions have been satisfied, the Secretary shall certify to the Congress the fact of such determination.

**SEC. 733. MONITORING OF COMPLIANCE WITH AGREEMENTS AND EFFECT OF FAILURE TO COMPLY.**

(a) MONITORING.—The Secretary shall determine the extent to which San Juan County and Auburn Corporation are carrying out their respective duties under the agreements made pursuant to the conditions described in section 732(a).

(b) FAILURE TO COMPLY.—

(1) If the conditions described in section 732(a) are not satisfied by San Juan County and Auburn Corporation within the period described in such section, the Secretary shall ensure that proceedings under section 609 of the Public Health Service Act (42 U.S.C. 291i) with respect to the sale described in section 731(a) are commenced or continued against San Juan County or Auburn Corporation, or both, as determined by the Secretary.

(2) If San Juan County or Auburn Corporation fails to carry out its duties under the agreements made pursuant to the conditions described in section 732(a), the Secretary shall

[1] So in law. Probably should be "subtitle".

ensure that proceedings described in paragraph (1) are commenced or continued against San Juan County or Auburn Corporation, respectively.

**SEC. 734. DEFINITIONS.**

For purposes of this subtitle:

(1) The term "Auburn Corporation" means Auburn Manor Holding Corporation, a corporation under the laws of the State of California.

(2) The term "San Juan County" means San Juan County, a political subdivision of the State of Utah.

(3) The term "Secretary" means the Secretary of Health and Human Services.

# MISCELLANEOUS PROVISIONS RELATING TO CONSTRUCTION OF CERTAIN BIOMEDICAL RESEARCH FACILITIES

# MISCELLANEOUS PROVISIONS RELATING TO CONSTRUCTION OF CERTAIN BIOMEDICAL RESEARCH FACILITIES

PUBLIC LAW 101–190 [1]

**SECTION 1. AUTHORITY FOR GRANT FOR CONSTRUCTION OF BIOMEDICAL RESEARCH FACILITIES.**

(a) IN GENERAL.—Of the aggregate amounts appropriated for fiscal years 1990 and 1991 to carry out the purposes of title IV of the Public Health Service Act through the National Institutes of Health, the Secretary of Health and Human Services, acting through the Director of the National Institutes of Health, may reserve not more than $25,000,000 for making a grant to a public or nonprofit private entity for constructing facilities for the purpose of the development and breeding of specialized strains of mice (including inbred and mutant mice) for use in biomedical research.

(b) COMPETITIVE AWARD PROCESS.—The grant under subsection (a) may be awarded only on a competitive basis after review in accordance with section 4(a).

**SEC. 2. TWENTY-YEAR OBLIGATION WITH RESPECT TO BREEDING OF SPECIALIZED MICE FOR BIOMEDICAL RESEARCH.**

(a) IN GENERAL.—The Secretary may not make a grant under section 1 unless, subject to subsection (b), the applicant for the contract [2] agrees that—

(1) throughout the 20-year period beginning 90-days after the date of the completion of the construction of facilities pursuant to the grant, the facilities will be utilized only for the purpose described in section 1(a);

(2) during such period, the applicant will, to the extent practicable, develop and breed such mice in numbers sufficient to assist in meeting the need for such mice in biomedical research conducted or supported by the Secretary; and

(3) during such period, the applicant will, upon the request of the Secretary, sell such mice to the Secretary for purposes of such research at a price reasonably related to the cost of the production of the mice.

(b) TRANSFER OF OBLIGATION.—

(1) IN GENERAL.—With respect to the obligation under subsection (a), the grantee under section 1 (and any transferee or purchaser under this subsection) may—

(A) transfer the obligation to a public or nonprofit private entity if the proposed transferee has entered into an agreement with the Secretary to assume the obligation; and

[1] Public Law 101–190 is codified at 42 U.S.C. 289e note. The Public Law was amended by section 4(a) of Public Law 101–374.

[2] So in law. Probably should be "grant".

(B) convey its interest in the facilities involved if the proposed purchaser of the interest is a public or nonprofit entity that has entered into an agreement with the Secretary to assume the obligation.

(2) TRANSFER PRIOR TO COMPLETION OF CONSTRUCTION.—If, for purposes of paragraph (1), a transfer or conveyance is proposed to be made before the completion of the construction of facilities pursuant to section 1, the Secretary may not authorize the transfer or conveyance unless the agreement involved provides that the transferee or purchaser will assume all remaining responsibilities under any agreements made pursuant to this Act by the grantee under such section and the Federal Government.

(3) TERMINATION OF OBLIGATION.—If, for purposes of paragraphs (1) and (2), a transfer or conveyance is made in accordance with such paragraphs, the obligation pursuant to subsection (a), and all other responsibilities pursuant to this Act, of the transferor involved shall terminate.

(c) REQUIREMENT OF STATUS AS PUBLIC OR NONPROFIT PRIVATE ENTITY.—The Secretary may not enter into any agreement under subsection (a) or (b) unless the agreement provides that the obligation involved includes the requirement that the obligation may be satisfied only by a public or nonprofit private entity.

(d) ASSURANCES OF SUFFICIENT FINANCIAL RESOURCES.—

(1) ORIGINAL CONTRACTOR [1].—The Secretary may not make a grant under section 1 unless the applicant for the contract provides assurances satisfactory to the Secretary that, throughout the 20-year period described in subsection (a), the applicant will have access to financial resources sufficient to comply with the agreement under such subsection.

(2) TRANSFEREES AND PURCHASERS.—The Secretary may not approve a transfer or conveyance under subsection (b) unless the transferee or purchaser provides assurances satisfactory to the Secretary that, throughout the remaining portion of the 20-year period described in subsection (a), the transferee or purchaser will have access to financial resources sufficient to comply with its obligation pursuant to such subsection.

**SEC. 3. REQUIREMENT OF MATCHING FUNDS.**

(a) IN GENERAL.—The Secretary may not make a grant under section 1 unless the applicant for the contract [2] agrees, with respect to the costs to be incurred by the applicant in carrying out the purpose described in such section, to make available (directly or through donations from public or private entities) contributions toward such costs in an amount equal to $1 for each $3 of Federal funds provided pursuant to the contract [2] under section 1.

(b) DETERMINATION OF AMOUNT OF CONTRIBUTION.—Contributions required in subsection (a) may be in cash or in kind, fairly evaluated, including existing plant and equipment or services

[1] Section 4(a) of Public Law 101–374 evinced the clear intent to strike the word "contractor" and insert "grantee", but the amendatory instructions connot be executed because the instruction used the incorrect typeface.

[2] Section 4(a) of Public Law 101–374 provided that section 3(a) is amended by striking "the contract" and inserting "the grant". The amendment cannot be executed because the amendment does not specify which of the two instances of such term is the subject of the amendment.

throughout the 20-year period described in section 2(a)(1) (and including such specialized strains of mice as the Secretary may request for purposes of biomedical research). Amounts provided by any agency of the Federal Government other than the Department of Health and Human Services, and services assisted or subsidized by any such agency, shall be included in the amount of such contributions.

**SEC. 4. ADDITIONAL REQUIREMENTS.**

(a) SUBMISSION AND APPROVAL OF CONSTRUCTION PLAN.—

(1) IN GENERAL.—The Secretary may not make a grant under section 1 unless the applicant for the grant submits to the Secretary a plan for the construction of facilities pursuant to such section and unless the Secretary approves the plan. The Secretary may not approve such a plan unless the plan has been recommended for approval by the panel convened under paragraph (2)(A).

(2) EXPERT PANEL FOR ADVISING SECRETARY WITH RESPECT TO PLAN.—

(A) The Secretary shall convene a panel of appropriately qualified individuals for the purpose of providing architectural, financial, and scientific advice to the Secretary regarding appropriate standards and specifications for the construction, financing, and use of facilities pursuant to section 1. The panel may not approve a plan submitted under paragraph (1) unless the panel determines that amounts provided under section 1 will not, during the twenty-year period described in section 2(a), be expended to increase significantly, relative to April 1989, the sale of mice other than mutant and inbred strains of mice necessary for the conduct of biomedical research.

(B) Members of the panel convened under paragraph (1) who are officers or employees of the United States may not receive compensation for service on the panel in addition to the compensation otherwise received for duties carried out as such officers or employees. Other members of such panel shall receive compensation for each day (including traveltime) engaged in carrying out the duties of the panel. Such compensation may not be in an amount in excess of the maximum rate of basic pay payable for GS–18 of the General Schedule.

(b) SITE OF CONSTRUCTION.—The Secretary may not make a grant under section 1 unless—

(1) the applicant for the grant provides to the Secretary a description of the site for the construction of facilities pursuant to such section; and

(2) the Secretary determines that title to the site is vested in the applicant or that the applicant has a sufficient possessory interest in such site for the twenty-year period described in section 2(a).

(c) REQUIREMENT OF APPLICATION.—The Secretary may not make a grant under section 1 unless—

(1) an application for the grant is submitted to the Secretary;

(2) the application contains the agreements required in this Act and 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 Act.

**SEC. 5. FAILURE TO COMPLY WITH AGREEMENTS.**

(a) REPAYMENT OF PAYMENTS.—

(1) IN GENERAL.—The Secretary may, subject to subsection (c), require the grantee under section 1 to repay any payments received under such section by the grantee that the Secretary determines were not expended by the grantee in accordance with the agreements required to be contained in the application submitted by the grantee pursuant to section 4(c).

(2) OFFSET AGAINST CURRENT PAYMENTS.—If a grantee under section 1 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 under such section to the grantee.

(b) WITHHOLDING OF PAYMENTS.—

(1) IN GENERAL.—The Secretary may, subject to subsection (c), withhold payments due under section 1 if the Secretary determines that the grantee under such section is not expending payments received under such section in accordance with the agreements required to be contained in the application submitted by the grantee pursuant to section 4(c).

(2) TERMINATION OF WITHHOLDING.—The Secretary shall cease withholding payments under paragraph (1) if the Secretary determines that there are reasonable assurances that the grantee under section 1 will expend amounts received under such section in accordance with the agreements referred to in such paragraph.

(3) EFFECT OF MINOR NONCOMPLIANCE.—The Secretary may not withhold funds under paragraph (1) from the grantee under section 1 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 grantee under section 1 an opportunity for a hearing conducted within the State in which facilities are constructed pursuant to such section.

**SEC. 6. RECOVERY PROCEEDINGS FOR VIOLATION OF REQUIREMENT WITH RESPECT TO MINIMUM PERIOD OF BREEDING OF SPECIALIZED MICE.**

(a) RIGHT OF RECOVERY.—If the grantee under section 1, or any transferee or purchaser under section 2, violates its obligation under such section (including any violation under subsection (c) of such section), the United States shall be entitled to recover an amount equal to the sum of—

(1) an amount determined in accordance with paragraph (1)(A) of subsection (b); and

(2) an amount determined in accordance with paragraph (2)(A) of such subsection.

(b) DETERMINATION OF AMOUNTS.—

(1) FEDERAL PERCENTAGE OF FAIR MARKET VALUE.—

(A) The amount referred to in paragraph (1) of subsection (a) is the product of—

(i) an amount equal to the fair market value, during the period in which recovery is sought under subsection (a), of the facilities constructed pursuant to section 1, as determined in accordance with subparagraph (B); and

(ii) a percentage equal to the quotient of—

(I) the total amounts provided by the Federal Government for the construction of such facilities; divided by

(II) the total costs of the construction of such facilities.

(B) For purposes of subparagraph (A)(i), fair market value shall be determined through—

(i) an agreement entered into by the United States and the entity from whom the United States is seeking recovery under subsection (a); or

(ii) an action brought in the district court of the United States for the district in which the facilities involved are located.

(2) INTEREST.—

(A) The amount referred to in paragraph (2) of subsection (a) is an amount representing interest on the amount determined under paragraph (1). Such interest shall accrue during the period described in subparagraph (B) and shall accrue at a rate determined by the Secretary on the basis of 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—

(i) beginning on the date of the violation of the obligation under section 2, or if the entity involved provides notice to the Secretary of the violation not later than 10 days after the date of the violation, beginning on the expiration of the 180-day period beginning on the date that the notice is received by the Secretary; and

(ii) ending on the date on which the United States collects the amount determined under paragraph (1).

(c) WAIVER OF RECOVERY RIGHTS.—The Secretary may waive, in whole or in part, the right of the United States to recover amounts under this section for good cause shown, as determined by the Secretary.

(d) CLARIFICATION WITH RESPECT TO LIEN ON FACILITIES.—The right of recovery of the United States under subsection (a) shall not constitute a lien on the facilities involved with respect to which such recovery is sought.

**SEC. 7.[1] DEFINITION.**

For purposes of this Act, the term "Secretary" means the Secretary of Health and Human Services.

[1] Public Law 101–190 contains a section 8. The section does not appear in this compilation because the section was amendatory in nature.

# MISCELLANEOUS PROVISIONS RELATING TO AGING RESEARCH

## MISCELLANEOUS PROVISIONS RELATING TO AGING RESEARCH

TITLE III OF PUBLIC LAW 101–557

**(References in brackets [ ] are to title 42, United States Code)**

# TITLE III—TASK FORCE ON AGING RESEARCH

**SEC. 301. [242q] ESTABLISHMENT AND DUTIES.**

(a) ESTABLISHMENT.—The Secretary of Health and Human Services shall establish a Task Force on Aging Research.

(b) DUTIES.—With respect to aging research (as defined in section 305), the Task Force each fiscal year shall—

(1) make recommendations to the Secretary specifying the particular projects of research, or the particular categories of research, that should be conducted or supported by the Secretary;

(2) of the projects specified under paragraph (1), make recommendations to the Secretary of the projects that should be given priority in the provision of funds; and

(3) make recommendations to the Secretary of the amount of funds that should be appropriated for such research.

(c) PROVISION OF INFORMATION TO THE PUBLIC.—The Task Force may make available to health professionals, and to other members of the public, information regarding the research described in subsection (b).

**SEC. 302. [242q–1] MEMBERSHIP.**

(a) COMPOSITION.—The Task Force shall be composed of—

(1) the Assistant Secretary for Health;

(2) the Surgeon General of the Public Health Service;

(3) the Assistant Secretary for Planning and Evaluation;

(4) the Director of the National Institute on Aging, and the Directors of such other agencies of the National Institutes of Health as the Secretary determines to be appropriate;

(5) the Commissioner of the Administration on Aging;

(6) the Commissioner of Food and Drugs;

(7) the Chief Medical Director of the Department of Veterans Affairs;

(8) the Administrator of the the [1] Alcohol, Drug Abuse, and Mental Health Administration; [2]

[1] So in law.
[2] Now the Substance Abuse and Mental Health Services Administration.

(9) the Administrator of the Health Care Financing Administration;

(10) the Commissioner of Social Security;

(11) the Administrator for Health Care Policy and Research [1];

(12) two Members of the House of Representatives appointed by the Speaker of the House in consultation with the Minority Leader, and two members of the Senate appointed by the Majority Leader in consultation with the Minority Leader, not more than one of whom from each body shall be members of the same political party; and

(13) three members of the general public, to be appointed by the Secretary, that shall include one representative each from—

(A) a nonprofit group representing older Americans;

(B) a private voluntary health organization concerned with the health problems affecting older Americans; and

(C) a nonprofit organization concerned with research related to the health and independence of older Americans.

(b) CHAIR.—The Secretary, acting through either the Assistant Secretary for Health or the Director of the National Institute on Aging, shall serve as the Chair of the Task Force.

(c) QUORUM.—A majority of the members of the Task Force shall constitute a quorum, and a lesser number may hold hearings.

(d) MEETINGS.—The Task Force shall meet periodically at the call of the Chair, but in no event less than twice each year.

(e) COMPENSATION AND EXPENSES.—

(1) COMPENSATION.—Members of the Task Force who are not regular full-time employees of the United States Government shall, while attending meetings and conferences of the Task Force or otherwise engaged in the business of the Task Force (including traveltime), be entitled to receive compensation at a rate fixed by the Secretary, but not exceeding the rate specified at the time of such service under GS–18 of the General Schedules established under section 5332 of title 5, United States Code.

(2) EXPENSES.—While away from their homes or regular places of business on the business of the Task Force, members of such Task Force may be allowed travel expenses, including per diem in lieu of subsistence, as is authorized under section 5703 of title 5, United States Code, for persons employed intermittently in the Government service.

**SEC. 303. [242q–2] ADMINISTRATIVE STAFF AND SUPPORT.**

The Secretary, acting through either the Assistant Secretary for Health or the Director of the National Institute on Aging, shall appoint an Executive Secretary for the Task Force and shall provide the Task Force with such administrative staff and support as may be necessary to enable the Task Force to carry out subsections (b) and (c) of section 301.

[1] Section 2 of Public Law 106–129 (113 Stat. 1653) designated such Agency as the Agency for Healthcare Research and Quality.

**SEC. 304. [242q–3] REPORTS.**

(a) IN GENERAL.—Not later than 1 year after the date of the enactment of this Act [1], and annually thereafter, the Task Force shall prepare and 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 providing the recommendations required in section 301(b).

(b) AVAILABILITY TO PUBLIC.—The Task Force may make available to the public copies of the reports required in subsection (a).

**SEC. 305. [242q–4] DEFINITIONS.**

For purposes of this title:

(1) AGING RESEARCH.—

(A) The term "aging research" means research on the aging process and on the diagnosis and treatment of diseases, disorders, and complications related to aging, including menopause. Such 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.

(B) For purposes of subparagraph (A), 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.

(2) SECRETARY.—The term "Secretary" means the Secretary of Health and Human Services.

(3) TASK FORCE.—The term "Task Force" means the Task Force on Aging Research established under section 301(a).

**SEC. 306. [242q–5] AUTHORIZATION OF APPROPRIATIONS.**

For the purpose of carrying out this title, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1991 through 1993.

[1] Enacted November 15, 1990.

# MISCELLANEOUS PROVISIONS RELATING TO CONSTRUCTION OF CERTAIN MEDICAL FACILITY

## MISCELLANEOUS PROVISIONS RELATING TO CONSTRUCTION OF CERTAIN MEDICAL FACILITY

SECTION 6 OF PUBLIC LAW 101–590

**SEC. 6. GRANT REGARDING MEDICAL FACILITIES.**

(a) IN GENERAL.—The Secretary of Health and Human Services may make a grant to the George Washington University Hospital, a nonprofit private hospital located in the District of Columbia, for the purpose of constructing or modernizing a medical facility of such Hospital.

(b) REQUIREMENT OF MATCHING FUNDS.—

(1) IN GENERAL.—The Secretary may not make a grant under subsection (a) unless the applicant for the grant agrees, with respect to the costs of 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 that is 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 has been provided for purposes of paragraph (1), the Secretary may not include any amounts provided by the Federal Government.

(c) OBLIGATIONS REGARDING FREE CARE AND COMMUNITY SERVICE.—The Secretary may not make a grant under subsection (a) unless the applicant for the grant agrees that clauses (i) and (ii) of section 1621(b)(1)(K) of the Public Health Service Act (and regulations issued under such clauses), and section 1622 of such Act (and regulations issued under such section), will apply with respect to the medical facility constructed or modernized with the grant to the same extent and in the same manner as such sections and regulations apply with respect to medical facilties constructed or modernized with funds that have been paid under title XVI of such Act.

(d) DEFINITION.—For purposes of this Act[1], the term "Secretary" means the Secretary of Health and Human Services.

(e) FUNDING.—

(1) AUTHORIZATION OF APPROPRIATIONS.—

(A) Subject to subparagraph (B), there is authorized to be appropriated an aggregate $50,000,000 for the fiscal years 1992 through 1995[2].

(B) The authorization of appropriations established in subparagraph (A) is effective only with respect to appropriations made from allocations under section 302(b) of the Congressional Budget Act of 1974—

[1] So in law. Probably should be "section".

[2] So in law. The provision probably should specify the purpose for which the authorization of appropriations is provided.

(i) for the Subcommittee on the District of Columbia of the Committee on Appropriations of the House of Representatives, in the case of any bill, resolution, or amendment considered in the House; and

(ii) for the Subcommittee on District of Columbia of the Committee on Appropriations of the Senate, in the case of any bill, resolution, or amendment considered in the Senate.

(2) AMOUNT OF GRANT.—Subject to the extent of amounts made available in appropriations Act, the amount of a grant under subsection (a) shall be $50,000,000.

# MISCELLANEOUS PROVISIONS RELATING TO FETAL TISSUE TRANSPLANTATION RESEARCH

## MISCELLANEOUS PROVISIONS RELATING TO FETAL TISSUE TRANSPLANTATION RESEARCH

SECTION 113 OF PUBLIC LAW 103–43 [1]

**SEC. 113. NULLIFICATION OF MORATORIUM.**

(a) IN GENERAL.—Except as provided in subsection (c), no official of the executive branch may impose a policy that the Department of Health and Human Services is prohibited from conducting or supporting any research on the transplantation of human fetal tissue for therapeutic purposes. Such research shall be carried out in accordance with section 498A of the Public Health Service Act (as added by section 111 of this Act), without regard to any such policy that may have been in effect prior to the date of the enactment of this Act.

(b) PROHIBITION AGAINST WITHHOLDING OF FUNDS IN CASES OF TECHNICAL AND SCIENTIFIC MERIT.—

(1) IN GENERAL.—Subject to subsection (b)(2) of section 492A of the Public Health Service Act (as added by section 101 of this Act), in the case of any proposal for research on the transplantation of human fetal tissue for therapeutic purposes, the Secretary of Health and Human Services may not withhold funds for the research if—

(A) the research has been approved for purposes of subsection (a) of such section 492A;

(B) the research will be carried out in accordance with section 498A of such Act (as added by section 111 of this Act); and

(C) there are reasonable assurances that the research will not utilize any human fetal tissue that has been obtained in violation of section 498B(a) of such Act (as added by section 112 of this Act).

(2) STANDING APPROVAL REGARDING ETHICAL STATUS.—In the case of any proposal for research on the transplantation of human fetal tissue for therapeutic purposes, the issuance in December 1988 of the Report of the Human Fetal Tissue Transplantation Research Panel shall be deemed to be a report—

(A) issued by an ethics advisory board pursuant to section 492A(b)(5)(B)(ii) of the Public Health Service Act (as added by section 101 of this Act); and

(B) finding, on a basis that is neither arbitrary nor capricious, that the nature of the research is such that it is not unethical to conduct or support the research.

(c) AUTHORITY FOR WITHHOLDING FUNDS FROM RESEARCH.—In the case of any research on the transplantation of human fetal tis-

[1] 42 U.S.C. 289g–1 note.

sue for therapeutic purposes, the Secretary of Health and Human Services may withhold funds for the research if any of the conditions specified in any of subparagraphs (A) through (C) of subsection (b)(1) are not met with respect to the research.

(d) DEFINITION.—For purposes of this section, the term "human fetal tissue" has the meaning given such term in section 498A(f) of the Public Health Service Act (as added by section 111 of this Act).

# REPORTS REGARDING AUTHORITIES UNDER THE PROJECT BIOSHIELD ACT OF 2004

## REPORTS REGARDING AUTHORITIES UNDER THE PROJECT BIOSHIELD ACT OF 2004

SECTION 5 OF PUBLIC LAW 108–276 [1]

**SEC. 5. REPORTS REGARDING AUTHORITIES UNDER THIS ACT.**

(a) SECRETARY OF HEALTH AND HUMAN SERVICES.—

(1) ANNUAL REPORTS ON PARTICULAR EXERCISES OF AUTHORITY.—

(A) RELEVANT AUTHORITIES.—The Secretary of Health and Human Services (referred to in this subsection as the "Secretary") shall submit reports in accordance with subparagraph (B) regarding the exercise of authority under the following provisions of law:

(i) With respect to section 319F–1 of the Public Health Service Act (as added by section 2 of this Act):

(I) Subsection (b)(1) (relating to increased simplified acquisition threshold).

(II) Subsection (b)(2) (relating to procedures other than full and open competition).

(III) Subsection (c) (relating to expedited peer review procedures).

(ii) With respect to section 319F–2 of the Public Health Service Act (as added by section 3 of this Act):

(I) Subsection (c)(7)(C)(iii) (relating to simplified acquisition procedures).

(II) Subsection (c)(7)(C)(iv) (relating to procedures other than full and open competition).

(III) Subsection (c)(7)(C)(v) (relating to premium provision in multiple-award contracts).

(iii) With respect to section 564 of the Federal Food, Drug, and Cosmetic Act (as added by section 4 of this Act):

(I) Subsection (a)(1) (relating to emergency uses of certain drugs and devices).

(II) Subsection (b)(1) (relating to a declaration of an emergency).

(III) Subsection (e) (relating to conditions on authorization).

(B) CONTENTS OF REPORTS.—The Secretary shall annually submit to the designated congressional committees a report that summarizes—

(i) the particular actions that were taken under the authorities specified in subparagraph (A), including, as applicable, the identification of the threat

[1] 42 U.S.C. 247d–6c.

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; and

(iv) whether, with respect to each procurement that is approved by the President under section 319F–2(c)(6) of the Public Health Service Act (as added by section 3 of this Act), a contract was entered into within one year after such approval by the President.

(2) ANNUAL SUMMARIES REGARDING CERTAIN ACTIVITY.—The Secretary shall annually submit to the designated congressional committees a report that summarizes the activity undertaken pursuant to the following authorities under section 319F–1 of the Public Health Service Act (as added by section 2 of this Act):

(A) Subsection (b)(3) (relating to increased micropurchase threshold).

(B) Subsection (d) (relating to authority for personal services contracts).

(C) Subsection (e) (relating to streamlined personnel authority).

With respect to subparagraph (B), the report shall include a provision specifying, for the one-year period for which the report is submitted, the number of persons who were paid amounts greater than $100,000 and the number of persons who were paid amounts between $50,000 and $100,000.

(3) REPORT ON ADDITIONAL BARRIERS TO PROCUREMENT OF SECURITY COUNTERMEASURES.—Not later than one year after the date of the enactment of this Act, the Secretary, in consultation with the Secretary of Homeland Security, shall report to the designated congressional committees any potential barriers to the procurement of security countermeasures that have not been addressed by this Act.

(b) GENERAL ACCOUNTING OFFICE REVIEW [1].—

(1) IN GENERAL.—Four years after the date of the enactment of this Act, the Comptroller General of the United States shall initiate a study—

(A)(i) to review the Secretary of Health and Human Services' utilization of the authorities granted under this Act with respect to simplified acquisition procedures, procedures other than full and open competition, increased

[1] Now the Government Accountability Office. See section 8 of Public Law 108–271 (118 Stat. 814).

micropurchase thresholds, personal services contracts, streamlined personnel authority, and the purchase of security countermeasures under the special reserve fund; and

(ii) to make recommendations to improve the utilization or effectiveness of such authorities in the future;

(B)(i) to review and assess the adequacy of the internal controls instituted by such Secretary with respect to such authorities, where required by this Act; and

(ii) to make recommendations to improve the effectiveness of such controls;

(C)(i) to review such Secretary's utilization of the authority granted under this Act to authorize an emergency use of a biomedical countermeasure, including the means by which the Secretary determines whether and under what conditions any such authorizations should be granted and the benefits and adverse impacts, if any, resulting from the use of such authority; and

(ii) to make recommendations to improve the utilization or effectiveness of such authority and to enhance protection of the public health;

(D) to identify any purchases or procurements that would not have been made or would have been significantly delayed except for the authorities described in subparagraph (A)(i); and

(E)(i) to determine whether and to what extent activities undertaken pursuant to the biomedical countermeasure research and development authorities established in this Act have enhanced the development of biomedical countermeasures affecting national security; and

(ii) to make recommendations to improve the ability of the Secretary to carry out these activities in the future.

(2) ADDITIONAL PROVISIONS REGARDING DETERMINATION ON DEVELOPMENT OF BIOMEDICAL COUNTERMEASURES AFFECTING NATIONAL SECURITY.—In the report under paragraph (1), the determination under subparagraph (E) of such paragraph shall include—

(A) the Comptroller General's assessment of the current availability of countermeasures to address threats identified by the Secretary of Homeland Security;

(B) the Comptroller General's assessment of the extent to which programs and activities under this Act will reduce any gap between the threat and the availability of countermeasures to an acceptable level of risk; and

(C)(i) the Comptroller General's assessment of threats to national security that are posed by technology that will enable, during the 10-year period beginning on the date of the enactment of this Act, the development of antibiotic resistant, mutated, or bioengineered strains of biological agents; and

(ii) recommendations on short-term and long-term governmental strategies for addressing such threats, including recommendations for Federal policies regarding research priorities, the development of countermeasures, and investments in technology.

(3) REPORT.—A report providing the results of the study under paragraph (1) shall be submitted to the designated congressional committees not later than five years after the date of the enactment of this Act.

(c) REPORT REGARDING BIOCONTAINMENT FACILITIES.—Not later than 120 days after the date of the enactment of this Act, the Secretary of Homeland Security and the Secretary of Health and Human Services shall jointly report to the designated congressional committees whether there is a lack of adequate large-scale biocontainment facilities necessary for the testing of security countermeasures in accordance with Food and Drug Administration requirements.

(d) DESIGNATED CONGRESSIONAL COMMITTEES.—For purposes of this section, the term "designated congressional committees" means the following committees of the Congress:

(1) In the House of Representatives: the Committee on Energy and Commerce, the Committee on Appropriations, the Committee on Government Reform, and the Select Committee on Homeland Security (or any successor to the Select Committee).

(2) In the Senate: the appropriate committees.

# CERTAIN REORGANIZATION PLANS

## REORGANIZATION PLAN NO. 1 OF 1953

### DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SECTION 1. *Creation of Department; Secretary.*—There is hereby established an executive department, which shall be known as the Department of Health, Education, and Welfare (hereafter in this reorganization plan referred to as the Department). There shall be at the head of the Department a Secretary of Health, Education, and Welfare (hereafter in this reorganization plan referred to as the Secretary), who shall be appointed by the President by and with the advise and consent of the Senate, and who shall receive compensation at the rate now or hereafter prescribed by law for the heads of executive departments. The Department shall be administered under the supervision and direction of the Secretary.

SEC. 2. Under Secretary and Assistant Secretaries.—There shall be in the Department an Under Secretary of Health, Education, and Welfare and five [1] Assistant Secretaries of Health, Education, and Welfare, each of whom shall be appointed by the President by and with the advice and consent of the Senate, shall perform such functions as the Secretary may prescribe, and shall receive compensation at the rate now or hereafter provided by law for under secretaries and assistant secretaries, respectively, of executive departments. The Under Secretary (or, during the absence or disability of the Under Secretary or in the event of a vacancy in the office of Under Secretary, an Assistant Secretary determined according to such order as the Secretary shall prescribe) shall act as Secretary during the absence or disability of the Secretary or in the event of a vacancy in the office of Secretary.

SEC. 4. [2] *Commissioner of Social Security.*—There shall be in the Department a Commissioner of Social Security who shall be appointed by the President by and with the advice and consent of the Senate, shall perform such functions concerning social security and public welfare as the Secretary may prescribe, and shall receive compensation at the rate now or hereafter fixed by law for grade GS–18 of the general schedule established by the Classification Act of 1949, as amended.

SEC. 5. *Transfers to the Department.*—All functions of the Federal Security Administrator are hereby transferred to the Secretary. All agencies of the Federal Security Agency, together with their respective functions, personnel, property, records, and unexpended balances of appropriations, allocations, and other funds (available or to be made available), and all other functions, personnel, property, records, and unexpended balances of appropriations, allocations, and other funds (available or to be made avail-

[1] Section 1(b) of Public Law 89–234 provided for an additional Assistant Secretary.
[2] Section 3 was repealed by section 4 of Public Law 89–115.

able) of the Federal Security Agency are hereby transferred to the Department.

SEC. 6. *Performance of functions of the Secretary.*—The Secretary may from time to time make such provisions as the Secretary deems appropriate authorizing the performance of any of the functions of the Secretary by any other officer, or by any agency or employee, of the Department.

SEC. 7. *Administrative services.*—In the interest of economy and efficiency the Secretary may from time to time establish central administrative services in the fields of procurement, budgeting, accounting, personnel, library, legal, and other services and activities common to the several agencies of the Department; and the Secretary may effect such transfers within the Department of the personnel employed, the property and records used or held, and the funds available for use in connection with such administrative-service activities as the Secretary may deem necessary for the conduct of any services so established: *Provided,* That no professional or substantive functions vested by law in any officer shall be removed from the jurisdiction of such officer under this section.

SEC. 8. *Abolitions.*—The Federal Security Agency (exclusive of the agencies thereof transferred by sec. 5 of this reorganization plan), the offices of Federal Security Administrator and Assistant Federal Security Administrator created by Reorganization Plan No. 1 (53 Stat. 1423), the two offices of assistant heads of the Federal Security Agency created by Reorganization Plan No. 2 of 1946 (60 Stat. 1095), and the office of Commissioner for Social Security created by section 701 of the Social Security Act, as amended (64 Stat. 558), are hereby abolished. The Secretary shall make such provisions as may be necessary in order to wind up any outstanding affairs of the Agency and the offices abolished by this section which are not otherwise provided for in this reorganization plan.

SEC. 9. *Interim provisions.*—The President may authorize the persons who immediately prior to the time this reorganization plan takes effect occupy the offices of Federal Security Administration, Assistant Security Administrator, assistant heads of the Federal Security Agency, the Commissioner for Social Security to act as Secretary, Under Secretary, and Assistant Secretaries of Health, Education, and Welfare and as Commissioner of Social Security, respectively, until those offices are filled by appointment in the manner provided by sections 1, 2, and 4 of this reorganization plan, but not for a period of more than 60 days. While so acting, such persons shall receive compensation at the rates provided by this reorganization plan for the offices the functions of which they perform.

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## REORGANIZATION PLAN NO. 3 OF 1966

### PUBLIC HEALTH SERVICE

SECTION 1. *Transfer of functions.*—(a) Except as otherwise provided in subsection (b) of this section, there are hereby transferred to the Secretary of Health, Education, and Welfare (hereinafter referred to as the Secretary) all functions of the Public Health Service, of the Surgeon General of the Public Health Service, and of all

other officers and employees of the Public Health Service, and all functions of all agencies of or in the Public Health Service.

(b) This section shall not apply to the functions vested by law in any advisory council, board, or committee of or in the Public Health Service which is established by law or is required by law to be established.

SEC. 2. *Performances of transferred functions.*—The Secretary may from time to time make such provisions as he shall deem appropriate authorizing the performance of any of the functions transferred to him by the provisions of this reorganization plan by any officer, employee, or agency of the Public Health Service or of the Department of Health, Education, and Welfare.

SEC. 3. *Abolitions.*—(a) The following agencies of the Public Health Service are hereby abolished:

(1) The Bureau of Medical Services, including the office of Chief of the Bureau of Medical Services.

(2) The Bureau of State Services, including the office of Chief of the Bureau of State Services.

(3) The agency designated as the National Institutes of Health (42 U.S.C. 203), including the office of Director of the National Institutes of Health (42 U.S.C. 206(b)) but excluding the several research Institutes in the agency designated as the National Institutes of Health.

(4) The agency designated as the Office of the Surgeon General (42 U.S.C. 203(1)), together with the office held by the Deputy Surgeon General (42 U.S.C. 206(a)).

(b) The Secretary shall make such provisions as he shall deem necessary respecting the winding up of any outstanding affairs of the agencies abolished by the provisions of this section.

SEC. 4. *Incidental transfers.*—As he may deem necessary in order to carry out the provisions of this reorganization plan, the Secretary may from time to time effect transfers within the Department of Health, Education, and Welfare of any of the records, property, personnel and unexpected balances (available or to be made available) of appropriations, allocations, and other funds of the Department which relate to functions affected by this reorganization plan.

# TABLES

## MAJOR AMENDMENTS SINCE 1944 TO THE PUBLIC HEALTH SERVICE ACT AND SELECTED OTHER ACTS INCLUDED IN THE COMPILATION

| | Title | Public law | Purpose of the Act |
|---|---|---|---|
| 1. | National Mental Health Act | Public Law 79–487, July 3, 1946 (60 Stat. 421), H.R. 4512, H. Rept. 1445, S. Rept. 1353. | To amend the PHS Act to provide for research relating to psychiatric disorders and to aid in the development of more effective methods of prevention, diagnosis, and treatment of such disorders, and for other purposes. |
| 2. | Hospital Survey and Construction Act. | Public Law 79–725, Aug. 13, 1946 (60 Stat. 1040), S. 191, S. Rept. 674, H. Rept. 2519. | To amend the PHS Act to authorize grants to the States for surveying their hospitals and public health centers and for planning construction of additional facilities, and to authorize grants to assist in such construction. |
| 3. | National Heart Act | Public Law 80–655, June 16, 1948 (62 Stat. 464), S. 2215, S. Rept. 1298, H. Rept. 2144. | To amend the PHS Act to support research and training in diseases of the heart and circulation, and to aid the States in the development of community programs for the control of these diseases, and for other purposes. |
| 4. | National Dental Research Act | Public Law 80–755, June 24, 1948 (62 Stat. 598), H.R. 6726 (S. 176), H. Rept. 2158. | To amend the PHS Act to provide for, foster, and aid in coordinating research relating to dental diseases and conditions, and for other purposes. |
| 5. | Hospital Survey and Construction Amendments of 1949. | Public Law 81–380, Oct. 25, 1949 (63 Stat. 898), S. 614 (H.R. 5903), S. Rept. 790. | To amend the Hospital Survey and Construction Act (title VI of the PHS Act), to extend its duration and provide greater financial assistance in the construction of hospitals, and for other purposes. |
| 6. | (No authorized title—Act authorizes establishment of research institutes; also adds sec. 208(g) to PHS Act.). | Public Law 81–692, Aug. 15, 1950 (64 Stat. 443), S. 2591 (H.R. 3943) S. Rept. 1102, C. Rept. (H. Rept.) 2750. | To amend the PHS Act to support research and training in matters relating to arthritis and rheumatism, multiple sclerosis, cerebral palsy, epilepsy, poliomyelitis, blindness, leprosy, and other diseases. |
| 7. | Medical Facilities Survey and Construction Act of 1954. | Public Law 83–482, July 12, 1954 (68 Stat. 461), H.R. 8149, H. Rept. 1268, S. Rept. 1612. | To amend the hospital survey and construction provisions of the PHS Act to provide assistance to the States for surveying the need for diagnosis or treatment centers, for hospitals for the chronically ill and impaired, for rehabilitation facilities, and for nursing homes, and to provide assistance in the construction of such facilities through grants to public and nonprofit agencies, and for other purposes. |
| 8. | National Health Survey Act | Public Law 84–652, July 3, 1956 (70 Stat. 489), S. 3076, S. Rept. 1718, H. Rept. 2108. | To provide for a continuing survey and special studies of sickness and disability in the United States, and for periodic reports of the results thereof, and for other purposes. |
| 9. | Alaska Mental Health Enabling Act | Public Law 84–830, July 28, 1956 (70 Stat. 709), H.R. 6376, H. Rept. 1399, S. Rept. 2053, C. Rept. 2735. | To confer upon Alaska autonomy in the field of mental health, transfer from the Federal Government to the Territory the fiscal and functional responsibilities for the hospitalization of committed mental patients, and for other purposes. (Includes PHS grants to Alaska for mental health program.) |
| 10. | Health Research Facilities Act of 1956 | Public Law 85–835, July 30, 1956 (70 Stat. 717), S. 849, S. Rept. 869, H. Rept. 2184, C. Rept. 2773. | To amend the PHS Act so as to provide for grants-in-aid to non-Federal public and nonprofit institutions for the constructing and equipping of facilities for research in the sciences related to health. |
| 11. | National Library of Medicine Act | Public Law 84–941, Aug. 3, 1956 (70 Stat. 960), S. 3430, S. Rept. 2071, H. Rept. 2826. | To amend title III of the PHS Act, and for other purposes. (Establishes in the PHS the National Library of Medicine.) |
| 12. | Health Amendments Act of 1956 | Public Law 84–911, Aug. 2, 1956 (70 Stat. 923), S. 3958, S. Rept. 2070, H. Rept. 2569. | To improve the health of the people by assisting in increasing the number of adequately trained professional and practical nurses and professional public health personnel assisting in the development of improved methods of care and treatment in the field of mental health, and for other purposes. |

MAJOR AMENDMENTS SINCE 1944 TO THE PUBLIC HEALTH SERVICE ACT AND SELECTED OTHER ACTS INCLUDED IN THE COMPILATION—Continued

| | Title | Public law | Purpose of the Act |
|---|---|---|---|
| 13. | Public Health Service Commissioned Corps Personnel Act of 1960. | Public Law 86–415, Apr. 8, 1960 (74 Stat. 32), S. 2220, S. Rept. 535, H. Rept. 1091. | To strengthen the Commissioned Corps of the Public Health Service through revision and extension of some of the provisions relating to retirement, appointment of personnel, and other related personnel matters, and for other purposes. |
| 14. | International Health Research Act of 1960 .. | Public Law 86–610, July 12, 1960 (74 Stat. 364), S.J. Res. 41 (H.J. Res. 649), S. Rept. 243. | * * * to provide for international cooperation in health research, research training, and research planning, and for other purposes. (Note: By error there was left in the purpose clause the phrase ''to establish a National Institute for International Health and Medical Research'' although as enacted, the law carried no such provision. We have used asterisks in lieu of that phrase to prevent confusion.) |
| 15. | Community Health Services and Facilities Act of 1961. | Public Law 87–395, Oct. 5, 1961 (75 Stat. 824), H.R. 4998, H. Rept. 599, S. Rept. 845, C. Rept. 1209. | To assist in expanding and improving community facilities and services for the health care of aged and other persons, and for other purposes. |
| 16. | (No authorized title—provides for PHS grants for family health clinics for migratory workers.). | Public Law 87–692, Sept. 25, 1962 (76 Stat. 592), S. 1130 (H.R. 12365), S. Rept. 699. | To amend title III of the PHS Act to authorize grants for family clinics for domestic agricultural migratory workers, and for other purposes. |
| 17. | (No authorized title—provides for establishment of an Institute of Child Health and Human Development and an Institute of General Medical Sciences; extends for 3 years research facilities construction program of title VII, PHS Act.). | Public Law 87–838, Oct. 17, 1962 (76 Stat. 1072), H.R. 11099, H. Rept. 1969, S. Rept. 2174. | To amend the PHS Act to provide for the establishment of an Institute of Child Health and Human Development, to extend for 3 additional years the authorization for grants for the construction of facilities for research in the sciences related to health, and for other purposes. |
| 18. | Vaccination Assistance Act of 1962 ..... | Public Law 87–868, Oct. 23, 1962 (76 Stat. 1155), H.R. 10541, H. Rept. 1835, S. Rept. 1907. | To assist States and communities to carry out intensive vaccination programs designed to protect their populations, particularly all preschool children, against poliomyelitis, diphtheria, whooping cough, and tetanus. |
| 19. | Health Professions Educational Assistance Act of 1963. | Public Law 88–129, Sept. 24, 1963 (77 Stat. 164), H.R. 12, H. Rept. 109, S. Rept. 485. | To increase the opportunities for training of physicians, dentists, and professional public health personnel, and for other purposes. |
| 20. | Sec. 101 of the Mental Retardation Facilities and Community Health Centers Construction Act of 1963. | Public Law 88–164, Oct. 31, 1963 (77 Stat. 282), S. 1576, S. Rept. 180, H. Rept. 694, C. Rept. 862. | To provide centers for research on mental retardation and related aspects of human development. |
| 21. | Hospital and Medical Facilities Amendments of 1964. | Public Law 88–443, Aug. 18, 1964 (78 Stat. 447), H.R. 10041, H. Rept. 1340, S. Rept. 1274. | To improve the public health through revising, consolidating, and improving the hospital and other medical facilities provisions of the Public Health Service Act. |
| 22. | Nurse Training Act of 1964 ..... | Public Law 88–581, Sept. 4, 1964 (78 Stat. 908), H.R. 11241, H. Rept. 1549, S. Rept. 1378. | To amend the Public Health Service Act to increase the opportunities for training professional nursing personnel, and for other purposes. |
| 23. | Community Health Services Extension Amendments of 1965. | Public Law 89–109, Aug. 5, 1965 (79 Stat. 435), S. 510 (H.R. 2986), S. Rept. 117, C. Rept. 676. | To extend and otherwise amend certain expiring provisions of the Public Health Service Act relating to community health services, and for other purposes. |
| 24. | Health Research Facilities Amendments of 1965. | Public Law 89–115, Aug. 9, 1965 (79 Stat. 448), H.R. 2984, H. Rept. 247, S. Rept. 367, C. Rept. 677. | To amend the Public Health Service Act provisions for construction of health research facilities by extending the expiration date thereof and providing increased support for the program, to authorize additional Assistant Secretaries in the Department of Health, Education, and Welfare, and for other purposes. |
| 25. | Heart Disease, Cancer, and Stroke Amendments of 1965. | Public Law 89–239, Oct. 6, 1965 (79 Stat. 926), S. 596 (H.R. 3140), S. Rept. 368. | To assist in combating heart disease, cancer, stroke, and related diseases. |
| 26. | Health Professions Educational Assistance Amendments of 1965. | Public Law 89–290, Oct. 22, 1965 (79 Stat. 1052), H.R. 3141, H. Rept. 781, S. Rept. 789. | To improve the educational quality of schools of medicine, dentistry, and osteopathy, to authorize grants under that Act to such schools for the awarding of scholarships to needy students and to extend expiring provisions of that Act for student loans and for aid in construction of teaching facilities for students in such schools and schools for other health professions, and for other purposes. |
| 27. | Medical Library Assistance Act of 1965. ..... | Public Law 89–291, Oct. 22, 1965 (79 Stat. 1059), S. 597 (H.R. 3142), S. Rept. 756. | To provide for a program of grants to assist in meeting the need for adequate medical library services and facilities. |

MAJOR AMENDMENTS SINCE 1944 TO THE PUBLIC HEALTH SERVICE ACT AND SELECTED OTHER ACTS INCLUDED IN THE COMPILATION—Continued

| | Title | Public law | Purpose of the Act |
|---|---|---|---|
| 28. | Comprehensive Health Planning and Public Health Services Amendments of 1966. | Public Law 89–749, Nov. 3, 1966, S. 3008 (H.R. 18231), S. Rept. 1665. | To amend the Public Health Service Act to promote and assist in the extension and improvement of comprehensive health planning and public health services, to provide for a more effective use of available Federal funds for such planning and services, and for other purposes. |
| 29. | Allied Health Professions Personnel Training Act of 1966. | Public Law 89–751, Nov. 3, 1966, H.R. 13196, H. Rept. 1628, S. Rept. 1722. | To amend the Public Health Service Act to increase the opportunities for training of medical technologists and personnel in other allied health professions, to improve the educational quality of the schools training such allied health professions personnel, and to strengthen and improve the existing student loan programs for medical, osteopathic, dental, podiatry, pharmacy, optometric, and nursing students, and for other purposes. |
| 30. | Partnership for Health Amendments of 1967 | Public Law 90–174, Dec. 5, 1976, H.R. 6418, H. Rept. 538, S. Rept. 724, C. Rept. 974. | To amend the Public Health Service Act to extend and expand the authorizations for grants for comprehensive health planning and services, to broaden and improve the authorization for research and demonstrations relating to the delivery of health services, to improve the performance of clinical laboratories, and to authorize cooperative activities between the Public Health Service hospitals and community facilities, and for other purposes. |
| 31. | Health Manpower Act of 1968. ..... | Public Law 90–490, August 16, 1968, S. 3095, S. Rept. 1307, H. Rept. 1634 (acc. H.R. 15757). | To amend the Public Health Service Act to extend and improve the programs relating to the training of nursing and other health professions and allied health professions personnel, the program relating to student aid for such personnel, and the program relating to health research facilities, and for other purposes. |
| 32. | Health Services Amendments of 1968. ..... | Public Law 90–574, Oct. 15, 1968, H.R. 15758, H. Rept. 1536, S. Rept. 1454, C. Rept. 1924. | To amend the Public Health Service Act so as to extend and improve the provisions relating to regional medical programs, to extend the authorization of grants for health of migratory agricultural workers, to provide for specialized facilities for alcoholics and narcotic addicts, and for other purposes. |
| . | (No short title—extends authorizations for grants to schools of Public Health). | Public Law 91–208, Mar. 12, 1970, S. 2809 (H.R. 14790), S. Rept. 586, C. Rept. 855. | To amend the Public Health Service Act so as to extend for an additional period the authority to make formula grants to schools of public health, project grants for graduate training in public health and traineeships for professional public health personnel. |
| 34. | (No short title—extends the Migrant Health Act). | Public Law 91–209, Mar. 12, 1970, H.R. 14733, H. Rept. 711, S. Rept. 618, C. Rept. 853. | To amend the Public Health Service Act to extend the program of assistance for health services for domestic migrant agricultural workers, and for other purposes. |
| 35. | Community Mental Health Centers Amendments of 1970. | Public Law 91–211, Mar. 13, 1970, S. 2523, S. Rept. 583, H. Rept. 91–735 (acc. 14986), C. Rept. 856. | To amend the Community Mental Health Centers Act to extend and improve the program of assistance under that Act for community mental health centers and facilities for the treatment of alcoholics and narcotic addicts, to establish programs for mental health of children, and for other purposes. |
| 36. | Medical Library Assistance Extension Act of 1970. | Public Law 91–212, Mar. 13, 1970, H.R. 11702, H. Rept. 313, S. Rept. 480, C. Rept. 854. | To amend the Public Health Service Act to improve and extend the provisions relating to assistance to medical libraries and related instrumentalities, and for other purposes. |
| 37. | Medical Facilities Construction and Modernization Amendments of 1970. | Public Law 91–296, June 30, 1970, H.R. 11102, H. Rept. 262, S. Rept. 657, C. Rept. 1167. | To amend the Public Health Service Act to revise extend, and improve the program established by title VI of such Act, and for other purposes. |
| 38. | Communicable Disease Control Amendments of 1970. | Public Law 91–464, Oct. 16, 1970, S. 2264, S. Rept 478, H. Rept. 1114 (acc. H.R. 11913), C. Rept. 1462. | To amend the Public Health Service Act to provide authorization for grants for communicable disease control and vaccination assistance. |

MAJOR AMENDMENTS SINCE 1944 TO THE PUBLIC HEALTH SERVICE ACT AND SELECTED OTHER ACTS INCLUDED IN THE COMPILATION—Continued

| | Title | Public law | Purpose of the Act |
|---|---|---|---|
| 39. | Comprehensive Drug Abuse Prevention and Control Act of 1970. | Public Law 91–513, Oct. 27, 1970, H.R. 18583, H. Rept. 1444 (pts. 1 and 2) S. Rept. 613, C. Rept. 1603. | To amend the Public Health Service Act and other laws to provide increased research into, and prevention of, drug abuse and drug dependence; to provide for treatment and rehabilitation of drug abusers and drug dependent persons; and to strengthen existing law enforcement authority in the field of drug abuse. |
| 40. | (No short title—amends titles III and IX of the Public Health Service Act). | Public Law 91–515, Oct. 30, 1970, H.R. 17570, H. Rept. 1297, S. Rept. 1090, C. Rept. 1590. | To amend titles III and IX of the Public Health Service Act so as to revise, extend, and improve the programs of research, investigation, education, training, and demonstration authorized thereunder, and for other purposes. |
| 41. | Developmental Disabilities Services and Facilities Construction Amendments of 1970. | Public Law 91–517, Oct. 30, 1970, S. 2846, S. Rept. 757, H. Rept. 1277 (acc. H.R. 14237) C. Rept. 1589. | To amend the Mental Retardation Facilities and Community Mental Health Centers Construction Act of 1968 to assist the States in developing a plan for the provision of comprehensive services to persons affected by mental retardation and other development disabilities originating in childhood to assist the States in the provision of such services in accordance with such plan, to assist in the construction of facilities to provide the services needed to carry out such plan, and for other purposes. |
| 42. | Health Training Improvement Act of 1970 ... | Public Law 91–519, Nov. 2, 1970, S. 3586, S. Rept. 1002, H. Rept. 1266, C. Rept. 1588. | To amend title VII of the Public Health Service Act to establish eligibility of new schools of medicine, dentistry, osteopathy, pharmacy, optometry, veterinary medicine, and podiatry for institutional grants under section 771 thereof, to extend and improve the program relating to training of personnel in the allied health professions, and for other purposes. |
| 43. | Family Planning Services and Population Research Act of 1970. | Public Law 91–572, Dec. 24, 1970, S. 2108, S. Rept. 1004, H. Rept. 1472, C. Rept. 1667. | To promote public health and welfare by expanding, improving, and better coordinating the family planning services and population research activities of the Federal Government, and for other purposes. (adds Title X to the Public Health Service Act.) |
| 44. | Comprehensive Alcohol Abuse and Alcoholism Prevention Treatment and Rehabilitation Act of 1970. | Public Law 91–616, Dec. 31, 1970, S. 3835, S. Rept. 1069, H. Rept. 1663 (acc. H.R. 18874). | To provide a comprehensive Federal program for the prevention and treatment of alcohol abuse and alcoholism. |
| 45. | Emergency Health Personnel Act of 1970 .... | Public Law 91–623, Dec. 31, 1970, S. 4106, S. Rept. 1194, H. Rept. 1662 (acc. H.R. 19860). | To amend the Public Health Service Act to authorize the assignment of commissioned officers of the Public Health Service to areas with critical medical manpower shortages, to encourage health personnel to practice in areas where shortages of such personnel exist, and for other purposes. |
| 46. | National Cancer Act of 1971 ..... | Public Law 92–218, Dec. 23, 1971, S. 1828, S. Rept. 247, H. Rept. 659 (acc. H.R. 11302), C. Repts. 722 (House), 565 (Senate). | To amend the PHS Act so as to strengthen the National Cancer Institute and the National Institutes of Health in order more effectively to carry out the national effort against cancer. |
| 47. | Communicable Disease Control Amendments Act of 1972. | Public Law 92–449, Sept. 30, 1972, S. 3442, S. Rept. 825, H. Rept. 1107 (acc. H.R. 14455), C. Repts. 1376 (House), 1087 (Senate). | To amend the PHS Act to extend and revise the program of assistance under that Act for the control and prevention of communicable diseases. |
| 48. | National Cooley's Anemia Control Act. ..... | Public Law 92–414, Aug. 29, 1972, H.R. 15474, H. Rept. 437, S. Rept. 924. | To amend the PHS Act to provide assistance for programs for the diagnosis, prevention, and treatment of, and research in, Cooley's anemia. |
| 49. | Comprehensive Health Manpower Training Act of 1971. | Public Law 92–157, Nov. 18, 1971, H.R. 8629, H. Rept. 258, S. Rept. 251 (acc. S. 934), C. Repts. 578 (House), 398 (Senate). | To amend title VII of the PHS Act to provide increased manpower for the health professions, and for other purposes. |
| 50. | Emergency Health Personnel Act Amendments of 1972. | Public Law 92–585, Oct. 27, 1972, S. 3858, S. Rept. 1062, H. Rept. 1547 (acc. H.R. 16755). | To amend the PHS Act to improve the program of medical assistance to areas with health manpower shortages, and for other purposes. |
| 51. | National Heart, Blood Vessel, Lung, and Blood Act of 1972. | Public Law 92–423, Sept. 19, 1972, S. 3323, S. Rept. 733, H. Rept. 1108 (acc. H.R. 15081), C. Repts. 1349 (House), 1068 (Senate). | To amend the PHS Act to enlarge the authority of the National Heart and Lung Institute in order to advance the national attack against diseases of the heart and blood vessels, the lungs, and blood, and for other purposes. |

MAJOR AMENDMENTS SINCE 1944 TO THE PUBLIC HEALTH SERVICE ACT AND SELECTED OTHER ACTS INCLUDED IN THE COMPILATION—Continued

| | Title | Public law | Purpose of the Act |
|---|---|---|---|
| 52. | (No short title) | Public Law 92–305, May 19, 1972, H.R. 13591, H. Rept. 940. | To amend the PHS Act to designate the National Institute of Arthritis and Metabolic Diseases as the National Institute of Arthritis, Metabolism, and for other purposes. |
| 53. | Nurse Training Act of 1971 | Public Law 92–158, Nov. 18, 1971, H.R. 8630, H. Rept. 259, S. Rept. 252 (acc. S. 1747), C. Repts. 577 (House), 399 (Senate). | To amend title VIII of the PHS Act to provide for training increased numbers of nurses. |
| 54. | National Sickle Cell Anemia Control Act | Public Law 92–294, May 16, 1972, S. 2676, S. Rept. 557, H. Rept. 923. | To amend the PHS Act to provide for the control of sickle cell anemia. |
| 55. | (No short title—extends Solid Waste Disposal Act.). | Public Law 93–14, Apr. 9, 1973, H.R. 5446, H. Rept. 78. | To extend the Solid Waste Disposal Act, as amended, for 1 yr. |
| 56. | (No short title—extends Clean Air Act.) | Public Law 93–15, Apr. 9, 1973, H.R. 5445, H. Rept. 77. | To extend the Clean Air Act, as amended, for 1 yr. |
| 57. | Health Programs Extension Act of 1973 | Public Law 93–45, June 18, 1973, S. 1136, S. Rept. 87, H. Rept. 227 (acc. H.R. 7806). | To extend through fiscal year 1974 certain expiring appropriations authorizations in the Public Health Service Act, the Community Mental Health Centers Act, and the Developmental Disabilities Services and Facilities Construction Act. |
| 58. | Emergency Medical Services System Act of 1973. | Public Law 93–154, Nov. 16, 1973, S. 2410, S. Rept. 397, H. Rept. 601 (acc. H.R. 10956). | To amend the Public Health Service Act to provide assistance and encouragement for the development of comprehensive area emergency medical services systems. |
| 59. | Health Maintenance Organization Act of 1973. | Public Law 93–222, Dec. 29, 1973, S. 14, S. Rept. 129, H. Rept. 451 (acc. H.R. 7974), C. Repts. 714 (House), 621 (Senate). | To amend the PHS Act to provide assistance and encouragement for the establishment and expansion of health maintenance organizations. |
| 60. | Sudden Infant Death Syndrome Act of 1974 | Public Law 93–270, Apr. 22, 1974, S. 1745, S. Rept. 606, H. Rept. 758 (acc. H.R. 11386). | To provide financial assistance for research activities for the study of sudden death syndrome. |
| 61. | Narcotic Addict Treatment Act of 1974 | Public Law 93–281, May 14, 1974, S. 1115, S. Rept. 192, H. Rept. 884 (acc. H.R. 12503). | To amend the Controlled Substances Act to provide for the registration of practitioners conducting narcotic treatment programs. |
| 62. | Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act Amendments of 1974. | Public Law 93–282, May 14, 1974, S. 1125, S. Rept. 208, H. Rept. 759 (acc. H.R. 11387). | To extend through fiscal year 1974 certain expiring appropriations authorizations in the Public Health Service Act, the Community Mental Centers Act, and the Developmental Disabilities Services and Facilities Construction Act. |
| 63. | Research on Aging Act of 1974 | Public Law 93–296, May 31, 1974, S. 775, S. Rept. 299, H. Rept. 900 (acc. H.R. 6175). | To amend the PHS Act to provide for the establishment of a National Institute on Aging. |
| 64. | National Research Service Award Act of 1974. | Public Law 93–348, July 12, 1974, H.R. 7724, H. Rept. 224, S. Rept. 381, C. Rept. 1148 (House), 960 (Senate). | To amend the PHS Act to establish a program of National Research Service Awards to assure the continued excellence of biomedical and behavioral research and to provide for the protection of human subjects involved in biomedical and behavioral research. |
| 65. | National Cancer Amendments of 1974 | Public Law 93–352, July 23, 1974, S. 2893, S. Rept. 736, H. Rept. 954 (acc. H.R. 13053), C. Rept. 1164 (House). | To amend the Public Health Service Act to improve the national cancer program and to authorize appropriations for such program for the next 3 fiscal years. |
| 66. | Health Services Research, Health Statistics, and Medical Libraries Act of 1974. | Public Law 93–353, July 23, 1974, H.R. 11385, S. Rept. 764, H. Rept. 757, C. Rept. 1170 (House). | To amend the PHS Act to revise the programs of health services research and to extend the program of assistance for medical libraries. |
| 67. | National Diabetes Mellitus Research and Education Act of 1974. | Public Law 93–354, July 23, 1974, S. 2830, S. Rept. 653, H. Rept. 894 (acc. H.R. 12417), C. Rept. 1147 (House). | To amend the PHS Act to provide for greater and more effective efforts in research and public education with regard to diabetes mellitus. |
| 68. | (No short title) | Public Law 93–385, Aug. 23, 1974, S. 3782, H. Rept. 1240 (acc. H.R. 16077). | To amend the Public Health Service Act to extend through fiscal year 1975 the scholarship program for the National Health Service Corps and the loan program for heatlh professions students. |
| 69. | (No short title—extends the Controlled Substances Act.). | Public Law 93–481, Oct. 26, 1974, S. 3355, S. Rept. 925, H. Rept. 1248 (acc. H.R. 14213), C. Repts. 1442 (House), 1271 (Senate). | To amend the Controlled Substance Act to extend for 3 fiscal years the authorizations of appropriations for the administration and enforcement of that Act. |
| 70. | Safe Drinking Water Act | Public Law 93–523, Dec. 16, 1974, S. 433, S. Rept. 231, H. Rept. 1185 (acc. H.R. 13002). | To amend the Public Health Service Act to assure that the public is provided with safe drinking water. |
| 71. | (No short title—extends Solid Waste Disposal Act.) | Public Law 93–611, Jan 2, 1975, H.R. 16045, H. Rept. 1235, S. Rept. 1402. | To amend the Solid Waste Disposal Act to authorized appropriations for fiscal year 1975. |

MAJOR AMENDMENTS SINCE 1944 TO THE PUBLIC HEALTH SERVICE ACT AND SELECTED OTHER ACTS INCLUDED IN THE COMPILATION—Continued

| | Title | Public law | Purpose of the Act |
|---|---|---|---|
| 72. | National Arthritis Act of 1974 ..... | Public Law 93–640, Jan. 4, 1975, S. 2854, S. Rept. 1251. | To amend the PHS Act to expand the authority of the National Institute of Arthritis, Metabolism, and Digestive Diseases in order to advance a national attack on arthritis. |
| 73. | National Health Planning and Resources Development Act of 1974. | Public Law 93–641, Jan. 4, 1975, S. 2994, S. Rept. 1285, H. Rept. 1382 (acc. H.R. 16204), C. Rept. 1640 (House). | To amend the PHS Act to assure the development of a national health policy and of effective State and area health planning and resources development programs. |
| 74. | (No short title—Health Services and Nurse Training Amendments.) | Public Law 94–63, July 29, 1975, S. 66, S. Rept. 94–29, H. Rept. 94–137 (acc. H.R. 4925), H. Rept. 94–143 (acc. H.R. 4115), H. Rept. 94–192 (acc. H.R. 4114), C. Rept. 94–348. | To amend the PHS Act and related laws to revise and extend the health revenue sharing program, the family planning program, the community mental health centers, the program for migrant health centers and community health centers, the National Health Service Corps program, and the programs for assistance for nurse training and for other purposes. |
| 75. | Development Ally Disabled Assistance and Bill of Rights Act. | Public Law 94–103, Oct. 4, 1975, H.R. 4005, H. Rept. 94–58, S. Rept. 94–160 (acc. S. 462), C. Rept. 94–473. | To amend the Developmental Disabilities Services and Facilities Construction Act to revise and extend the programs authorized by that Act. |
| 76. | Health Research and Health Services Amendments of 1976. | Public Law 94–278, Apr. 22, 1976, H.R. 7988, H. Rept. 94–498, S. Rept. 94–509 (acc. S. 988), C. Rept. 94–1005. | To amend the PHS Act to revise and extend the program under the National Heart and Lung Institute, to revise and extend the program of National Research Service Awards, and to establish a national program with respect to genetic diseases; and to require a study and report on the release of research information. |
| 77. | (No short title—National Health Information and Disease Prevention Act.) | Public Law 94–317, June 23, 1976, S. 1466, S. Rept. 94–330, H. Rept. 94–1007 (acc. H.R. 12678). | To amend the PHS Act to provide authority for health information and health promotion programs, to revise and extend authority for disease prevention and control programs, and to revise and extend authority for venereal disease programs, and to amend the Lead-Based Paint Poisioning Prevention Act to revise and extend that Act. |
| 78. | Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act Amendments of 1976. | Public Law 94–371, July 26, 1976, S. 3184, S. Rept. 94–705 (parts 1 and 2), H. Rept. 94–1092 (acc. H.R. 12677), C. Rept. 94–1285. | To amend the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1976, and for other purposes. |
| 79. | National Swine Flu Immunization Program of 1976. | Public Law 94–380, Aug. 12, 1976, S. 3735, S. Rept. 94–1147 (see also remarks by Honorable Paul G. Rogers in Cong. Rec. for Aug. 26, 1976). | To amend the PHS Act to authorize the establishment and implementation of an emergency national swine flu immunization program and to provide an exclusive remedy for personal injury or death arising out of the manufacture, distribution, or administration of the swine flu vaccine under such program. |
| 80. | Indian Health Care Improvement Act ..... | Public Law 94–437, Sept. 30, 1976, S. 522, S. Rept. 94–133, H. Rept. 94–1026, parts I-IV (acc. H.R. 2525). | To implement the Federal responsibility for the care and education of the Indian people by improving the services and facilities of Federal Indian health programs and encouraging maximum participation of Indians in such programs, and for other purposes. |
| 81. | Health Maintenance Organization Amendments of 1976. | Public Law 94–460, Oct. 8, 1976, H.R. 9019, H. Rept. 94–518, S. Rept. 94–844 (acc. S. 1926), C. Rept. 94–1513. | To amend title XIII of the PHS Act to revise and extend the program for the establishment of HMO's. |
| 82. | Health Professions Educational Assistance Act of 1976. | Public Law 94–484, Oct. 12, 1976, H.R. 5546, H. Rept. 94–266, S. Rept. 94–886 and No. 94–887 (acc. S. 3239), C. Rept. 94–1612. | To amend the PHS Act to revise and extend the programs under title VII for training in the health and allied professions, to revise the National Health Service Corps program and the National Health Service Corps scholarship training program, and for other purposes. |
| 83. | Arthritis, Diabetes, and Digestive Diseases Amendments of 1976. | Public Law 94–562, Oct. 19, 1976, S. 2910 | To amend the PHS Act to revise and extend provisions respecting arthritis and diabetes. |
| 84. | Emergency Medical Services Amendments of 1976. | Public Law 94–573, Oct. 21, 1976, S. 2548, S. Rept. 94–889, H. Rept. 94–1089 (acc. H.R. 12664). | To revise and extend the provisions of title XII of the PHS Act relating to emergency medical services systems; to establish programs relating to burn injuries, and for other purposes. |
| 85. | Health Planning and Health Services Research and Statistics Extension Act of 1977. | Public Law 95–83, Aug. 1, 1977, H.R. 4975, H. Repts. 95–117, 95–118, 95–500, S. Rept. 95–102. | To extend through fiscal year 1978 funding for health programs. |

MAJOR AMENDMENTS SINCE 1944 TO THE PUBLIC HEALTH SERVICE ACT AND SELECTED OTHER ACTS INCLUDED IN THE COMPILATION—Continued

| | Title | Public law | Purpose of the Act |
|---|---|---|---|
| 86. | (No short title—revision of capitation grants.) | Public Law 95–215, Dec. 19, 1977, H.R. 9418, H. Repts. 95–707, 95–828, S. Rept. 95–545. | To revise the conditions under which schools may receive capitation grants under sec. 770 of the PHS Act. |
| 87. | Drug Abuse Prevention and Treatment Amendments of 1978. | Public Law 95–461, Oct. 14, 1978, S. 2916, S. Repts. 95–820, 95–151, H. Rept. 95–1187. | To amend the Drug Abuse Office and Treatment Act of 1972 to extend the programs of assistance under that Act. |
| 88. | Health Maintenance Organization Amendments of 1978. | Public Law 95–559, Nov. 1, 1978, S. 2534, S. Rept. 95–837, H. Repts. 95–1479, 95–1784. | To amend the PHS Act to revise and extend the program of assistance under title XIII for HMO's. |
| 89. | Title V of the Rehabilitation, Comprehensive Services, and Developmental Disabilities Amendments of 1978. | Public Law 95–602, Nov. 6, 1978, H.R. 12467, H. Rept. 95–1780. | To revise and extend the programs of assistance under the Developmental Disabilities Services and Facilities Construction Act. |
| 90. | (No short title—extension of title X and part B of title XI.) | Public Law 95–613, Nov. 8, 1978, S. 2522, S. Rept. 95–822, H. Rept. 95–1191. | To extend family planning assistance and sudden infant death assistance through fiscal year 1981. |
| 91. | Community Mental Health Center Extension Act of 1978 and Biomedical Research and Research Training Amendments of 1978. | Public Law 95–622, Nov. 9, 1978, S. 2450, S. Rept. 95–838, H. Repts. 95–1192, 95–1780. | To revise and extend the Community Mental Health Centers Act, to revise and extend the cancer and heart and lung programs, to revise and extend the National Research Services awards programs, and to establish the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. |
| 92. | Health Services Research, Health Statistics, and Health Care Technology Act of 1978. | Public Law 95–623, Nov. 9, 1978, S. 2466, S. Rept. 95–839, H. Repts. 95–1190, 95–1783. | To amend the PHS Act to revise and extend the authorities relating to health services research and health statistics and to establish a National Center for Health Care Technology. |
| 93. | Health Services and Centers Amendments of 1978. | Public Law 95–626, Nov. 10, 1978, S. 2474, S. Rept. 95–860, H. Repts. 95–1191, 95–1799. | To amend the PHS Act to revise and extend the programs for migrant and community health centers, to establish a program for primary health centers, to revise and extend secs. 314 and 317, to provide assistance to other preventive health service programs, to place home health services and lead-based paint programs in the PHS Act, and to establish an adolescent pregnancy program. |
| | | Public Law 96–32, July 10, 1979, S.J. Res. 14, H. Rept. 96–187. | To amend the Public Health Service Act and related health laws to correct printing and other technical errors. |
| | | Public Law 96–33, July 16, 1979, H.R. 4556. | To amend section 1521 of the Public Health Service Act to authorize the Secretary of Health, Education, and Welfare to extend conditional designations of State health planning and development agencies. |
| | | Public Law 96–63, Sept. 6, 1979, S. 1146, S. Rept. 96–161, H.R. 3509, H. Rept. 96–186. | To extend for 3 fiscal years the authorizations for appropriations under the Safe Drinking Water Act. |
| | | Public Law 96–76, Sept. 29, 1979, S. 230, S. Rept. 96–101, H.R. 3633, H. Rept. 96–183. | To amend title VIII of the Public Health Service Act to extend through fiscal year 1980 the program of assistance for nurse training, and for other purposes. |
| 94. | Health Planning and Resources Development Amendments of 1979. | Public Law 96–79, Oct. 4, 1979, S. 544, S. Rept. 96–96, H.R. 3917, H. Rept. 96–190, S. Conf. Rept. 96–309. | To amend titles XV and XVI of the Public Health Service Act to revise and extend the authorities and requirements under those titles for health planning and health resources development, and for other purposes. |
| | | Public Law 96–142, Dec. 12, 1979, S. 497, S. Rept. 96–102, H.R. 3642, H. Rept. 96–185. | To extend for 3 fiscal years the authorizations of appropriations under section 789 and title XII of the Public Health Service Act relating to emergency medical services, to revise and improve the authorities for assistance under such title XII, to increase the authorizations of appropriations and revise and improve the authorities for assistance under part B of title XI of such Act for sudden infant death syndrome counseling and information projects, and for other purposes. |
| 95. | Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act Amendments of 1979. | Public Law 96–180, Jan. 2, 1980, S. 440, S. Rept. 96–103, H.R. 3916, H. Rept. 96–193. | To revise and extend the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970. |
| 96. | Mental Health Systems Act ..... | Public Law 96–398, Oct. 7, 1980, S. 1177, S. Rept. 96–712, H.R. 7299, H. Rept. 96–977, H. Conf. Rept. 96–1367. | To improve the provision of mental health services and otherwise promote mental health throughout the United States, and for other purposes. |

MAJOR AMENDMENTS SINCE 1944 TO THE PUBLIC HEALTH SERVICE ACT AND SELECTED OTHER ACTS INCLUDED IN THE COMPILATION—Continued

| | Title | Public law | Purpose of the Act |
|---|---|---|---|
| 97. | Health Programs Extension Act of 1980 ..... | Public Law 96–538, Dec. 17, 1980, S. 988, S. Rept. 96–714, H.R. 7036, H. Rept. 96–997, H. Conf. Rept. 96–1478. | To amend the Public Health Service Act to revise and extend the authorities under that Act relating to national research institutes, and for other purposes. |
| 98. | Omnibus Budget Reconciliation Act of 1981 | Public Law 97–35, title IX, Aug. 13, 1981, H.R. 3982, S. 1377, S. Rept. 97–139, H. Rept. 97–158, H. Conf. Rept. 97–208.. | To provide for reconciliation pursuant to section 301 of the first concurrent resolution on the budget for the fiscal year 1982. |
| 99. | Alcohol and Drug Abuse Amendments of 1983. | Public Law 98–24, Apr. 26, 1983, S. 126, S. Rept. 98–29. | To remedy alcohol and drug abuse. |
| | | Public Law 98–49, July 13, 1983, H.R. 2713, H. Rept. 98–143. | To amend the Public Health Service Act to authorize appropriations to be made available to the Secretary of Health and Human Services for research for the cause, treatment, and prevention of public health emergencies. |
| 100. | Rural Health Clinics Act of 1983 ..... | Public Law 98–194, Dec. 1, 1983, S. 2129 | To provide revised reimbursement criteria for small rural health clinics utilizing National Health Service Corps personnel. |
| 101. | Alcohol and Drug Abuse Amendments of 1983. | Public Law 98–24, Apr. 26, 1983, S. 126, S. Rept. 98–29. | To remedy alcohol and drug abuse. |
| | | Public Law 98–49, July 13, 1983, H.R. 2713, H. Rept. 98–143. | To amend the Public Health Service Act to authorize appropriations to be made available to the Secretary of Health and Human Services for research for the cause, treatment, and prevention of public health emergencies. |
| 102. | Rural Health Clinics Act of 1983 ..... | Public Law 98–194, Dec. 1, 1983, S. 2129 | To provide revised reimbursement criteria for small rural health clinics utilizing National Health Service Corps personnel. |
| 103. | National Organ Transplant Act ..... | Public Law 98–507, Oct. 19, 1984, S. 2048, H.R. 4080, H. Rept. 98–575; H.R. 5580, H. Rept. 98–769; S. Rept. 98–382, H. Conf. Rept. 98–1127. | To provide for the establishment of the Task Force on Organ Transplantation and the Organ Procurement and Transplantation Network, to authorize financial assistance for organ procurement organizations, and for other purposes. |
| 104. | Alcohol Abuse, Drug Abuse, and Mental Health Amendments of 1984. | Public Law 98–509, Oct. 19, 1984, S. 2303, H. Conf. Rept. 98–1123, S. Rept. 98–381. | To amend the Public Health Service Act to revise and extend the authorities of that Act for assistance for alcohol and drug abuse and mental health services. |
| | | Public Law 98–512, Oct. 19, 1984, S. 2616, H. Conf. Rept. 98–1154, S. Rept. 98–496. | To revise and extend the programs of assistance under titles X and XX of the Public Health Service Act. |
| 105. | Developmental Disabilities Act of 1984 ..... | Public Law 98–527, Oct. 19, 1984, H.R. 5603, H. Rept. 98–826, H. Conf. Rept. 98–1074. | To revise and extend programs for persons with developmental disabilities. |
| 106. | Health Promotion and Disease Prevention Amendments of 1984. | Public Law 98–551, Oct. 30, 1984, S. 771, S. Rept. 98–158. | To revise and extend provisions of the Public Health Service Act relating to health promotion and disease prevention, to provide for the establishment of centers for research and demonstrations concerning health promotion and disease prevention, and for other purposes. |
| 107. | Preventive Health Amendments of 1984 ..... | Public Law 98–555, Oct. 30, 1984, S. 2301, H.R. 5538, H. Rept. 98–1063, S. Rept. 98–393. | To revise and extend programs for the provision of health services and preventive health services, and for other purposes. |
| 108. | Nurse Education Amendments of 1985 ..... | Public Law 99–92, Aug. 16, 1985, H.R. 2370, S. 1284, S. Rept. 99–106, H. Rept. 99–161. | To amend the Public Health Service Act to extend the programs of assistance for nurse education. |
| 109. | Health Services Amendments of 1985 ..... | Public Law 99–117, Oct. 7, 1985, S. 1689 | To amend various provisions of the Public Health Service Act. |
| 110. | Health Professions Training Assistance Act of 1985. | Public Law 99–129, Oct. 22, 1985, H.R. 2410, S. 1283, S. Rept. 99–105, H. Rept. 99–145. | To amend the Public Health Service Act to revise and extend the programs under title VII of that Act. |
| 111. | Health Research Extension Act of 1985 ..... | Public Law 99–158, Nov. 20, 1985, H.R. 2409, S. 1309, S. Rept. 99–108, S. Conf. Rept. 99–157, H. Rept. 99–158, H. Conf. Rept. 99–309. | To amend the Public Health Service Act to revise and extend the authorities under that Act relating to the National Institutes of Health and National Research Institutes, and for other purposes. |
| 112. | Injury Prevention Act of 1986 ..... | Public Law 99–649, Nov. 10, 1986, S. 2648, S. Rept. 99–434. | To improve the public health through the prevention of injuries. |
| 113. | Stewart B. McKinney Homeless Assistance Act. | Public Law 100–77, Sec. 601–602 & 611–613, July 22, 1987, H.R. 558, H.R. 177, H. Rept. 100–10, H. Rept. 100–8, H. Conf. Rept. 100–174. | To provide urgently needed assistance to protect and improve the lives and safety of the homeless, with special emphasis on elderly persons, handicappted persons, and families with children. |
| 114. | Excellence in Minority Health Education and Care Act. | Public Law 100–97, Aug. 18, 1987, S. 769, S. Rept. 100–110. | To provide grants to support excellence in minority health professsions education. |
| 115. | Developmental Disabilities Assistance and Bill of Rights Act Amendments of 1987. | Public Law 100–146, Oct. 29, 1987, S. 1417, H. Rept. 100–265, S. Rept. 100–113. | To amend the Developmental Disabilities Assistance and Bill of Rights Act to extend the programs established in such Act, and for other purposes. |

MAJOR AMENDMENTS SINCE 1944 TO THE PUBLIC HEALTH SERVICE ACT AND SELECTED OTHER ACTS INCLUDED IN THE COMPILATION—Continued

| | Title | Public law | Purpose of the Act |
|---|---|---|---|
| 116. | Health Care Services in the Home Act of 1987. | Public Law 100–175, Sec. 602, Nov. 29, 1987, H.R. 1451, H. Rept. 100–97, H. Conf. Rept. 100–427. | To amend the Older Americans Act of 1965 to authorize appropriations for the fiscal years 1988, 1990, and 1991; to amend the Native Americans Programs Act of 1974 to authorize appropriations for such fiscal year, and for other purposes. |
| 117. | Public Health Service Amendments of 1987 | Public Law 100–177, December 1, 1987, S. 1158, S. Rept. 100–108. | To amend the Public Health Service Act to establish a National Health Service Corps Loan Repayment Program and to otherwise revise and extend the program for the National Health Service Corps. |
| 118. | Omnibus Budget Reconciliation Act of 1987 | Public Law 100–203, Sec. 4052 & 4301–4307, December 22, 1987, H.R. 3545, H. Rept. 100–391, H. Conf. Rept. 100–495. | To provide for reconciliation pursuant to section 4 of the concurrent resolution on the budget for the fiscal year 1988. |
| 119. | Community and Migrant Health Centers Amendments of 1988. | Public Law 100–386, August 10, 1988, S. 2385, S. Rept. 100–343. | To amend the Public Health Service Act to revise and extend the programs establishing migrant health centers and community health centers. Public Law 100–509. |
| 120. | Protection and Advocacy for Mentally Ill Individuals Amendments Act of 1988. | Public Law 100–509, October 20, 1988, S.2393, H. Rept. 100–903, S. Rept. 100–454. | To amend the Protection and Advocacy for Mentally Ill Individuals Act of 1986 to reauthorize such Act, and for other purposes. |
| 121. | Health Maintenance Organization Amendments of 1988. | Public Law 100–517, October 24, 1988, H.R. 3235, H. Rept. 100–417, S. Rept. 100–304, H. Conf. Rept. 100–1056. | To amend the Public Health Service Act to revise the program of assistance for health maintenance organizations. |
| 122. | National Deafness and Other Communication Disorders Act of 1988. | Public Law 100–553, Sec. 2, October 28, 1988, S. 1727. | To amend the Public Health Service Act to establish within the National Institutes of Health a National Institute on Deafness and Other Communication Disorders. |
| 123. | Lead Contamination Control Act of 1988 ..... | Public Law 100–572, Sec. 3, October 31, 1988, H.R. 4939, H. Rept. 100–1041. | To amend the Safe Drinking Water Act to control lead in drinking water. |
| 124. | Clinical Laboratory Improvement Amendments of 1988. | Public Law 100–578, October 31, 1988, H.R. 5471. | To amend the Public Health Service Act to revise the authority for the regulation of clinical laboratories. |
| 125. | Health Omnibus Programs Extension of 1988. | Public Law 100–607, November 4, 1988, S. 2889. | To amend the Public Health Service Act to establish certain health programs, to revise and extend certain health programs, and for other purposes. |
| 126. | Stewart B. McKinney Homeless Assistance Amendments Act of 1988. | Public Law 100–628, Title VI, November 7, 1988, H.R. 4352, H. Rept. 100–718, S. Rept. 100–343, H. Conf. Rept. 100–1089. | To amend the Stewart B. McKinney Homeless Assistance Act to extend programs providing urgently needed assistance for the homeless, and for other purposes. |
| 127. | Technical and Miscellaneous Revenue Act of 1988. | Public Law 100–647, Sec. 3011(b)(7), November 10, 1988, H.R. 4333, H. Rept. 100–795, S. Rept. 100–445, H. Conf. Rept. 100–1104. | To make technical corrections relating to the Tax Reform Act of 1986, and for other purposes. |
| 128. | Anti-Drug Abuse Act of 1988 ..... | Public Law 100–690, Sec. 1007(c) & Title II, November 18, 1988, H.R. 5210. | To prevent the manufacturing, distribution, and use of illegal drugs, and for other purposes. |
| 129. | Indian Health Care Amendments of 1988 .... | Public Law 100–713, Sec. 104(b), 106, & 714, November 23, 1988, H.R. 5261, S. Rept. 100–508, H. Conf. Rept. 100–1075. | To reauthorize and amend the Indian Health Care Improvement Act, and for other purposes. |
| 130. | Drug Abuse Treatment Technical Corrections Act of 1989. | Public Law 101–93, August 16, 1989, H.R. 1426. | To amend the Public Health Service Act to make technical corrections relating to subtitles A and G of title II of the Anti-Drug Abuse Act of 1988, and for other purposes. |
| 131. | (No short title–construction of biomedical facilities). | Public Law 101–190, November 29, 1989, S. 1390, S. Rept. 101–101. | To provide for the construction of biomedical facilities in order to ensure a continued supply of specialized strains of mice essential to biomedical research in the United States, and for other purposes. |
| 132. | Omnibus Budget Reconciliation Act of 1989 | Public Law 101–239, December 19, 1989, H.R. 3299. | To provide for reconciliation pursuant to section 5 of the concurrent resolution on the budget for the fiscal year 1990. |
| 133. | Breast and Cervical Cancer Mortality Prevention Act of 1990. | Public Law 101–354, August 10, 1990, H.R. 4790. | To amend the Public Health Service Act to establish a program of grants for the detection and control of breast and cervical cancer. |
| 134. | Tuberculosis Prevention Amendments of 1990. | Public Law 101–368, August 15, 1990, H.R. 4273. | To amend the Public Health Service Act to extend the program of grants for preventive health services with respect to tuberculosis, and for other purposes. |
| 135. | Drug Abuse Treatment Waiting Period Reduction Amendments of 1990. | Public Law 101–374, August 15, 1990, S. 2461. | To amend the Public Health Service Act to revise and extend the program of grants for reducing the waiting period for receiving treatment services for drug abuse, and for other purposes. |

MAJOR AMENDMENTS SINCE 1944 TO THE PUBLIC HEALTH SERVICE ACT AND SELECTED OTHER ACTS INCLUDED IN THE COMPILATION—Continued

| | Title | Public law | Purpose of the Act |
|---|---|---|---|
| 136. | Ryan White Comprehensive Aids Resources Emergency Act of 1990. | Public Law 101–381, August 18, 1990, S. 2240. | To amend the Public Health Service Act to provide grants to improve the quality and availability of care for individuals and families with HIV disease, and for other purposes. |
| 137. | Vaccine and Immunization Amendments of 1990. | Public Law 101–502, November 3, 1990, H.R. 4238. | To amend the Public Health Service Act to extend various programs with respect to vaccine-prevention diseases. |
| 138. | Treasury, Postal Service and General Government Appropriations Act, 1991. | Public Law 101–509, November 5, 1990. H.R. 5241. | Making appropriations for the Treasury Department, the United States Postal Service, the Executive Office of the President, and certain Independent Agencies, for the fiscal year ending September 30, 1991. |
| 139. | Disadvantaged Minority Health Improvement Act of 1990. | Public Law 101–527, November 6, 1990, H.R. 5702. | To amend the Public Health Service Act to improve the health of individuals who are members of minority groups and who are from disadvantaged backgrounds, and for other purposes. |
| 140. | Home Health Care and Alzheimer's Disease Amendments of 1990. | Public Law 101–557, November 15, 1990, H.R. 5112. | To amend the Public Health Service Act regarding certain programs for health care services in the hom and certain programs relating to Alzheimer's disease, and for other purposes. |
| 141. | Injury Control Act of 1990 ..... | Public Law 101–558, November 15, 1990, H.R. 5113. | To amend the Public Health Service Act to revise and extend the program for the prevention and control of injuries. |
| 142. | Trauma Care Systems Planning and Development Act of 1990. | Public Law 101–590, November 16, 1990, H.R. 1602. | To amend the Public Health Service Act to improve emergency medical services and trauma care, and for other purposes. |
| 143. | National Health Service Corps Revitalization Amendments of 1990. | Public Law 101–597, November 16, 1990, H.R. 4487. | To amend the Public Health Service Act to revise and extend the program for the National Service Corps, and to establish certain programs of grants to the States for improving health services in the States. |
| 144. | National Institutes of Health Amendments of 1990. | Public Law 101–613, November 16, 1990, S. 2857, (H.R. 5661). | To amend the Public Health Service Act with respect to certain programs for the National Institutes of Health. |
| 145. | Transplant Amendments Act of 1990 ..... | Public Law 101–616, November 16, 1990, S. 2946. | To amend the Public Health Service Act to revise and extend the program establishing the National Bone Marrow Donor Registry, and for other purposes. |
| 146. | Safe Medical Devices Act of 1990 ..... | Public Law 101–629, November 28, 1990, H.R. 3095. | To amend the Federal Food, Drug, and Cosmetic Act to make improvements in the regulation of medical devices, and for other purposes. |
| 147. | Mental Health Amendments of 1990 ..... | Public Law 101–639, November 28, 1990, S. 2628. | To amend the Public Health Service Act to reauthorize certain National Institute of Mental Health grants and to improve provisions concerning the State comprehensive mental health services plan, and for other purposes. |
| 148. | Indian Arts and Crafts Act of 1990 ..... | Public Law 101–644, November 29, 1990, H.R. 2006. | To expand the powers of the Indian Arts and Crafts Board, and for other purposes. |
| 149. | Stewart B. McKinney Homeless Assistance Amendments Act of 1990. | Public Law 101–645, November 29, 1990, H.R. 3789. | To amend the Stewart B. McKinney Homeless Assistance Act to extend programs providing urgently needed assistance for the homeless, and for other purposes. |
| 150. | Crime Control Act of 1990 ..... | Public Law 101–647, November 29, 1990, S. 3266, (H.R. 5269). | To control crime. |
| 151. | Persian Gulf Conflict Supplemental Authorization and Personnel Benefits Act of 1991. | Public Law 102–25, April 6, 1991, S. 724 .. | Persian Gulf Conflict Supplemental Authorization and Personnel Benefits Act of 1991. |
| 152. | Terry Beirn Community Based AIDS Research Initiative Act of 1991. | Public Law 102–96, August 14, 1991, S. 1594. | To honor and commend the efforts of Terry Beirn, to amend the Public Health Service Act to rename and make technical amendments to the community-based AIDS research initiative, and for other purposes. |
| 153. | Health Information, Health Promotion, and Vaccine Injury Compensation Amendments of 1991. | Public Law 102–168, November 26, 1991, H.R. 3402. | To amend the Public Health Service Act to revise and extend certain programs regarding health information, health promotion, and vaccine injury compensation. |
| 154. | (No short title) ..... | Public Law 102–54, June 13, 1991, H.R. 232. | To amend title 38, United States Code, with respect to veterans programs for housing and memorial affairs. |

MAJOR AMENDMENTS SINCE 1944 TO THE PUBLIC HEALTH SERVICE ACT AND SELECTED OTHER ACTS INCLUDED IN THE COMPILATION—Continued

| | Title | Public law | Purpose of the Act |
|---|---|---|---|
| 155. | ADAMHA Reorganization Act ..... | Public Law 102–321, July 10, 1992, S. 1306. | To amend the Public Health Service Act to restructure the Alcohol, Drug Abuse, and Mental Health Administration and the authorities of such Administration, including establishing separate block grants to enhance the delivery of services regarding drug abuse and mental health, and for other purposes. |
| 156. | Public Health Service Act Technical Amendments Act. | Public Law 102–352, August 26, 1992, S. 3112. | To amend the Public Health Service Act to make certain technical corrections, and for other purposes. |
| 157. | Health Professions Education Extension Amendments of 1992. | Public Law 102–408, October 13, 1992, H.R. 3508. | To amend the Public Health Service Act to revise and extend certain programs relating to the education of individuals as health professionals, and for other purposes. |
| 158. | DES Education and Research Amendments of 1992. | Public Law 102–409, October 13, 1992, H.R. 4178. | To amend the Public Health Service Act to provide for a program to carry out research on the drug known as diethylstilbestrol, to educate health professionals and the public on the drug, and to provide for certain longitudinal studies regarding individuals who have been exposed to the drug. |
| 159. | Agency for Health Care Policy and Research Reauthorization Act of 1992. | Public Law 102–410, October 13, 1992, H.R.5673. | To amend the Public Health Service Act to revise and extend the programs of the Agency for Health Care Policy and Research. |
| 160. | Federally Supported Health Centers Assistance Act of 1992. | Public Law 102–501, October 24, 1992, H.R. 6183. | To amend the Public Health Service Act to provide protections from legal liability for certain health care professionals providing services pursuant to such Act. |
| 161. | Alzheimer's Disease Research, Training, and Education Amendments of 1992. | Public Law 102–507, October 24, 1992, S. 1577. | To amend the Alzheimer's Disease and Related Dementias Services Research Act of 1986 to reauthorize the Act, and for other purposes. |
| 162. | Cancer Registries Amendment Act ..... | Public Law 102–515, October 24, 1992, S. 3312. | Entitled the ''Cancer Registries Amendment Act''. |
| 163. | Preventive Health Amendments of 1992 ..... | Public Law 102–531, October 27, 1992, H.R. 3635. | To amend the Public Health Service Act to revise and extend the program of block grants for preventive health services, and for other purposes. |
| 164. | Mammography Quality Standards Act of 1992. | Public Law 102–539, October 27, 1992, H.R. 6182. | To amend the Public Health Service Act to establish the authority for the regulation of mammography services and radiological equipment, and for other purposes. |
| 165. | Veterans Health Care Act of 1992 ..... | Public Law 102–585, November 4, 1992, H.R. 5193. | To amend title 38, United States Code, to improve health care services for women veterans, to expand authority for health care sharing agreements between the Department of Veterans Affairs and the Department of Defense to revise certain pay authorities that apply to Department of Veterans Affairs nurses, to improve preventive health services for veterans, to establish discounts on pharmaceuticals purchased by the Department of Veterans Affairs, to provide for a Persian Gulf War Veterans Health Registry, and to make other improvements in the delivery and administration of health care by the Department of Veterans Affairs. |
| 166. | National Institutes of Health Revitalization Act of 1993. | Public Law 103–43, June 10, 1993, S. 1 .... | To amend the Public Health Service Act to revise and extend the programs of the National Institutes of Health, and for other purposes. |
| 167. | Omnibus Budget Reconciliation Act of 1993 | Public Law 103–66, August 10, 1993, H.R. 2264. | To provide for reconciliation pursuant to section 7 of the concurrent resolution on the budget for fiscal year 1994. |
| 168. | Preventive Health Amendments of 1993 ..... | Public Law 103–183, December 14, 1983, H.R. 2202. | To amend the Public Health Service Act to revise and extend the program of grants relating to preventive health measures with respect to breast and cervical cancer. |

MAJOR AMENDMENTS SINCE 1944 TO THE PUBLIC HEALTH SERVICE ACT AND SELECTED OTHER ACTS INCLUDED IN THE COMPILATION—Continued

| | Title | Public law | Purpose of the Act |
|---|---|---|---|
| 169. | Developmental Disabilities Assistance and Bill of Rights Act Amendments of 1994. | Public Law 103–230, April 6, 1994, S. 1284. | To amend the Developmental Disabilities Assistance and Bill of Rights Act to modify certain provisions relating to programs for individuals with developmental disabilities, Federal assistance for priority area activities for individuals with developmental disabilities, protection and advocacy of individual rights, university affiliated programs, and projects of national significance, and for other purposes. |
| 170. | Federally Supported Health Centers Assistance Act of 1995. | Public Law 104–73, December 26, 1995, H.R. 1747. | To amend the Public Health Service Act to permanently extend and clarify malpractice coverage for health centers, and for other purposes. |
| 171. | Ryan White Care Act Amendments of 1996 | Public Law 104–146, May 20, 1996, S. 641 | To amend the Public Health Service Act to revise and extend programs established pursuant to the Ryan White Comprehensive AIDS Resources Emergency Act of 1990. |
| 172. | (No short title–expansion and innovation programs with respect to traumatic brain injury). | Public Law 104–166, July 29, 1996, H.R. 248. | To amend the Public Health Service Act to provide for the conduct of expanded studies and the establishment of innovative programs with respect to traumatic brain injury, and for other purposes. |
| 173. | Health Insurance Portability and Accountability Act of 1996. | Public Law 104–191, August 21, 1996, H.R. 3103. | To amend the Internal Revenue Code of 1986 to improve portability and continuity of health insurance coverage in the group and individual markets, to combat waste, fraud, and abuse in health insurance and health care delivery, to promote the use of medical savings accounts, to improve access to long-term care services and coverage, to simplify the administration of health insurance, and for other purposes. |
| 174. | Health Centers Consolidation Act of 1996 ... | Public Law 104–299, October 11, 1996, S. 1044. | To amend title III of the Public Health Service Act to consolidate and reauthorize provisions relating to health centers, and for other purposes. |
| 175. | Assisted Suicide Funding Restriction Act of 1997. | Public Law 105–12, April 30, 1997, H.R. 1003. | To clarify Federal law with respect to restricting the use of Federal funds in support of assisted suicide. |
| 176. | Food and Drug Administration Modernization Act of 1997. | Public Law 105–115, November 21, 1997, S. 830. | To amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to improve the regulation of food, drugs, devices, and biological products, and for other purposes. |
| 177. | Birth Defects Prevention Act of 1998 ..... | Public Law 105–168, April 21, 1998, S. 419. | To provide surveillance, research, and services aimed at prevention of birth defects, and for other purposes. |
| 178. | National Bone Marrow Registry Reauthorization Act of 1998. | Public Law 105–196, July 16, 1998, H.R. 2202. | To amend the Public Health Service Act to revise and extend the bone marrow donor program, and for other purposes. |
| 179. | Mammography Quality Standards Reauthorization Act of 1998. | Public Law 105–248, October 9, 1998, H.R. 4382. | To amend the Public Health Service Act to revise and extend the program for mammography quality standards. |
| 180. | Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999. | Public Law 105–277, October 21, 1999, H.R. 4328. | Making appropriations for Agriculture, Rural Development, Food and Drug Administration, and Related Agencies for the fiscal year ending September 30, 1999, and for other purposes. |
| 181. | Health Professions Education Partnerships Act of 1998. | Public Law 105–392, November 13, 1998, S. 1754. | To amend the Public Health Service Act to consolidate and reauthorize health professions and minority and disadvantaged health education programs, and for other purposes. |
| 182. | Healthcare Research and Quality Act of 1999. | Public Law 106–129, December 6, 1999, S. 580. | To amend title IX of the Public Health Service Act to revise and extend the Agency for Healthcare Policy and Research. |
| 183. | Children's Health Act of 2000 ..... | Public Law 106–310, October 17, 2000, H.R. 4365. | To amend the Public Health Service Act with respect to children's health. |
| 184. | Ryan White CARE Act Amendments of 2000 | Public Law 106–345, October 20, 2000, S. 2311. | To amend the Public Health Service Act to revise and extend programs established under the Ryan White Comprehensive AIDS Resources Emergency Act of 1990, and for other purposes. |
| 185. | Developmental Disabilities Assistance and Bill of Rights Act of 2000. | Public Law 106–402, October 30, 2000, S. 1809. | To improve service systems for individuals with developmental disabilities, and for other purposes. |

MAJOR AMENDMENTS SINCE 1944 TO THE PUBLIC HEALTH SERVICE ACT AND SELECTED OTHER ACTS INCLUDED IN THE COMPILATION—Continued

| | Title | Public law | Purpose of the Act |
|---|---|---|---|
| 186. | Public Health Improvement Act ..... | Public Law 106–505, November 13, 2000, H.R. 2498. | To amend the Public Health Service Act to provide for recommendations of the Secretary of Health and Human Services regarding the placement of automatic external defibrillators in Federal buildings in order to improve survival rates of individuals who experience cardiac arrest in such buildings, and to establish protections from civil liability arising from the emergency use of the devices. |
| 187. | Minority Health and Health Disparities Research and Education Act of 2000. | Public Law 106–525, November 22, 2000, S. 1880. | To amend the Public Health Service Act to improve the health of minority individuals. |
| 188. | Chimpanzee Health Improvement, Maintenance, and Protection Act. | Public Law 106–551, December 20, 2000, H.R. 3514. | To amend the Public Health Service Act to provide for a system of sanctuaries for chimpanzees that have been designated as being no longer needed in research conducted or supported by the Public Health Service, and for other purposes. |
| 189. | National Institute of Biomedical Imaging and Bioengineering Establishment Act. | Public Law 106–580, December 29, 2000, H.R. 1795. | To amend the Public Health Service Act to establish the National Institute of Biomedical Imaging and Bioengineering. |
| 190. | Public Health Security and Bioterrorism Preparedness and Response Act of 2002. | Public Law 107-188, June 12, 2002, H.R. 3448. | To improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies. |
| 191. | Health Care Safety Net Amendments of 2002. | Public Law 107-251, October 26, 2002, S. 1533.. | To amend the Public Health Service Act to reauthorize and strengthen the health centers program and the National Health Service Corps, and to establish the Healthy Communities Access Program, which will help coordinate services for the uninsured and underinsured, and for other purposes. |
| 192. | Smallpox Emergency Personnel Protection Act of 2003. | Public Law 108-20, Apr. 30, 2003, H.R. 1770. | To provide benefits and other compensation for certain individuals with injuries resulting from administration of smallpox countermeasures, and for other purposes. |
| 193. | Project BioShield Act of 2004 ..... | Public Law 108-276, July 21, 2004, S. 15 .. | To amend the Public Health Service Act to provide protections and countermeasures against chemical, radiological, or nuclear agents that may be used in a terrorist attack against the United States by giving the National Institutes of Health contracting flexibility, infrastructure improvements, and expediting the scientific peer review process, and streamlining the Food and Drug Administration approval process of countermeasures. |