PUBLIC HEALTH SERVICE ACT

[As Amended Through P.L. 119–118, Enacted September 30, 2026]

[Currency: This publication is a compilation of the text of title III of Chapter 373 of the 78th Congress. It was last amended by the public law listed in the As Amended Through note above and below at the bottom of each page of the pdf version and reflects current law through the date of the enactment of the public law listed at https://www.govinfo.gov/app/collection/comps/]

[Note: While this publication does not represent an official version of any Federal statute, substantial efforts have been made to ensure the accuracy of its contents. The official version of Federal law is found in the United States Statutes at Large and in the United States Code. The legal effect to be given to the Statutes at Large and the United States Code is established by statute (1 U.S.C. 112, 204).]

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;

AUTHENTICATED U.S. GOVERNMENT INFORMATION GPO

(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 3861 and 4141, 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.

(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)(1)(A) If a person is engaged in biomedical, behavioral, clinical, or other research, in which identifiable, sensitive information is collected (including research on mental health and research on the use and effect of alcohol and other psychoactive drugs), the Secretary, in coordination with other agencies, as applicable—

(i) shall issue to such person a certificate of confidentiality to protect the privacy of individuals who are the subjects of such research if the research is funded wholly or in part by the Federal Government; and

(ii) may, upon application by a person engaged in research, issue to such person a certificate of confidentiality to protect the privacy of such individuals if the research is not so funded.

(B) Except as provided in subparagraph (C), any person to whom a certificate is issued under subparagraph (A) to protect the

privacy of individuals described in such subparagraph shall not disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.

(C) The disclosure prohibition in subparagraph (B) shall not apply to disclosure or use that is—

(i) required by Federal, State, or local laws, excluding instances described in subparagraph (D);

(ii) necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual;

(iii) made with the consent of the individual to whom the information, document, or biospecimen pertains; or

(iv) made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.

(D) Any person to whom a certificate is issued under subparagraph (A) to protect the privacy of an individual described in such subparagraph shall not, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, disclose or provide the name of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, except in the circumstance described in subparagraph (C)(iii).

(E) Identifiable, sensitive information protected under subparagraph (A), and all copies thereof, shall be immune from the legal process, and shall not, without the consent of the individual to whom the information pertains, be admissible as evidence or used for any purpose in any action, suit, or other judicial, legislative, or administrative proceeding.

(F) Identifiable, sensitive information collected by a person to whom a certificate has been issued under subparagraph (A), and all copies thereof, shall be subject to the protections afforded by this section for perpetuity.

(G) The Secretary shall take steps to minimize the burden to researchers, streamline the process, and reduce the time it takes to comply with the requirements of this subsection.

(2) The Secretary shall coordinate with the heads of other applicable Federal agencies to ensure that such departments have policies in place with respect to the issuance of a certificate of confidentiality pursuant to paragraph (1) and other requirements of this subsection.

(3) Nothing in this subsection shall be construed to limit the access of an individual who is a subject of research to information about himself or herself collected during such individual's participation in the research.

(4) For purposes of this subsection, the term "identifiable, sensitive information" means information that is about an individual and that is gathered or used during the course of research described in paragraph (1)(A) and—

(A) through which an individual is identified; or

(B) for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual.

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

(f)(1) The Secretary may exempt from disclosure under section 552(b)(3) of title 5, United States Code, biomedical information that is about an individual and that is gathered or used during the course of biomedical research if—

(A) an individual is identified; or

(B) there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, the request, and other available data sources could be used to deduce the identity of an individual.

(2)(A) Each determination of the Secretary under paragraph (1) to exempt information from disclosure shall be made in writing and accompanied by a statement of the basis for the determination.

(B) Each such determination and statement of basis shall be available to the public, upon request, through the Office of the Chief FOIA Officer of the Department of Health and Human Services.

(3) Nothing in this subsection shall be construed to limit a research participant's access to information about such participant collected during the participant's participation in the research.

(g) Subchapter I of chapter 35 of title 44, United States Code, shall not apply to the voluntary collection of information during the conduct of research by the National Institutes of Health.

(h)(1) 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.

(2) Where research substances and living organisms are made available under paragraph (1) through contractors, the Secretary may direct such contractors to collect payments on behalf of the Secretary for the costs incurred to make available such substances and organisms and to forward amounts so collected to the Secretary, in the time and manner specified by the Secretary.

(3) Amounts collected under paragraph (2) shall be credited to the appropriations accounts that incurred the costs to make available the research substances and living organisms involved, and shall remain available until expended for carrying out activities under such accounts.

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.

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

(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.

(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.

SEC. 305. [242c] APPOINTMENT AND AUTHORITY OF THE DIRECTOR OF THE CENTERS FOR DISEASE CONTROL AND PREVENTION.

(a) IN GENERAL.—The Centers for Disease Control and Prevention (referred to in this section as the "CDC") shall be headed by the Director of the Centers for Disease Control and Prevention (referred to in this section as the "Director"), who shall be appointed by the President, by and with the advice and consent of the Senate.[3] Such individual shall also serve as the Administrator of the Agency for Toxic Substances and Disease Registry consistent with section 104(i) of the Comprehensive Environmental Response, Compensation, and Liability Act. The Director shall perform functions

[2] See footnote for section 306.

[3] Section 2101(b) of division FF of Public Law 117-328 states: "The first sentence of section 305(a) of the Public Health Service Act, as added by subsection (a), shall take effect on January 20, 2025.".

provided for in subsection (b) and such other functions as the Secretary may prescribe.

(b) FUNCTIONS.—The Secretary, acting through the Director, shall—

(1) implement and exercise applicable authorities and responsibilities provided for in this Act or other applicable law related to the investigation, detection, identification, prevention, or control of diseases or conditions to preserve and improve public health domestically and globally and address injuries and occupational and environmental hazards, as appropriate;

(2) be responsible for the overall direction of the CDC and for the establishment and implementation of policies related to the management and operation of programs and activities within the CDC;

(3) coordinate and oversee the operation of centers, institutes, and offices within the CDC;

(4) support, in consultation with the heads of such centers, institutes, and offices, program coordination across such centers, institutes, and offices, including through priority setting reviews and the development of strategic plans, to reduce unnecessary duplication and encourage collaboration between programs;

(5) oversee the development, implementation, and updating of the strategic plan established pursuant to subsection (c);

(6) ensure that appropriate strategic planning, including the use of performance metrics, is conducted by such centers, institutes, and offices to facilitate and improve CDC programs and activities;

(7) communicate, including through convening annual meetings, with public and private entities regarding relevant public health programs and activities, and, as applicable, the strategic plan established pursuant to subsection (c).

(c) STRATEGIC PLAN.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of the PREVENT Pandemics Act, and at least every 4 years thereafter, the Director shall develop and submit to the Committee on Health, Education, Labor, and Pensions 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, and post on the website of the CDC, a coordinated strategy to provide strategic direction and facilitate collaboration across the centers, institutes, and offices within the CDC. Such strategy shall be known as the "CDC Strategic Plan".

(2) REQUIREMENTS.—The CDC Strategic Plan shall—

(A) identify strategic priorities and objectives related to—

(i) preventing, reducing, and eliminating the spread of communicable and noncommunicable diseases or conditions, and addressing injuries, and occupational and environmental hazards;

(ii) supporting the efforts of State, local, and Tribal health departments to prevent and reduce the prevalence of the diseases or conditions under clause (i);

(iii) containing, mitigating, and ending disease outbreaks;

(iv) enhancing global and domestic public health capacity, capabilities, and preparedness, including public health data, surveillance, workforce, and laboratory capacity and safety; and

(v) other priorities, as established by the Director;

(B) describe the capacity and capabilities necessary to achieve the priorities and objectives under subparagraph (A), and progress towards achieving such capacity and capabilities, as appropriate; and

(C) include a description of how the CDC Strategic Plan incorporates—

(i) strategic communications;

(ii) partnerships with private sector entities, and State, local, and Tribal health departments, and other public sector entities, as appropriate; and

(iii) coordination with other agencies and offices of the Department of Health and Human Services and other Federal departments and agencies, as appropriate.

(3) USE OF PLANS.—Strategic plans developed and updated by the centers, institutes, and offices of the CDC shall be prepared regularly and in such a manner that such plans will be informed by the CDC Strategic Plan developed and updated under this subsection.

(d) APPEARANCES BEFORE CONGRESS.—

(1) IN GENERAL.—Each fiscal year, the Director shall appear before the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives at hearings on topics such as—

(A) support for State, local, and Tribal public health preparedness and responses to any recent or ongoing public health emergency, including—

(i) any objectives, activities, or initiatives that have been carried out, or are planned, by the Director to prepare for, or respond to, the public health emergency, including relevant strategic communications or partnerships and any gaps or challenges identified in such objectives, activities, or initiatives;

(ii) any objectives and planned activities for the upcoming fiscal year to address gaps in, or otherwise improve, State, local, and Tribal public health preparedness; and

(iii) other potential all-hazard threats that the Director is preparing to address;

(B) activities related to public health and functions of the Director described in subsection (b); and

(C) updates on other relevant activities supported or conducted by the CDC, or in collaboration or coordination

with the heads of other Federal departments, agencies, or stakeholders, as appropriate.

(2) CLARIFICATIONS.—

(A) WAIVER AUTHORITY.—The Chair of the Committee on Health, Education, Labor, and Pensions of the Senate or the Chair of the Committee on Energy and Commerce of the House of Representatives may waive the requirements of paragraph (1) for the applicable fiscal year with respect to the applicable Committee.

(B) SCOPE OF REQUIREMENTS.—The requirements of this subsection shall not be construed to impact the appearance of other Federal officials or the Director at hearings of either Committee described in paragraph (1) at other times and for purposes other than the times and purposes described in paragraph (1).

(3) CLOSED HEARINGS.—Information that is not appropriate for disclosure during an open hearing under paragraph (1) in order to protect national security may instead be discussed in a closed hearing that immediately follows the open hearing.

(e) OTHER TRANSACTIONS.—

(1) IN GENERAL.—In carrying out activities of the Centers for Disease Control and Prevention, the Director may enter into transactions other than a contract, grant, or cooperative agreement for purposes of infectious disease research, biosurveillance, infectious disease modeling, and public health preparedness and response.

(2) WRITTEN DETERMINATION.—With respect to a project that is expected to cost the Centers for Disease Control and Prevention more than $40,000,000, the Director may exercise the authority under paragraph (1) only upon a written determination by the Assistant Secretary for Financial Resources of the Department of Health and Human Services, that the use of such authority is essential to promoting the success of the project. The authority of the Assistant Secretary for Financial Resources under this paragraph may not be delegated.

(3) GUIDELINES.—The Director, in consultation with the Secretary, shall establish guidelines regarding the use of the authority under paragraph (1). Such guidelines shall include auditing requirements.

SEC. 305A. [242c-1] ADVISORY COMMITTEE TO THE DIRECTOR.

(a) IN GENERAL.—Not later than 60 days after the date of the enactment of the PREVENT Pandemics Act, the Secretary, acting through the Director of the Centers for Disease Control and Prevention (referred to in this section as the "Director"), shall maintain or establish an advisory committee within the Centers for Disease Control and Prevention to advise the Director on policy and strategies that enable the agency to fulfill its mission.

(b) FUNCTIONS AND ACTIVITIES.—The Advisory Committee may—

(1) make recommendations to the Director regarding ways to prioritize the activities of the agency in alignment with the CDC Strategic Plan required under section 305(c);

(2) advise on ways to achieve or improve performance metrics in relation to the CDC Strategic Plan, and other relevant metrics, as appropriate;

(3) provide advice and recommendations on the development of the CDC Strategic Plan, and any subsequent updates, as appropriate;

(4) advise on grants, cooperative agreements, contracts, or other transactions, as applicable;

(5) provide other advice to the Director, as requested, to fulfill duties under sections 301 and 311; and

(6) appoint subcommittees.

(c) MEMBERSHIP.—

(1) IN GENERAL.—The Advisory Committee shall consist of not more than 15 non-Federal members, including the Chair, to be appointed by the Secretary under paragraph (3).

(2) EX OFFICIO MEMBERS.—Any ex officio members of the Advisory Council may consist of—

(A) the Secretary;

(B) the Assistant Secretary for Health;

(C) the Director; and

(D) such additional officers or employees of the United States as the Secretary determines necessary for the advisory committee to effectively carry out its functions.

(3) APPOINTED MEMBERS.—Individuals shall be appointed to the Advisory Committee under paragraph (1) as follows:

(A) Twelve of the members shall be appointed by the Director from among the leading representatives of the health disciplines (including public health, global health, health disparities, biomedical research, public health preparedness, and other fields, as applicable) relevant to the activities of the agency or center, as applicable.

(B) Three of the members may be appointed by the Secretary from the general public and may include leaders in fields of innovation, public policy, public relations, law, economics, or management.

(4) COMPENSATION.—Ex officio members of the Advisory Council who are officers or employees of the United States shall not receive any compensation for service on the advisory committee. The remaining members of the advisory committee may receive, for each day (including travel time) they are engaged in the performance of the functions of the advisory committee, compensation at rates not to exceed the daily equivalent to the annual rate of basic pay for level III of the Executive Schedule under section 5314 of title 5, United States Code.

(5) TERMS OF OFFICE.—

(A) IN GENERAL.—The term of office of a member of the advisory committee appointed under paragraph (3) 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 the advisory committee in such a manner as to ensure that the terms of the members not all expire in the same year. A member of the advisory committee may serve

after the expiration of such member's term until a successor has been appointed and taken office.

(B) REAPPOINTMENTS.—A member who has been appointed to the advisory committee for a term of 4 years may not be reappointed to the advisory committee during the 2-year period beginning on the date on which such 4-year term expired.

(C) TIME FOR APPOINTMENT.—If a vacancy occurs in the advisory committee among the members appointed under paragraph (3), 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 the advisory committee to serve as the Chair of the committee. The Secretary may so select an individual from among the appointed members. The term of office of the chair shall be 2 years.

(e) MEETINGS.—The advisory committee shall meet at the call of the Chair or upon request of the Director, but in no event less than 2 times during each fiscal year.

(f) EXECUTIVE SECRETARY AND STAFF.—The Director shall designate a member of the staff of the agency to serve as the executive secretary of the advisory committee. The Director shall make available to the advisory committee such staff, information, and other assistance as it may require to carry out its functions. The Director shall provide orientation and training for new members of the advisory committee to provide for their effective participation in the functions of the advisory committee.

NATIONAL CENTER FOR HEALTH STATISTICS

SEC. 306.[4] **[**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,

[4] 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.

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

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

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

(H) family formation, growth, and dissolution;

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

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

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

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

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

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

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

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

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

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

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

States participating in the System shall designate a State agency to administer or be responsible for the administration of the statistical activities within the State under the System. The Secretary, acting through the Center, shall prescribe guidelines to assure that statistical activities within States participating in the system[5] 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

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

injuries, prevalence of chronic diseases and impairments, disability, physician visits, hospitalizations, and the relationship between demographic and socioeconomic characteristics and health characteristics.

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

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

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

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

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

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

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

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

(2) The members of the Committee shall be appointed from among persons who have distinguished themselves in the fields of health statistics, electronic interchange of health care information, privacy and security of electronic information, population-based public health, purchasing or financing health care services, integrated computerized health information systems, health services research, consumer interests in health information, health data

standards, epidemiology, and the provision of health services. Members of the Committee shall be appointed for terms of 4 years.

(3) Of the members of the Committee—

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

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

(C) 16 shall be appointed by the Secretary.

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

(5) The Committee—

(A) shall assist and advise the Secretary—

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

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

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

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

(v) to review and comment on findings and proposals developed by other organizations and agencies and to make recommendations for their adoption or implementation by local, State, national, or international agencies;

(vi) to cooperate with national committees of other countries and with the World Health Organization and other national agencies in the studies of problems of mutual interest;

(vii) to issue an annual report on the state of the Nation's health, its health services, their costs and distribu-

tions, and to make proposals for improvement of the Nation's health statistics and health information systems; and

(viii) in complying with the requirements imposed on the Secretary under part C of title XI of the Social Security Act;

(B) shall study the issues related to the adoption of uniform data standards for patient medical record information and the electronic exchange of such information;

(C) shall report to the Secretary not later than 4 years after the date of the enactment of the Health Insurance Portability and Accountability Act of 1996 recommendations and legislative proposals for such standards and electronic exchange; and

(D) shall be responsible generally for advising the Secretary and the Congress on the status of the implementation of part C of title XI of the Social Security Act.

(6) In carrying out health statistical activities under this part, the Secretary shall consult with, and seek the advice of, the Committee and other appropriate professional advisory groups.

(7) Not later than 1 year after the date of the enactment of the Health Insurance Portability and Accountability Act of 1996, and annually thereafter, the Committee shall submit to the Congress, and make public, a report regarding the implementation of part C of title XI of the Social Security Act. Such report shall address the following subjects, to the extent that the Committee determines appropriate:

(A) The extent to which persons required to comply with part C of title XI of the Social Security Act are cooperating in implementing the standards adopted under such part.

(B) The extent to which such entities are meeting the security standards adopted under such part and the types of penalties assessed for noncompliance with such standards.

(C) Whether the Federal and State Governments are receiving information of sufficient quality to meet their responsibilities under such part.

(D) Any problems that exist with respect to implementation of such part.

(E) The extent to which timetables under such part are being met.

(l) In carrying out this section, the Secretary, acting through the Center, shall collect and analyze adequate health data that is specific to particular ethnic and racial populations, including data collected under national health surveys. Activities carried out under this subsection shall be in addition to any activities carried out under subsection (m).

(m)(1) The Secretary, acting through the Center, may make grants to public and nonprofit private entities for—

(A) the conduct of special surveys or studies on the health of ethnic and racial populations or subpopulations;

(B) analysis of data on ethnic and racial populations and subpopulations; and

(C) research on improving methods for developing statistics on ethnic and racial populations and subpopulations.

(2) The Secretary, acting through the Center, may provide technical assistance, standards, and methodologies to grantees supported by this subsection in order to maximize the data quality and comparability with other studies.

(3) Provisions of section 308(d) do not apply to surveys or studies conducted by grantees under this subsection unless the Secretary, in accordance with regulations the Secretary may issue, determines that such provisions are necessary for the conduct of the survey or study and receives adequate assurance that the grantee will enforce such provisions.

(4)(A) Subject to subparagraph (B), the Secretary, acting through the Center, shall collect data on Hispanics and major Hispanic subpopulation groups and American Indians, and for developing special area population studies on major Asian American and Pacific Islander populations.

(B) The provisions of subparagraph (A) shall be effective with respect to a fiscal year only to the extent that funds are appropriated pursuant to paragraph (3) of subsection (n), and only if the amounts appropriated for such fiscal year pursuant to each of paragraphs (1) and (2) of subsection (n) equal or exceed the amounts so appropriated for fiscal year 1997.

(n)(1) For health statistical and epidemiological activities undertaken or supported under subsections (a) through (l), there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1991 through 2003.

(2) For activities authorized in paragraphs (1) through (3) of subsection (m), there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1999 through 2003. Of such amounts, the Secretary shall use not more than 10 percent for administration and for activities described in subsection (m)(2).

(3) For activities authorized in subsection (m)(4), there are authorized to be appropriated $1,000,000 for fiscal year 1998, and such sums as may be necessary for each of the fiscal years 1999 through 2002.

INTERNATIONAL COOPERATION

SEC. 307. [242*l*] (a) The Secretary may participate with other countries in cooperative endeavors in—

(1) biomedical research, health care technology, and the health services research and statistical analysis authorized under section 306 and title IX; and

(2) biomedical research, health care services, health care research, or other related activities in furtherance of the activities, objectives or goals authorized under the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008.

(b) In connection with the cooperative endeavors authorized by subsection (a), the Secretary may—

(1) make such use of resources offered by participating foreign countries as he may find necessary and appropriate;

(2) establish and maintain fellowships in the United States and in participating foreign countries;

(3) make grants to public institutions or agencies and to nonprofit private institutions or agencies in the United States and in participating foreign countries for the purpose of establishing and maintaining the fellowships authorized by paragraph (2);

(4) make grants or loans of equipment and materials, for use by public or nonprofit private institutions or agencies, or by individuals, in participating foreign countries;

(5) participate and otherwise cooperate in any international meetings, conferences, or other activities concerned with biomedical research, health services research, health statistics, or health care technology;

(6) facilitate the interchange between the United States and participating foreign countries, and among participating foreign countries, of research scientists and experts who are engaged in experiments or programs of biomedical research, health services research, health statistical activities, or health care technology activities, and in carrying out such purpose may pay per diem compensation, subsistence, and travel for such scientists and experts when away from their places of residence at rates not to exceed those provided in section 5703(b) of title 5, United States Code, for persons in the Government service employed intermittently;

(7) procure, in accordance with section 3109 of title 5, United States Code, the temporary or intermittent services of experts or consultants;

(8) enter into contracts with individuals for the provision of services (as defined in section 104 of part 37 of title 48, Code of Federal Regulations (48 CFR 37.104)) in participating foreign countries, which individuals may not be deemed employees of the United States for the purpose of any law administered by the Office of Personnel Management;

(9) provide such funds by advance or reimbursement to the Secretary of State, as may be necessary, to pay the costs of acquisition, lease, construction, alteration, equipping, furnishing or management of facilities outside of the United States; and

(10) in consultation with the Secretary of State, through grant or cooperative agreement, make funds available to public or nonprofit private institutions or agencies in foreign countries in which the Secretary is participating in activities described under subsection (a) to acquire, lease, construct, alter, or renovate facilities in those countries.

(c) The Secretary may provide to personnel appointed or assigned by the Secretary to serve abroad, allowances and benefits similar to those provided under chapter 9 of title I of the Foreign Service Act of 1980 (22 U.S.C. 4081 et seq.). Leaves of absence for personnel under this subsection shall be on the same basis as that provided under subchapter I of chapter 63 of title 5, United States Code or section 903 of the Foreign Service Act of 1980 (22 U.S.C. 4083), to individuals serving in the Foreign Service.

(d) In carrying out immunization programs and other programs in developing countries for the prevention, treatment, and control of infectious diseases, including HIV/AIDS, tuberculosis, and malaria, the Director of the Centers for Disease Control and Preven-

tion, in coordination with the Coordinator of United States Government Activities to Combat HIV/AIDS Globally, the National Institutes of Health, national and local government, and other organizations, such as the World Health Organization and the United Nations Children's Fund, shall develop and implement effective strategies to improve injection safety, including eliminating unnecessary injections, promoting sterile injection practices and technologies, strengthening the procedures for proper needle and syringe disposal, and improving the education and information provided to the public and to health professionals.

GENERAL PROVISIONS RESPECTING EFFECTIVENESS, EFFICIENCY, AND QUALITY OF HEALTH SERVICES

SEC. 308. [242m] (a)(1) Not later than March 15 of each year, the Secretary shall submit to the President and Congress the following reports:

(A) A report on health care costs and financing. Such report shall include a description and analysis of the statistics collected under section 306(b)(1)(G).

(B) A report on health resources. Such report shall include a description and analysis, by geographical area, of the statistics collected under section 306(b)(1)(E).

(C) A report on the utilization of health resources. Such report shall include a description and analysis, by age, sex, income, and geographic area, of the statistics collected under section 306(b)(1)(F).

(D) A report on the health of the Nation's people. Such report shall include a description and analysis, by age, sex, income, and geographic area, of the statistics collected under section 306(b)(1)(A).

(2) The reports required in paragraph (1) shall be prepared through the National Center for Health Statistics.

(3) The Office of Management and Budget may review any report required by paragraph (1) of this subsection before its submission to Congress, but the Office may not revise any such report or delay its submission beyond the date prescribed for its submission, and may submit to Congress its comments respecting any such report.

(b)(1) No grant or contract may be made under section 304, 306, or 307 unless an application therefor has been submitted to the Secretary in such form and manner, and containing such information, as the Secretary may by regulation prescribe and unless a peer review group referred to in paragraph (2) has recommended the application for approval.

(2)(A) Each application submitted for a grant or contract under section 306 in an amount exceeding $50,000 of direct costs and for a health services research, evaluation, or demonstration project, or for a grant under section 306(m), shall be submitted to a peer review group for an evaluation of the technical and scientific merits of the proposals made in each such application. The Director of the National Center for Health Statistics shall establish such peer review groups as may be necessary to provide for such an evaluation of each such application.

(B) A peer review group to which an application is submitted pursuant to subparagraph (A) shall report its finding and recommendations respecting the application to the Secretary, acting through the Director of the National Center for Health Statistics, in such form and manner as the Secretary shall by regulation prescribe. The Secretary may not approve an application described in such subparagraph unless a peer review group has recommended the application for approval.

(C) The Secretary, acting through the Director of the National Center for Health Statistics, shall make appointments to the peer review groups required in subparagraph (A) from among persons who are not officers or employees of the United States and who possess appropriate technical and scientific qualifications, except that peer review groups regarding grants under section 306(m) may include appropriately qualified such officers and employees.

(c) The Secretary shall take such action as may be necessary to assure that statistics developed under sections 304 and 306 are of high quality, timely, comprehensive as well as specific, standardized, and adequately analyzed and indexed, and shall publish, make available, and disseminate such statistics on as wide a basis as is practicable.

(d) No information, if an establishment or person supplying the information or described in it is identifiable, obtained in the course of activities undertaken or supported under section 304, 306, or 307 may be used for any purpose other than the purpose for which it was supplied unless such establishment or person has consented (as determined under regulations of the Secretary) to its use for such other purpose and in the case of information obtained in the course of health statistical or epidemiological activities under section 304 or 306, such information may not be published or released in other form if the particular establishment or person supplying the information or described in it is identifiable unless such establishment or person has consented (as determined under regulations of the Secretary) to its publication or release in other form.

(e)(1) Payments of any grant or under any contract under section 304, 306, or 307 may be made in advance or by way of reimbursement, and in such installments and on such conditions, as the Secretary deems necessary to carry out the purposes of such section.

(2) The amounts otherwise payable to any person under a grant or contract made under section 304, 306, or 307 shall be reduced by—

(A) amounts equal to the fair market value of any equipment or supplies furnished to such person by the Secretary for the purpose of carrying out the project with respect to which such grant or contract is made, and

(B) amounts equal to the pay, allowances, traveling expenses, and related personnel expenses attributable to the performance of services by an officer or employee of the Government in connection with such project, if such officer or 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.[6] [242o] (a) A conference of the health authorities in and among the several States shall be called annually by the Secretary. Whenever in his opinion the interests of the public health would be promoted by a conference, the Secretary may invite as many of such health authorities and officials of other State or local public or private agencies, institutions, or organizations to confer as he deems necessary or proper. Upon the application of health authorities of five or more States it shall be the duty of the Secretary to call a conference of all State health authorities joining in the request. Each State represented at any conference shall be entitled to a single vote. Whenever at any such conference matters relating to mental health are to be discussed, the mental health authorities of the respective States shall be invited to attend.

(b) From time to time the Secretary shall issue information related to public health, in the form of publications or otherwise, for the use of the public, and shall publish weekly reports of health conditions in the United States and other countries and other pertinent health information for the use of persons and institutions concerned with health services.

SEC. 310A. [242s] CENTERS FOR DISEASE CONTROL AND PREVENTION OFFICE OF WOMEN'S HEALTH.

(a) ESTABLISHMENT.—There is established within the Office of the Director of the Centers for Disease Control and Prevention, an office to be known as the Office of Women's Health (referred to in this section as the "Office"). The Office shall be headed by a director who shall be appointed by the Director of such Centers.

(b) PURPOSE.—The Director of the Office shall—

(1) report to the Director of the Centers for Disease Control and Prevention on the current level of the Centers' activity regarding women's health conditions across, where appropriate, age, biological, sociocultural (including among American Indians, Native Hawaiians, and Alaska Natives), and geographical contexts, in all aspects of the Centers' work, including prevention programs, public and professional education, services, and treatment;

(2) establish short-range and long-range goals and objectives within the Centers for women's health and, as relevant and appropriate, coordinate with other appropriate offices on activities within the Centers that relate to prevention, research, education and training, service delivery, and policy development, for issues of particular concern to women;

(3) identify projects in women's health that should be conducted or supported by the Centers;

(4) consult with health professionals, nongovernmental organizations, consumer organizations, women's health profes-

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

sionals, and other individuals and groups, as appropriate, on the policy of the Centers with regard to women; and

(5) serve as a member of the Department of Health and Human Services Coordinating Committee on Women's Health (established under section 229(b)(4)).

(c) DEFINITION.—As used in this section, the term "women's health conditions", with respect to women of all age, ethnic, and racial groups, means diseases, disorders, and conditions—

(1) unique to, significantly more serious for, or significantly more prevalent in women; and

(2) for which the factors of medical risk or type of medical intervention are different for women, or for which there is reasonable evidence that indicates that such factors or types may be different for women.

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

SEC. 310B. [242u] IMPROVING STATE, LOCAL, AND TRIBAL INFORMATION SHARING.

(a) IN GENERAL.—The Secretary may, in consultation with State, local, and Tribal public health officials, carry out activities to improve the availability of appropriate and applicable public health data related to communicable diseases, and information sharing between, the Director of the Centers for Disease Control and Prevention, the Assistant Secretary for Preparedness and Response, and such State, local, and Tribal public health officials, which may include such data from—

(1) health care providers and facilities;

(2) public health and clinical laboratories;

(3) health information exchanges and health information networks; and

(4) State, local, and Tribal health departments.

(b) CONTENT, FORM, AND MANNER.—The Secretary shall, consistent with the requirements of this section, work with such officials and relevant stakeholders to provide information on the content, form, and manner in which such data, deidentified as applicable, may most effectively support the ability of State, local, and Tribal health departments to respond to such communicable diseases, including related to the collection and reporting of demographic and other relevant data elements. Such form and manner requirements shall align with the standards and implementation specifications adopted by the Secretary under section 3004, as applicable.

(c) DECREASED BURDEN.—In facilitating the coordination of efforts under subsection (a), the Secretary shall make reasonable efforts to limit reported public health data to the minimum necessary information needed to accomplish the intended public health purpose.

(d) EXEMPTION OF CERTAIN PUBLIC HEALTH DATA FROM DISCLOSURE.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may exempt from disclosure under section 552(b)(3) of title 5, United States Code, public health data that are gathered under this section if—

(1) an individual is identified through such data; or

(2) there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, the request, and other available data sources or the application of technology could be used to deduce the identity of an individual.

PART B—FEDERAL-STATE COOPERATION

IN GENERAL

SEC. 311. [243] (a) The Secretary is authorized to accept from State and local authorities any assistance in the enforcement of quarantine regulations made pursuant to this Act which such authorities may be able and willing to provide. The Secretary shall also assist States and their political subdivisions in the prevention and suppression of communicable diseases and with respect to other public health matters, shall cooperate with and aid State and local authorities in the enforcement of their quarantine and other health regulations, and shall advise the several States on matters relating to the preservation and improvement of the public health.

(b) The Secretary shall encourage cooperative activities between the States with respect to comprehensive and continuing planning as to their current and future health needs, the establishment and maintenance of adequate public health services, and otherwise carrying out the public health activities. The Secretary is also authorized to train personnel for State and local health work. The Secretary may charge only private entities reasonable fees for the training of their personnel under the preceding sentence.

(c)(1) The Secretary is authorized to develop (and may take such action as may be necessary to implement) a plan under which personnel, equipment, medical supplies, and other resources of the Service and other agencies under the jurisdiction of the Secretary may be effectively used to control epidemics of any disease or condition and to meet other health emergencies or problems. The Secretary may enter into agreements providing for the cooperative planning between the Service and public and private community health programs and agencies to cope with health problems (including epidemics and health emergencies).

(2) The Secretary may, at the request of the appropriate State or local authority, extend temporary (not in excess of six months) assistance to States or localities in meeting health emergencies of such a nature as to warrant Federal assistance. The Secretary may require such reimbursement of the United States for assistance provided under this paragraph as he may determine to be reasonable under the circumstances. Any reimbursement so paid shall be credited to the applicable appropriation for the Service for the year in which such reimbursement is received.

SEC. 312. [244] PUBLIC ACCESS DEFIBRILLATION PROGRAMS.

(a) IN GENERAL.—The Secretary shall award grants to States, political subdivisions of States, Indian tribes, and tribal organizations to develop and implement public access defibrillation programs—

(1) by training and equipping local emergency medical services personnel, including firefighters, police officers, paramedics, emergency medical technicians, and other first responders, to administer immediate care, including cardiopulmonary resuscitation and automated external defibrillation, to cardiac arrest victims;

(2) by purchasing automated external defibrillators, placing the defibrillators in public places where cardiac arrests are likely to occur, and training personnel in such places to administer cardiopulmonary resuscitation and automated external defibrillation to cardiac arrest victims;

(3) by setting procedures for proper maintenance and testing of such devices, according to the guidelines of the manufacturers of the devices;

(4) by providing training to members of the public in cardiopulmonary resuscitation and automated external defibrillation;

(5) by integrating the emergency medical services system with the public access defibrillation programs so that emergency medical services personnel, including dispatchers, are informed about the location of automated external defibrillators in their community; and

(6) by encouraging private companies, including small businesses, to purchase automated external defibrillators and provide training for their employees to administer cardiopulmonary resuscitation and external automated defibrillation to cardiac arrest victims in their community.

(b) PREFERENCE.—In awarding grants under subsection (a), the Secretary shall give a preference to a State, political subdivision of a State, Indian tribe, or tribal organization that—

(1) has a particularly low local survival rate for cardiac arrests, or a particularly low local response rate for cardiac arrest victims; or

(2) demonstrates in its application the greatest commitment to establishing and maintaining a public access defibrillation program.

(c) USE OF FUNDS.—A State, political subdivision of a State, Indian tribe, or tribal organization that receives a grant under subsection (a) may use funds received through such grant to—

(1) purchase automated external defibrillators that have been approved, or cleared for marketing, by the Food and Drug Administration;

(2) provide automated external defibrillation and basic life support training in automated external defibrillator usage through nationally recognized courses;

(3) provide information to community members about the public access defibrillation program to be funded with the grant;

(4) provide information to the local emergency medical services system regarding the placement of automated external defibrillators in public places;

(5) produce materials to encourage private companies, including small businesses, to purchase automated external defibrillators;

(6) establish an information clearinghouse, that shall be administered by an organization that has substantial expertise in pediatric education, pediatric medicine, and electrophysiology and sudden death, that provides information to increase public access to defibrillation in schools; and

(7) further develop strategies to improve access to automated external defibrillators in public places.

(d) APPLICATION.—

(1) IN GENERAL.—To be eligible to receive a grant under subsection (a), a State, political subdivision of a State, Indian tribe, or tribal organization shall prepare and submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may reasonably require.

(2) CONTENTS.—An application submitted under paragraph (1) shall—

(A) describe the comprehensive public access defibrillation program to be funded with the grant and demonstrate how such program would make automated external defibrillation accessible and available to cardiac arrest victims in the community;

(B) contain procedures for implementing appropriate nationally recognized training courses in performing cardiopulmonary resuscitation and the use of automated external defibrillators;

(C) contain procedures for ensuring direct involvement of a licensed medical professional and coordination with the local emergency medical services system in the oversight of training and notification of incidents of the use of the automated external defibrillators;

(D) contain procedures for proper maintenance and testing of the automated external defibrillators, according to the labeling of the manufacturer;

(E) contain procedures for ensuring notification of local emergency medical services system personnel, including dispatchers, of the location and type of devices used in the public access defibrillation program; and

(F) provide for the collection of data regarding the effectiveness of the public access defibrillation program to be funded with the grant in affecting the out-of-hospital cardiac arrest survival rate.

(e) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $25,000,000 for for[7] each of fiscal years 2003 through 2014. Not more than 10 percent of amounts received under a grant awarded under this section may be used for administrative expenses.

SEC. 312A. [244a] MATERIALS AND RESOURCES TO INCREASE EDUCATION AND AWARENESS OF CARDIOMYOPATHY AMONG SCHOOL ADMINISTRATORS, EDUCATORS, AND FAMILIES.

(a) MATERIALS AND RESOURCES.—Not later than 18 months after the date of the enactment of the HEARTS Act of 2024, the Secretary, in consultation with the Director of the Centers for Dis-

[7] The words "for for" so in law.

ease Control and Prevention, shall develop public education materials and resources to be disseminated to school administrators, educators, school health professionals, coaches, families, guardians, caregivers, and other appropriate individuals. The materials and resources shall include—

(1) information on the signs, symptoms, and risk factors associated with high-risk cardiac conditions and genetic heart rhythm abnormalities that may cause sudden cardiac arrest in children, adolescents, and young adults, including—

(A) cardiomyopathy;

(B) long QT syndrome, Brugada syndrome, catecholaminergic polymorphic ventricular tachycardia, short QT syndrome, and Wolff-Parkinson-White syndrome; and

(C) other high-risk cardiac conditions, as determined by the Secretary;

(2) guidelines regarding the placement of automated external defibrillators in schools, early childhood education programs, and child care centers;

(3) training information on automated external defibrillators and cardiopulmonary resuscitation; and

(4) recommendations for how schools, early childhood education programs, and child care centers can develop and implement a cardiac emergency response plan.

(b) DISSEMINATION OF MATERIALS AND RESOURCES.—Not later than 30 months after the date of the enactment of the HEARTS Act of 2024, the Secretary shall disseminate the materials and resources developed under subsection (a) in accordance with the following:

(1) DISTRIBUTION BY STATE EDUCATIONAL AGENCIES.—The Secretary shall make available such materials and resources to State educational agencies to distribute—

(A) to school administrators, educators, school health professionals, coaches, families, guardians, caregivers, and other appropriate individuals, the information developed under subsection (a)(1);

(B) to parents, guardians, or other caregivers, the cardiomyopathy risk assessment developed pursuant to section 312B(b)(1); and

(C) to school administrators, educators, school health professionals, and coaches—

(i) the guidelines described in subsection (a)(2);

(ii) the training information described in subsection (a)(3); and

(iii) the recommendations described in subsection (a)(4).

(2) DISSEMINATION TO HEALTH DEPARTMENTS AND PROFESSIONALS.—The Secretary shall make available the materials and resources developed under subsection (a) to State and local health departments, pediatricians, hospitals, and other health professionals, such as nurses and first responders.

(3) POSTING ON WEBSITE.—

(A) CDC.—

(i) IN GENERAL.—The Secretary, through the Director, shall post the materials and resources developed under subsection (a) on the public Internet website of the Centers for Disease Control and Prevention.

(ii) ADDITIONAL INFORMATION.—The Director is encouraged to maintain on such public Internet website such additional information regarding cardiomyopathy as deemed appropriate by the Director.

(B) STATE EDUCATIONAL AGENCIES.—State educational agencies are encouraged to create public Internet webpages dedicated to cardiomyopathy and post the materials and resources developed under subsection (a) on such webpages.

(c) DEFINITIONS.—In this section:

(1) The term "cardiomyopathy" means a heart disease that affects the heart's muscle (myocardium)—

(A) the symptoms of which may vary from case to case, including—

(i) cases in which no symptoms are present (asymptomatic); and

(ii) cases in which there are symptoms of a progressive condition that may result from an impaired ability of the heart to pump blood, such as fatigue, irregular heartbeats (arrhythmia), heart failure, and, potentially, sudden cardiac death; and

(B) the recognized types of which include dilated, hypertrophic, restrictive, arrhythmogenic right ventricular dysplasia, and left ventricular non-compaction.

(2) The term "Director" means the Director of the Centers for Disease Control and Prevention.

(3) The terms "early childhood education program", "elementary school", and "secondary school" have the meanings given to those terms in section 8101 of the Elementary and Secondary Education Act of 1965.

(4) The term "school administrator" means a principal, director, manager, or other supervisor or leader within an elementary school, secondary school, State-based early childhood education program, or child care center.

(5) The term "school health professional" means a health professional serving at an elementary school, secondary school, State-based early childhood education program, or child care center.

SEC. 312B. [244b] ACTIVITIES RELATING TO CARDIOMYOPATHY.

(a) REPORT ON CDC NATIONAL CARDIOMYOPATHY ACTIVITIES.—

(1) IN GENERAL.—Not later than 18 months after the date of the enactment of the HEARTS Act of 2024, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall submit to Congress a report on findings generated from existing activities conducted by the Centers for Disease Control and Prevention to improve the understanding of the prevalence and epidemiology of cardiomyopathy across

the lifespan, from birth to adulthood, with particular interest in the following:

(A) The natural history of individuals with cardiomyopathy, in both the pediatric and adult population.

(B) Estimates of cardiomyopathy-related emergency department visits and hospitalizations, in both the pediatric and adult population.

(2) PUBLIC ACCESS.—Subject to paragraph (3), the report submitted under this subsection shall be made available to the public.

(3) PRIVACY PROTECTIONS.—The Secretary shall ensure that this subsection is carried out in a manner that complies with all applicable privacy laws under Federal and State law.

(b) IMPROVING RISK ASSESSMENTS FOR INDIVIDUALS WITH CARDIOMYOPATHY.—

(1) IN GENERAL.—The Secretary shall develop and make publicly available a cardiomyopathy risk assessment for health care providers and individuals. Such risk assessment shall, at a minimum, include the following:

(A) Background information on the prevalence, incidence, and health impact of cardiomyopathy, including all forms of cardiomyopathy and their effects on pediatric, adolescent, and adult individuals.

(B) A worksheet with variables and conditions for an individual or health care provider to use in assessing whether an individual is at risk for cardiomyopathy.

(C) A worksheet with variables and stages of progression for an individual or health care provider to use in assessing whether and to what extent cardiomyopathy has progressed in an individual.

(D) Guidelines on cardiomyopathy screenings for individuals who are at risk for, or have a family history of, cardiomyopathy.

(2) STAKEHOLDER INPUT.—In carrying out paragraph (1), the Director of the Centers for Disease Control and Prevention shall seek input from external stakeholders including—

(A) representatives from national patient advocacy organizations expert in all forms of cardiomyopathy;

(B) representatives from medical professional societies that specialize in the care of adults and pediatrics with cardiomyopathy; and

(C) representatives from other relevant Federal agencies.

(c) DEFINITION.—In this section, the term "cardiomyopathy" has the meaning given to such term in section 312A.

SEC. 312C. [244c] CARDIOMYOPATHY RESEARCH.

(a) IN GENERAL.—The Secretary, in consultation with the Director of the National Institutes of Health, may expand and coordinate research and related activities of the National Institutes of Health with respect to cardiomyopathy, which may include research with respect to—

(1) causation of cardiomyopathy, including genetic causes and molecular biomarkers;

(2) long-term health outcomes in individuals with cardiomyopathy, including infants, children, teenagers, adults, and elderly individuals; and

(3) studies using longitudinal data and retrospective analysis to identify effective treatments and outcomes for individuals with cardiomyopathy.

(b) NONDUPLICATION.—The Secretary shall ensure that any research and activities related to cardiomyopathy under this section do not unnecessarily duplicate activities, programs, or efforts of other agencies and offices within the Department of Health and Human Services.

(c) NIH REPORT.—Not later than 18 months after the date of the enactment of the HEARTS Act of 2024, the Secretary, in consultation with the Director of the National Institutes of Health, shall submit to Congress a report—

(1) outlining the ongoing research efforts of the National Institutes of Health regarding cardiomyopathy; and

(2) identifying—

(A) a research agenda regarding adult forms of cardiomyopathy;

(B) plans for researching cardiomyopathy affecting the pediatric population; and

(C) the areas of greatest need for such research.

(d) CARDIOMYOPATHY DEFINED.—In this section, the term "cardiomyopathy" has the meaning given to such term in section 312A.

SEC. 312D. [244d] PROMOTING STUDENT ACCESS TO AEDS AND CPR.

(a) IN GENERAL.—The Secretary may award grants to eligible entities to develop and implement a comprehensive program to promote student access to automated external defibrillators (in this section referred to as "AEDs") and cardiopulmonary resuscitation (in this section referred to as "CPR") in public elementary schools and secondary schools.

(b) USE OF FUNDS.—An eligible entity receiving a grant under subsection (a) may use funds received through such grant to carry out any of the following activities:

(1) Developing and providing comprehensive materials to establish AED and CPR programs in public elementary schools and secondary schools.

(2) Providing support for CPR and AED training programs in such schools for students, staff, and related sports volunteers.

(3) Providing support for developing a cardiac emergency response plan within such schools.

(4) Purchasing AEDs that have been approved under section 515 of the Federal Food, Drug, and Cosmetic Act, cleared under section 510(k) of such Act, or classified under section 513(f)(2) of such Act.

(5) Purchasing necessary AED batteries and performing necessary AED maintenance (such as by replacing AED pads) in accordance with the labeling of the AED involved.

(6) Replacing old and outdated AED and CPR equipment, machinery, and educational materials.

(c) ELIGIBILITY; APPLICATION.—To be eligible for a grant under subsection (a), an entity shall—

(1) be a local educational agency (including a public charter school operating as a local educational agency under State law), in consultation with a qualified health care entity; and

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

(d) DEFINITIONS.—In this section:

(1) ESEA TERMS.—The terms "elementary school", "local educational agency", and "secondary school" have the meanings given such terms in section 8101 of the Elementary and Secondary Education Act of 1965.

(2) QUALIFIED HEALTH CARE ENTITY.—The term "qualified health care entity" means a health care entity that—

(A) is—

(i) a public entity; or

(ii) an organization that is described in section 501(c) of the Internal Revenue Code of 1986 and exempt from taxation under section 501(a) of such Code;

(B) demonstrates an ability to develop, train, and implement a comprehensive program to promote student access to defibrillation in public elementary and secondary schools; and

(C) is qualified in providing technical assistance in AED and CPR training.

SEC. 313. [245] PUBLIC AWARENESS CAMPAIGN ON THE IMPORTANCE OF VACCINATIONS.

(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention and in coordination with other offices and agencies, as appropriate, shall award competitive grants or contracts to one or more public or private entities to carry out a national, evidence-based campaign to increase awareness and knowledge of the safety and effectiveness of vaccines for the prevention and control of diseases, combat misinformation about vaccines, and disseminate scientific and evidence-based vaccine-related information, with the goal of increasing rates of vaccination across all ages, as applicable, particularly in communities with low rates of vaccination, to reduce and eliminate vaccine-preventable diseases.

(b) CONSULTATION.—In carrying out the campaign under this section, the Secretary shall consult with appropriate public health and medical experts, including the National Academy of Medicine and medical and public health associations and nonprofit organizations, in the development, implementation, and evaluation of the evidence-based public awareness campaign.

(c) REQUIREMENTS.—The campaign under this section shall—

(1) be a nationwide, evidence-based media and public engagement initiative;

(2) include the development of resources for communities with low rates of vaccination, including culturally and linguistically appropriate resources, as applicable;

(3) include the dissemination of vaccine information and communication resources to public health departments, health

care providers, and health care facilities, including such providers and facilities that provide prenatal and pediatric care;

(4) be complementary to, and coordinated with, any other Federal, State, local, or Tribal efforts, as appropriate; and

(5) assess the effectiveness of communication strategies to increase rates of vaccination.

(d) ADDITIONAL ACTIVITIES.—The campaign under this section may—

(1) include the use of television, radio, the internet, and other media and telecommunications technologies;

(2) include the use of in-person activities;

(3) be focused to address specific needs of communities and populations with low rates of vaccination; and

(4) include the dissemination of scientific and evidence-based vaccine-related information, such as—

(A) advancements in evidence-based research related to diseases that may be prevented by vaccines and vaccine development;

(B) information on vaccinations for individuals and communities, including individuals for whom vaccines are not recommended by the Advisory Committee for Immunization Practices, and the effects of low vaccination rates within a community on such individuals;

(C) information on diseases that may be prevented by vaccines; and

(D) information on vaccine safety and the systems in place to monitor vaccine safety.

(e) EVALUATION.—The Secretary shall—

(1) establish benchmarks and metrics to quantitatively measure and evaluate the awareness campaign under this section;

(2) conduct qualitative assessments regarding the awareness campaign under this section; and

(3) prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and Committee on Energy and Commerce of the House of Representatives an evaluation of the awareness campaign under this section.

(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 described in this section.

(g) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section and subsections (k) and (n) of section 317, $15,000,000 for each of fiscal years 2021 through 2025.

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)[8] 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.

(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.

[8] 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.

(B) The amount of any allotment to a State under subparagraph (A) for any fiscal year which the Secretary determines will not be required by the State, during the period for which it is available, for the purposes for which allotted shall be available for reallotment by the Secretary from time to time, on such date or dates as he may fix, to other States with respect to which such a determination has not been made, in proportion to the original allotments to such States under subparagraph (A) for such fiscal year, but with such proportionate amount for any of such other States being reduced to the extent it exceeds the sum the Secretary estimates such State needs and will be able to use during such period; and the total of such reductions shall be similarly reallotted among the States whose proportionate amounts were not so reduced. Any amount so reallotted to a State from funds appropriated pursuant to this subsection for a fiscal year shall be deemed part of its allotment under subparagraph (A) for such fiscal year.

(4) PAYMENTS TO STATES.—From each State's allotment for a fiscal year under this subsection, the State shall from time to time be paid the Federal share of the expenditures incurred during that year or the succeeding year pursuant to its State plan approved under this subsection. Such payments shall be made on the basis of estimates by the Secretary of the sums the State will need in order to perform the planning under its approved State plan under this subsection, but with such adjustments as may be necessary to take account of previously made underpayments or overpayments. The "Federal share" for any State for purposes of this subsection shall be all, or such part as the Secretary may determine, of the cost of such planning, except that in the case of the allotments for the fiscal year ending June 30, 1970, it shall not exceed 75 per centum, of such cost.

Project Grants for Areawide Health Planning

(b)(1)(A) The Secretary is authorized, during the period beginning July 1, 1966, and ending June 30, 1974, to make, with the approval of the State agency administering or supervising the administration of the State plan approved under subsection (a), project grants to any other public or nonprofit private agency or organization (but with appropriate representation of the interests of local government where the recipient of the grant is not a local government or combination thereof or an agency of such government or combination) to cover not to exceed 75 per centum of the costs of projects for developing (and from time to time revising) comprehensive regional, metropolitan area, or other local area plans for coordination of existing and planned health services, including the facilities and persons required for provision of such services; and including the provision of such services through home health care; except that in the case of project grants made in any State prior to July 1, 1968, approval of such State agency shall be required only if such State has such a State plan in effect at the time of such grants. No grant may be made under this subsection after June 30, 1970, to any agency or organization to develop or revise health plans for an area unless the Secretary determines that such agency or organization provides means for appropriate representa-

tion 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.

SEC. 315. [42 U.S.C. 247] ASSISTING VETERANS WITH MILITARY EMERGENCY MEDICAL TRAINING TO MEET REQUIREMENTS FOR BECOMING CIVILIAN HEALTH CARE PROFESSIONALS.

(a) PROGRAM.—

(1) IN GENERAL.—The Secretary may establish a program, in consultation with the Secretary of Labor, consisting of awarding demonstration grants to States to streamline State requirements and procedures in order to assist veterans who held certain military occupational specialties related to medical care or who have completed certain medical training while serving in the Armed Forces of the United States to meet certification, licensure, and other requirements applicable to civilian health care professions (such as emergency medical technician, paramedic, licensed practical nurse, registered nurse, physical therapy assistant, or physician assistant professions) in the State.

(2) CONSULTATION AND COLLABORATION.—In determining the eligible military occupational specialties or training courses and the assistance required as described in paragraph (1), the Secretary shall consult with the Secretary of Defense, the Secretary of Veterans Affairs, and the Assistant Secretary of Labor for Veterans' Employment and Training, and shall collaborate with the initiatives carried out under section 4114 of title 38, United States Code, and sections 1142 through 1144 of title 10, United States Code.

(b) USE OF FUNDS.—Amounts received as a demonstration grant under this section shall be used to—

(1) prepare and implement a plan to streamline State requirements and procedures as described in subsection (a), including by—

(A) determining the extent to which the requirements for the education, training, and skill level of civilian health care professions (such as emergency medical technicians, paramedics, licensed practical nurses, registered nurses, physical therapy assistants, or physician assistants) in the State are equivalent to requirements for the education, training, and skill level of veterans who served in medical related fields while a member of the Armed Forces of the United States; and

(B) identifying methods, such as waivers, for veterans who served in medical related fields while a member of the Armed Forces of the United States to forgo or meet any such equivalent State requirements; and

(2) if necessary to meet workforce shortages or address gaps in education, training, or skill level to meet certification, licensure or other requirements applicable to becoming a civil-

ian health care professional (such as an emergency medical technician, paramedic, licensed practical nurse, registered nurse, physical therapy assistant, or physician assistant professions) in the State, develop or expand career pathways at institutions of higher education to support veterans in meeting such requirements.

(c) REPORT.—Upon the completion of the demonstration program under this section, the Secretary shall submit to Congress a report on the program.

(d) FUNDING.—No additional funds are authorized to be appropriated for the purpose of carrying out this section. This section shall be carried out using amounts otherwise available for such purpose.

(e) SUNSET.—The demonstration program under this section shall not exceed 5 years.

FAMILY SUPPORT GROUPS FOR ALZHEIMER'S DISEASE PATIENTS

SEC. 316.[9] **[**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) a complete description of the type and extent of the program for which the applicant is seeking a grant under subsection (a);

[9] 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).

(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. Not more than 10 percent ot the total amount appropriated under the preceding sentence for any fiscal year shall be available for grants under subsection (k)(1) for such fiscal year.

(2) For grants under subsection (a) for preventive health service programs for the provision without charge of immunizations with vaccines approved for use, and recommended for routine use, there are authorized to be appropriated such sums as may be necessary.

(k)(1) The Secretary may make grants to States, political subdivisions of States, and other public and nonprofit private entities for—

(A) research into the prevention and control of diseases that may be prevented through vaccination;

(B) demonstration projects for the prevention and control of such diseases;

(C) public information and education programs for the prevention and control of such diseases;

(D) education, training, and clinical skills improvement activities in the prevention and control of such diseases for health professionals (including allied health personnel);

(E) planning, implementation, and evaluation of activities to address vaccine-preventable diseases, including activities to—

(i) identify communities at high risk of outbreaks related to vaccine-preventable diseases, including through improved data collection and analysis;

(ii) pilot innovative approaches to improve vaccination rates in communities and among populations with low rates of vaccination;

(iii) reduce barriers to accessing vaccines and evidence-based information about the health effects of vaccines;

(iv) partner with community organizations and health care providers to develop and deliver evidence-based interventions, including culturally and linguistically appropriate interventions, to increase vaccination rates;

(v) improve delivery of evidence-based vaccine-related information to parents and others; and

(vi) improve the ability of State, local, Tribal, and territorial public health departments to engage communities at high risk for outbreaks related to vaccine-preventable diseases, including, as appropriate, with local educational

agencies, as defined in section 8101 of the Elementary and Secondary Education Act of 1965; and

(F) research related to strategies for improving awareness of scientific and evidence-based vaccine-related information, including for communities with low rates of vaccination, in order to understand barriers to vaccination, improve vaccination rates, and assess the public health outcomes of such strategies.

(2) The Secretary may make grants to States, political subdivisions of States, and other public and nonprofit private entities for—

(A) research into the prevention and control of diseases and conditions;

(B) demonstration projects for the prevention and control of such diseases and conditions;

(C) public information and education programs for the prevention and control of such diseases and conditions; and

(D) education, training, and clinical skills improvement activities in the prevention and control of such diseases and conditions for health professionals (including allied health personnel).

(3) No grant may be made under this subsection unless an application therefor is submitted to the Secretary in such form, at such time, and containing such information as the Secretary may by regulation prescribe.

(4) Subsections (d), (e), and (f) shall apply to grants under this subsection in the same manner as such subsections apply to grants under subsection (a).

(l) AUTHORITY TO PURCHASE RECOMMENDED VACCINES FOR ADULTS.—

(1) IN GENERAL.—The Secretary may negotiate and enter into contracts with manufacturers of vaccines for the purchase and delivery of vaccines for adults as provided for under subsection (e).

(2) STATE PURCHASE.—A State may obtain additional quantities of such adult vaccines (subject to amounts specified to the Secretary by the State in advance of negotiations) through the purchase of vaccines from manufacturers at the applicable price negotiated by the Secretary under this subsection.

(m) DEMONSTRATION PROGRAM TO IMPROVE IMMUNIZATION COVERAGE.—

(1) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish a demonstration program to award grants to States to improve the provision of recommended immunizations for children, adolescents, and adults through the use of evidence-based, population-based interventions for high-risk populations.

(2) STATE PLAN.—To be eligible for a grant under paragraph (1), a State shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require, including a State plan that describes the interventions to be implemented under the grant and how such interventions match with local needs and capabilities, as determined through consultation with local authorities.

(3) USE OF FUNDS.—Funds received under a grant under this subsection shall be used to implement interventions that are recommended by the Task Force on Community Preventive Services (as established by the Secretary, acting through the Director of the Centers for Disease Control and Prevention) or other evidence-based interventions, including—

(A) providing immunization reminders or recalls for target populations of clients, patients, and consumers;

(B) educating targeted populations and health care providers concerning immunizations in combination with one or more other interventions;

(C) reducing out-of-pocket costs for families for vaccines and their administration;

(D) carrying out immunization-promoting strategies for participants or clients of public programs, including assessments of immunization status, referrals to health care providers, education, provision of on-site immunizations, or incentives for immunization;

(E) providing for home visits that promote immunization through education, assessments of need, referrals, provision of immunizations, or other services;

(F) providing reminders or recalls for immunization providers;

(G) conducting assessments of, and providing feedback to, immunization providers;

(H) any combination of one or more interventions described in this paragraph; or

(I) immunization information systems to allow all States to have electronic databases for immunization records.

(4) CONSIDERATION.—In awarding grants under this subsection, the Secretary shall consider any reviews or recommendations of the Task Force on Community Preventive Services.

(5) EVALUATION.—Not later than 3 years after the date on which a State receives a grant under this subsection, the State shall submit to the Secretary an evaluation of progress made toward improving immunization coverage rates among high-risk populations within the State.

(6) REPORT TO CONGRESS.—Not later than 4 years after the date of enactment of the Affordable Health Choices Act, the Secretary shall submit to Congress a report concerning the effectiveness of the demonstration program established under this subsection together with recommendations on whether to continue and expand such program.

(7) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this subsection, such sums as may be necessary for each of fiscal years 2010 through 2014.

(n) VACCINATION DATA.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall expand and enhance, and, as appropriate, establish and improve, programs and conduct activities to collect, monitor, and analyze vaccination coverage data to assess levels of protection from vaccine-preventable diseases, including by assessing factors contributing to

underutilization of vaccines and variations of such factors, and identifying communities at high risk of outbreaks associated with vaccine-preventable diseases.

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 [10], 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

[10] 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 [11].

(B) RELEVANT PROGRAMS.—The programs and functions described in this subparagraph are all programs and functions that—

(i) relate to birth defects; folic acid; cerebral palsy; intellectual disabilities; child development; newborn screening; autism; fragile X syndrome; fetal alcohol syndrome; pediatric genetic disorders; disability prevention; or other relevant diseases, disorders, or conditions as determined the Secretary; and

(ii) were carried out through the National Center for Environmental Health as of the day before the date of the enactment of the Act referred to in subparagraph (A).

(C) RELATED TRANSFERS.—Personnel employed in connection with the programs and functions specified in sub-

[11] 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 [12].

(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.

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

(3) RELATIONSHIP TO ITEMS AND SERVICES UNDER OTHER PROGRAMS.—The Secretary may not make a grant under subsection (a) unless the applicant involved agrees that the grant will not be expended to make payment for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to such item or service—

(A) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program; or

(B) by an entity that provides health services on a prepaid basis.

(4) COORDINATION WITH OTHER PROSTATE CANCER PROGRAMS.—The Secretary may not make a grant under subsection (a) unless the applicant involved agrees that the services and activities funded through the grant will be coordinated with other Federal, State, and local prostate cancer programs.

(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 [13] 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 co-

[13] So in law.

ordinated with any similar services or activities of public or nonprivate entities; and

(4) the description provides assurances that the grant funds will be used in the most cost-effective manner.

(h) REQUIREMENT OF SUBMISSION OF APPLICATION.—The Secretary may not make a grant under subsection (a) unless an application for the grant is submitted to the Secretary, the application contains the description of intended uses required in subsection (g), and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(i) METHOD AND AMOUNT OF PAYMENT.—The Secretary shall determine the amount of a grant made under subsection (a). Payments under such grants may be made in advance on the basis of estimates or by way of reimbursement, with necessary adjustments on account of the underpayments or overpayments, and in such 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).

NATIONAL STRATEGY FOR COMBATING AND ELIMINATING TUBERCULOSIS

SEC. 317E. [247b–6] (a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make grants to States, political subdivisions, and other public entities for preventive health service programs for the prevention, control, and elimination of tuberculosis.

(b) RESEARCH AND DEVELOPMENT; DEMONSTRATION PROJECTS; EDUCATION AND TRAINING.—With respect to the prevention, treatment, control, and elimination of tuberculosis, the Secretary may, directly or through grants to public or nonprofit private entities, carry out the following:

(1) Research, with priority given to research and development concerning latent tuberculosis infection, strains of tuberculosis resistant to drugs, and research concerning cases of tuberculosis that affect certain populations at risk for tuberculosis.

(2) Research and development and related activities to develop new tools for the elimination of tuberculosis, including drugs, diagnostics, vaccines, and public health interventions, such as directly observed therapy and non-pharmaceutical intervention, and methods to enhance detection and response to outbreaks of tuberculosis, including multidrug resistant tuberculosis. The Secretary is encouraged to give priority to programmatically relevant research so that new tools can be utilized in public health practice.

(3) Demonstration projects for—

(A) the development of regional capabilities to prevent, control, and eliminate tuberculosis and prevent multidrug resistant and extensively drug resistant strains of tuberculosis;

(B) the intensification of efforts to reduce health disparities in the incidence of tuberculosis;

(C) the intensification of efforts to control tuberculosis along the United States-Mexico border and among United States-Mexico binational populations, including through expansion of the scope and number of programs that—

(i) detect and treat binational cases of tuberculosis; and

(ii) treat high-risk cases of tuberculosis referred from Mexican health departments;

(D) the intensification of efforts to prevent, detect, and treat tuberculosis among foreign-born persons who are in the United States;

(E) the intensification of efforts to prevent, detect, and treat tuberculosis among populations and settings documented as having a high risk for tuberculosis; and

(F) tuberculosis detection, control, and prevention.

(4) Public information and education activities.

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

(6) Support of Centers to carry out activities under paragraphs (1) through (4).

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

(8) Develop, enhance, and expand information technologies that support tuberculosis control including surveillance and database management systems with cross-jurisdictional capabilities, which shall conform to the standards and implementation specifications for such information technologies as recommended by the Secretary.

(c) COOPERATION WITH PROVIDERS OF PRIMARY HEALTH SERVICES.—The Secretary may make a grant under subsection (a) or (b) only if the applicant for the grant agrees that, in carrying out 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.

(3) DETERMINATION OF AMOUNT OF NONFEDERAL CONTRIBUTIONS.—

(A) PRIORITY.—In awarding grants under subsection (a) or (b), the Secretary shall give highest priority to an applicant that provides assurances that the applicant will contribute non-Federal funds to carry out activities under this section, which may be provided directly or through donations from public or private entities and may be in cash or in kind, including equipment or services.

(B) FEDERAL AMOUNTS NOT TO BE INCLUDED AS CONTRIBUTIONS.—Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of non-Federal contributions as described in subparagraph (A).

(e) SUPPLIES AND SERVICES IN LIEU OF GRANT FUNDS.—

(1) IN GENERAL.—Upon the request of a grantee under subsection (a) or (b), the Secretary may, subject to paragraph (2), provide supplies, equipment, and services for the purpose of aiding the grantee in carrying out the subsection involved and,

for such purpose, may detail to the State any officer or employee of the Department of Health and Human Services.

(2) CORRESPONDING REDUCTION IN PAYMENTS.—With respect to a request described in paragraph (1), the Secretary shall reduce the amount of payments under the grant involved by an amount equal to the costs of detailing personnel and the fair market value of any supplies, equipment, or services provided by the Secretary. The Secretary shall, for the payment of expenses incurred in complying with such request, expend the amounts withheld.

(f) ADVISORY COUNCIL.—

(1) IN GENERAL.—The Secretary shall establish an advisory council to be known as the Advisory Council for the Elimination of Tuberculosis (in this subsection referred to as the "Council").

(2) DUTIES.—The Council shall provide advice and recommendations regarding the elimination of tuberculosis to the Secretary. In addition, the Council shall, with respect to eliminating such disease, provide to the Secretary and other appropriate Federal officials advice on—

(A) coordinating the activities of the Department of Health and Human Services and other Federal agencies that relate to the disease, including activities under subsection (b);

(B) responding rapidly and effectively to emerging issues in tuberculosis; and

(C) efficiently utilizing the Federal resources involved.

(3) COMPREHENSIVE PLAN.—

(A) IN GENERAL.—In carrying out paragraph (2), the Council shall make or update recommendations on the development, revision, and implementation of a comprehensive plan to eliminate tuberculosis in the United States.

(B) CONSULTATION.—In carrying out subparagraph (A), the Council may consult with appropriate public and private entities, which may, subject to the direction or discretion of the Secretary, include—

(i) individuals who are scientists, physicians, laboratorians, and other health professionals, who are not officers or employees of the Federal Government and who represent the disciplines relevant to tuberculosis elimination;

(ii) members of public-private partnerships or private entities established to address the elimination of tuberculosis;

(iii) members of national and international nongovernmental organizations whose purpose is to eliminate tuberculosis;

(iv) members from the general public who are knowledgeable with respect to tuberculosis elimination including individuals who have or have had tuberculosis; and

(v) scientists, physicians, laboratorians, and other health professionals who reside in a foreign country with a substantial incidence or prevalence of tuber-

culosis, and who represent the specialties and disciplines relevant to the research under consideration.

(C) CERTAIN COMPONENTS OF PLAN.—In carrying out subparagraph (A), the Council shall, subject to the direction or discretion of the Secretary—

(i) consider recommendations for the involvement of the United States in continuing global and cross-border tuberculosis control activities in countries where a high incidence of tuberculosis directly affects the United States; and

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

(4) BIENNIAL REPORT.—

(A) IN GENERAL.—The Council shall submit a biennial report to the Secretary, as determined necessary by the Secretary, on the activities carried under this section. Each such report shall include the opinion of the Council on the extent to which its recommendations regarding the elimination of tuberculosis have been implemented, including with respect to—

(i) activities under subsection (b); and

(ii) the national plan referred to in paragraph (3).

(B) PUBLIC.—The Secretary shall make a report submitted under subparagraph (A) public.

(5) COMPOSITION.—The Council shall be composed of—

(A) ex officio representatives from the Centers for Disease Control and Prevention, the National Institutes of Health, the United States Agency for International Development, the Agency for Healthcare Research and Quality, the Health Resources and Services Administration, the United States-Mexico Border Health Commission, and other Federal departments and agencies that carry out significant activities related to tuberculosis;

(B) State and local tuberculosis control and public health officials;

(C) individuals who are scientists, physicians, laboratorians, and other health professionals who represent disciplines relevant to tuberculosis elimination; and

(D) members of national and international nongovernmental organizations established to address the elimination of tuberculosis.

(6) STAFF, INFORMATION, AND OTHER ASSISTANCE.—The Secretary shall provide to the Council such staff, information, and other assistance as may be necessary to carry out the duties of the Council.

(g) FEDERAL TUBERCULOSIS TASK FORCE.—

(1) DUTIES.—The Federal Tuberculosis Task Force (in this subsection referred to as the "Task Force") shall provide to the Secretary and other appropriate Federal officials advice on research into new tools under subsection (b)(2), including advice regarding the efficient utilization of the Federal resources involved.

(2) COMPREHENSIVE PLAN FOR NEW TOOLS DEVELOPMENT.—In carrying out paragraph (1), the Task Force shall make rec-

ommendations on the development of a comprehensive plan for the creation of new tools for the elimination of tuberculosis, including drugs, diagnostics, and vaccines.

(3) CONSULTATION.—In developing the comprehensive plan under paragraph (1), the Task Force shall consult with external parties including representatives from groups such as—

(A) scientists, physicians, laboratorians, and other health professionals who represent the specialties and disciplines relevant to the research under consideration;

(B) members from public-private partnerships, private entities, or foundations (or both) engaged in activities relevant to research under consideration;

(C) members of national and international nongovernmental organizations established to address tuberculosis elimination;

(D) members from the general public who are knowledgeable with respect to tuberculosis including individuals who have or have had tuberculosis; and

(E) scientists, physicians, laboratorians, and other health professionals who reside in a foreign country with a substantial incidence or prevalence of tuberculosis, and who represent the specialties and disciplines relevant to the research under consideration.

(h) AUTHORIZATION OF APPROPRIATIONS.—

(1) GENERAL PROGRAM.—

(A) IN GENERAL.—For the purpose of carrying out this section, there are authorized to be appropriated $200,000,000 for fiscal year 2009, $210,000,000 for fiscal year 2010, $220,500,000 for fiscal year 2011, $231,525,000 for fiscal year 2012, and $243,101,250 for fiscal year 2013.

(B) RESERVATION FOR EMERGENCY GRANTS.—Of the amounts appropriated under subparagraph (A) for a fiscal year, the Secretary may reserve not more than 25 percent for emergency grants under subsection (a) for any geographic area, State, political subdivision of a State, or other public entity in which there is, relative to other areas, a substantial number of cases of tuberculosis, multidrug resistant tuberculosis, or extensively drug resistant tuberculosis or a substantial rate of increase in such cases.

(C) PRIORITY.—In allocating amounts appropriated under subparagraph (A), the Secretary shall give priority to allocating such amounts for grants under subsection (a).

(D) ALLOCATION OF FUNDS.—

(i) REQUIREMENT OF FORMULA.—Of the amounts appropriated under subparagraph (A), not reserved under subparagraph (B), and allocated by the Secretary for grants under subsection (a), the Secretary shall distribute a portion of such amounts to grantees under subsection (a) on the basis of a formula.

(ii) RELEVANT FACTORS.—The formula developed by the Secretary under clause (i) shall take into account the level of tuberculosis morbidity and case complexity in the respective geographic area and may con-

sider other factors relevant to tuberculosis in such area.

(iii) NO CHANGE TO FORMULA REQUIRED.—This subparagraph does not require the Secretary to modify the formula that was used by the Secretary to distribute funds to grantees under subsection (a) for fiscal year 2009.

(2) LIMITATION.—The authorization of appropriations established in paragraph (1) for a fiscal year is effective only if the amount appropriated under such paragraph for such year equals or exceeds the amount appropriated to carry out this section for fiscal year 2009.

LOAN REPAYMENT PROGRAM

SEC. 317F. [247b–7] (a) IN GENERAL.—

(1) AUTHORITY.—Subject to paragraph (2), the Secretary may carry out a program of entering into contracts with appropriately qualified health professionals under which such health professionals agree to conduct prevention activities or preparedness and response activities, including rapid response to public health emergencies and significant public health threats, as employees of the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry, in consideration of the Federal Government agreeing to repay, for each year of such service, not more than $50,000 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 2 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.—

(1) IN GENERAL.—For the purpose of carrying out this section, except as described in paragraph (2), 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.

(2) EPIDEMIC INTELLIGENCE SERVICE PROGRAM.—For purposes of carrying out this section with respect to qualified health professionals serving in the Epidemic Intelligence Service, as authorized under section 317G, there is authorized to be

appropriated $1,000,000 for each of fiscal years 2019 through 2023.

(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 activi-

ties 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 purposes of this subsection are to establish or continue a Federal initiative to support State and tribal maternal mortality review committees, to improve data collection and reporting around maternal mortality, and to develop or support 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 populations at risk of death and severe 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 continue and improve activities related to a national maternal mortality data collection and surveillance program to identify and support the review of pregnancy-associated deaths and pregnancy-related deaths that occur during, or within 1 year following, pregnancy, including improving disaggregation of data (in a manner consistent with applicable State and Federal privacy laws).

(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.

(D) The Secretary may, in cooperation with States, Indian tribes, and tribal organizations, develop a program to support States, Indian tribes, and tribal organizations in establishing or operating maternal mortality review committees, in accordance with subsection (d).

(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) prepregnancy counseling, especially for at risk populations such as women with diabetes and women with substance use disorder;

(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) the identification of the determinants of disparities in maternal care, health risks, and health outcomes, including an examination of the higher rates of maternal mortality among African American women and other groups of women with disproportionately high rates of maternal mortality;

(I) activities to reduce disparities in maternity services and outcomes;

(J) an examination of the relationship between interpersonal violence and maternal complications and mortality;

(K) preventing and reducing adverse health consequences that may result from smokingand substance abuse and misuse before, during and after pregnancy;

(L) preventing infections that cause maternal and infant complications;

(M) an examination of the relationship between maternal health and obstetric services in rural areas and outcomes in delivery and postpartum care; and

(N) other areas determined appropriate by the Secretary.

(c) PREVENTION PROGRAMS.—The Secretary may carry out activities to promote safe motherhood, including—

(1) public education campaigns on healthy pregnancies;

(2) education programs for physicians, nurses and other health care providers;

(3) activities to promote community support services for pregnant women; and

(4) activities to promote physical, mental, and behavioral health during, and up to 1 year following, pregnancy, with an emphasis on prevention of, and treatment for, mental health disorders and substance use disorder.

(d) MATERNAL MORTALITY REVIEW COMMITTEES.—

(1) IN GENERAL.—In order to participate in the program under subsection (a)(2)(D), the applicable maternal mortality review committee of the State, Indian tribe, or tribal organization shall—

(A) include multidisciplinary and diverse membership that represents a variety of clinical specialties (including obstetricians and gynecologists), State, tribal, or local public health officials, epidemiologists, statisticians, community organizations, geographic regions within the area covered by such committee, and individuals or organizations that represent the populations in the area covered by such committee that are most affected by pregnancy-related deaths or pregnancy-associated deaths and lack of access to maternal health care services; and

(B) demonstrate to the Centers for Disease Control and Prevention that such maternal mortality review committee's methods and processes for data collection and review, as required under paragraph (3), use best practices to reliably determine and include all pregnancy-associated deaths and pregnancy-related deaths, regardless of the outcome of the pregnancy.

(2) PROCESS FOR CONFIDENTIAL REPORTING.—States, Indian tribes, and tribal organizations that participate in the program described in this subsection shall, through the State maternal mortality review committee, develop a process that—

(A) provides for confidential case reporting of pregnancy-associated and pregnancy-related deaths to the appropriate State or tribal health agency, including such reporting by—

(i) health care professionals;

(ii) health care facilities;

(iii) any individual responsible for completing death records, including medical examiners and medical coroners; and

(iv) other appropriate individuals or entities; and

(B) provides for voluntary and confidential case reporting of pregnancy-associated deaths and pregnancy-related deaths to the appropriate State or tribal health agency by family members of the deceased, and other appropriate individuals, for purposes of review by the applicable maternal mortality review committee; and

(C) shall include—

(i) making publicly available contact information of the committee for use in such reporting; and

(ii) conducting outreach to local professional organizations, community organizations, and social services agencies regarding the availability of the review committee.

(3) DATA COLLECTION AND REVIEW.—States, Indian tribes, and tribal organizations that participate in the program described in this subsection shall—

(A) annually identify pregnancy-associated deaths and pregnancy-related deaths—

(i) through the appropriate vital statistics unit by—

(I) matching each death record related to a pregnancy-associated death or pregnancy-related death in the State or tribal area in the applicable

year to a birth certificate of an infant or fetal death record, if available;

(II) to the extent practicable, identifying an underlying or contributing cause of each pregnancy-associated death and each pregnancy-related death in the State or tribal area in the applicable year; and

(III) collecting data from medical examiner and coroner reports and coordinating with individuals responsible for certifying deaths to improve the collection and quality of death record reports, including by amending errors and missing or incomplete information to cause-of-death information on a death certificate, as appropriate;

(ii) using other appropriate methods or information to identify pregnancy-associated deaths and pregnancy-related deaths, including deaths from pregnancy outcomes not identified through clause (i)(I);

(B) through the maternal mortality review committee, review data and information to identify adverse outcomes that may contribute to pregnancy-associated death and pregnancy-related death, and to identify trends, patterns, and disparities in such adverse outcomes to allow the State, Indian tribe, or tribal organization to make recommendations to individuals and entities described in paragraph (2)(A), as appropriate, to improve maternal care and reduce pregnancy-associated death and pregnancy-related death;

(C) identify training available to the individuals and entities described in paragraph (2)(A) for accurate identification and reporting of pregnancy-associated and pregnancy-related deaths;

(D) ensure that, to the extent practicable, the data collected and reported under this paragraph is in a format that allows for analysis by the Centers for Disease Control and Prevention; and

(E) publicly identify the methods used to identify pregnancy-associated deaths and pregnancy-related deaths in accordance with this section.

(4) CONFIDENTIALITY.—States, Indian tribes, and tribal organizations participating in the program described in this subsection shall establish confidentiality protections to ensure, at a minimum, that—

(A) there is no disclosure by the maternal mortality review committee, including any individual members of the committee, to any person, including any government official, of any identifying information about any specific maternal mortality case; and

(B) no information from committee proceedings, including deliberation or records, is made public unless specifically authorized under State and Federal law.

(5) REPORTS TO CDC.—For fiscal year 2019, and each subsequent fiscal year, each maternal mortality review committee participating in the program described in this subsection shall

submit to the Director of the Centers for Disease Control and Prevention a report that includes—

(A) data, findings, and any recommendations of such committee; and

(B) as applicable, information on the implementation during such year of any recommendations submitted by the committee in a previous year.

(6) STATE PARTNERSHIPS.—States may partner with one or more neighboring States to carry out the activities under this subparagraph. With respect to the States in such a partnership, any requirement under this subparagraph relating to the reporting of information related to such activities shall be deemed to be fulfilled by each such State if a single such report is submitted for the partnership.

(7) APPROPRIATE MECHANISMS FOR INDIAN TRIBES AND TRIBAL ORGANIZATIONS.—The Secretary, in consultation with Indian tribes, shall identify and establish appropriate mechanisms for Indian tribes and tribal organizations to demonstrate, report data, and conduct the activities as required for participation in the program described in this subsection. Such mechanisms may include technical assistance with respect to grant application and submission procedures, and award management activities.

(8) RESEARCH AVAILABILITY.—The Secretary shall develop a process to ensure that data collected under paragraph (5) is made available, as appropriate and practicable, for research purposes, in a manner that protects individually identifiable or potentially identifiable information and that is consistent with State and Federal privacy law.

(e) BEST PRACTICES RELATING TO THE PREVENTION OF MATERNAL MORTALITY.—

(1) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall, in consultation with the Administrator of the Health Resources and Services Administration, identify and disseminate to health care providers, relevant professional societies, and perinatal quality collaboratives, best practices related to preventing maternal morbidity and mortality, taking into consideration any relevant findings from other Federal maternal health programs.

(2) FREQUENCY.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall disseminate the best practices referred to in paragraph (1) not less than once per fiscal year.

(f) DEFINITIONS.—In this section—

(1) the terms "Indian tribe" and "tribal organization" have the meanings given such terms in section 4 of the Indian Self-Determination and Education Assistance Act;

(2) the term "pregnancy-associated death" means a death of a woman, by any cause, that occurs during, or within 1 year following, her pregnancy, regardless of the outcome, duration, or site of the pregnancy; and

(3) the term "pregnancy-related death" means a death of a woman that occurs during, or within 1 year following, her

pregnancy, regardless of the outcome, duration, or site of the pregnancy—

(A) from any cause related to, or aggravated by, the pregnancy or its management; and

(B) not from accidental or incidental causes.

(g) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $100,000,000 for each of fiscal years 2026 through 2030.

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 and alcohol and other substance abuse and misuse, including—

(A) data on—

(i) the incidence, prevalence, and implications of such activities; and

(ii) the incidence and prevalence of implications and outcomes, including neonatal abstinence syndrome and other maternal and child health outcomes associated with such activities; and

(B) additional information or data, as appropriate, on family health history, medication exposures during pregnancy, demographic information, such as race, ethnicity, geographic location, and family history, and other relevant information, to inform such analysis;

(2) to conduct applied epidemiological research on the prevention and long-term outcomes associated with prenatal and postnatal smoking, alcohol and other substance abuse and misuse;

(3) to support, conduct, and evaluate the effectiveness of educational, treatment, and cessation programs;

(4) to provide information and education to the public on the prevention and implications of prenatal and postnatal smoking, alcohol and other substance abuse and misuse; and

(5) to issue public reports on the analysis of data described in paragraph (1), including analysis of—

(A) long-term outcomes of children affected by neonatal abstinence syndrome;

(B) health outcomes associated with prenatal smoking, alcohol, and substance abuse and misuse; and

(C) relevant studies, evaluations, or information the Secretary determines to be appropriate.

(b) GRANTS.—In carrying out subsection (a), the Secretary may award grants to and enter into contracts with States, local governments, tribal entities, 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) COORDINATING ACTIVITIES.—To carry out this section, the Secretary may—

(1) provide technical and consultative assistance to entities receiving grants under subsection (b);

(2) ensure a pathway for data sharing between States, tribal entities, and the Centers for Disease Control and Prevention;

(3) ensure data collection under this section is consistent with applicable State, Federal, and Tribal privacy laws; and

(4) coordinate with the National Coordinator for Health Information Technology, as appropriate, to assist States and Tribes in implementing systems that use standards recognized by such National Coordinator, as such recognized standards are available, in order to facilitate interoperability between such systems and health information technology systems, including certified health information technology.

(d) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $4,250,000 for each of fiscal years 2026 through 2030.

SEC. 317L–1. [247b–13a] SCREENING AND TREATMENT FOR MATERNAL MENTAL HEALTH AND SUBSTANCE USE DISORDERS.

(a) GRANTS.—The Secretary shall make grants to States, Indian Tribes and Tribal organizations (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act) to establish, improve, or maintain programs for screening, assessment, and treatment services, including culturally and linguistically appropriate services, as appropriate, for women who are postpartum, pregnant, or have given birth within the preceding 12 months, for maternal mental health and substance use disorders.

(b) APPLICATION.—To seek a grant under this section, an entity listed in subsection (a) shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require. At a minimum, any such application shall include explanations of—

(1) how a program, or programs, will increase the percentage of women screened and treated, as appropriate, for maternal mental health and substance use disorders in 1 or more communities; and

(2) how a program, or programs, if expanded, would increase access to screening and treatment services for maternal mental health and substance use disorders.

(c) PRIORITY.—In awarding grants under this section, the Secretary shall, as appropriate, give priority to entities listed in subsection (a) that—

(1) are proposing to create, improve, or enhance screening, prevention, and treatment services for maternal mental health and substance use disorders in primary care settings;

(2) are currently partnered with, or will partner with, one or more community-based organizations to address maternal mental health and substance use disorders;

(3) are located in, or provide services under this section in, an area with disproportionately high rates of maternal mental health or substance use disorders or other related disparities; and

(4) operate in a health professional shortage area designated under section 332, including maternity care health professional target areas.

(d) USE OF FUNDS.—The activities eligible for funding through a grant under subsection (a)—

(1) shall include—

(A) providing appropriate training on maternal mental health and substance use disorder screening, brief intervention, treatment (as applicable for health care providers), and referrals for treatment to health care providers in the primary care setting and, as applicable, relevant health paraprofessionals;

(B) providing information on maternal mental health and substance use disorder screening, brief intervention, treatment (as applicable for health care providers) and referrals for treatment, follow-up support services, and linkages to community-based resources to health care providers in the primary care setting and, as applicable, relevant health paraprofessionals; and

(C) to the extent practicable and appropriate, enabling health care providers (such as obstetrician-gynecologists, nurse practitioners, nurse midwives, pediatricians, psychiatrists, mental and other behavioral health care providers, and adult primary care clinicians) to provide or receive real-time psychiatric consultation (in-person or remotely), including through the use of technology-enabled collaborative learning and capacity building models (as defined in section 330N), to aid in the treatment of pregnant and postpartum women; and

(2) may include—

(A) establishing linkages with and among community-based resources, including mental health resources, primary care resources, and support groups;

(B) utilizing telehealth services, including for rural areas and medically underserved areas (as defined in section 330I(a));

(C) providing assistance to pregnant and postpartum women to receive maternal mental health and substance use disorder treatment, including patient consultation, care coordination, and navigation for such treatment;

(D) coordinating, as appropriate, with maternal and child health programs of State, local, and Tribal governments, including child psychiatric access programs;

(E) conducting public outreach and awareness regarding grants under subsection (a);

(F) creating multistate consortia to carry out the activities required or authorized under this subsection; and

(G) training health care providers in the primary care setting and relevant health paraprofessionals on trauma-informed care, culturally and linguistically appropriate services, and best practices related to training to improve the provision of maternal mental health and substance use disorder care for racial and ethnic minority populations and reduce related disparities in the delivery of such care.

(e) TECHNICAL ASSISTANCE.—The Secretary shall provide technical assistance to grantees and entities listed in subsection (a) for carrying out activities pursuant to this section.

(f) DISSEMINATION OF BEST PRACTICES.—The Secretary, based on evaluation of the activities funded pursuant to this section, shall identify and disseminate evidence-based or evidence-informed practices for screening, assessment, treatment, and referral to treatment services for maternal mental health and substance use disorders, including culturally and linguistically appropriate services, for women during pregnancy and 12 months following pregnancy.

(g) MATCHING REQUIREMENT.—The Federal share of the cost of the activities for which a grant is made to an entity under subsection (a) shall not exceed 90 percent of the total cost of such activities.

(h) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $24,000,000 for each of fiscal years 2023 through 2027.

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, shall award a grant to each of the 50 States and territories and to Indians, Indian tribes, tribal organizations and urban Indian organizations (as such terms are defined in section 4 of the Indian Health Care Improvement Act) to provide for the development of school-based dental sealant programs to improve the access of children to sealants.

(2) USE OF FUNDS.—A State shall use amounts received under a grant under paragraph (1) to provide funds to eligible school-based entities or to public elementary or secondary schools to enable such entities or schools to provide children with access to dental care and dental sealant services. Such services shall be provided by licensed dental health professionals in accordance with State practice licensing laws.

(3) ELIGIBILITY.—To be eligible to receive funds under paragraph (1), an entity shall—

(A) prepare and submit to the State an application at such time, in such manner and containing such information as the State may require; and

(B) be a public elementary or secondary school—

(i) that is located in an urban area in which and more than 50 percent of the student population is participating in Federal or State free or reduced meal programs; or

(ii) that is located in a rural area and, with respect to the school district in which the school is located, the district involved has a median income that is at or below 235 percent of the poverty line, as defined in section 673(2) of the Community Services Block Grant Act (42 U.S.C. 9902(2)).

(d) ORAL HEALTH INFRASTRUCTURE.—

(1) COOPERATIVE AGREEMENTS.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall enter into cooperative agreements with State, territorial, and Indian tribes or tribal organizations (as those terms are defined in section 4 of the Indian Health Care Improvement Act) to establish oral health leadership and program guidance, oral health data collection and interpretation, (including determinants of poor oral health among vulnerable populations), a multi-dimensional delivery system for oral health, and to implement science-based programs (including dental sealants and community water fluoridation) to improve oral health.

(2) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated such sums as necessary to carry out this subsection for fiscal years 2010 through 2014.

(e) DEFINITIONS.—For purposes of this section, the term "Indian tribe" means an Indian tribe or tribal organization as defined in section 4(b) and section 4(c) of the Indian Self-Determination and Education Assistance Act.

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

SEC. 317N. [247b–15] SURVEILLANCE AND EDUCATION REGARDING INFECTIONS ASSOCIATED WITH ILLICIT DRUG USE AND OTHER RISK FACTORS.

(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may (directly or through grants to public and nonprofit private entities) provide for programs for the following:

(1) To cooperate with States and Indian tribes in implementing or maintaining a national system to determine the incidence of infections commonly associated with illicit drug use, such as viral hepatitis, human immunodeficiency virus, and infective endocarditis, and to assist the States in determining the prevalence of such infections, which may include the reporting of cases of such infections.

(2) To identify, counsel, and offer testing to individuals who are at risk of infections described in paragraph (1) resulting from illicit drug use, receiving blood transfusions prior to July 1992, or 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 infections described in paragraph (1), 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 infections described in paragraph (1), including to improve coordination of treatment of substance use disorders and infectious diseases, with priority given to substance use disorder treatment providers, pediatricians and other primary care providers, obstetrician-gynecologists, and infectious disease clinicians, including HIV clinicians.

(b) LABORATORY PROCEDURES.—The Secretary may (directly or through grants to public and nonprofit private entities) carry out programs to provide for improvements in the quality of clinical-laboratory procedures regarding infections described in subsection (a)(1).

(c) DEFINITION.—In this section, the term "Indian tribe" has the meaning given that term in section 4 of the Indian Self-Determination and Education Assistance Act.

(d) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $40,000,000 for each of the fiscal years 2026 through 2030.

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 (JOHANNA'S LAW [14])

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

(1) IN GENERAL.—The Secretary, acting through the Centers for Disease Control and Prevention, shall—

[14] The typeface and casing of the parenthetical matter in the section heading appears in law with all letter cased in lowercase and in bold face type; however, it is reflect here as it should appear in light face and all small caps.

(A) enter into cooperative agreements with States and other entities to conduct sentinel surveillance or other special studies that would determine the prevalence in various age groups and populations of specific types of human papillomavirus (referred to in this section as "HPV") in different sites in various regions of the United States, through collection of special specimens for HPV using a variety of laboratory-based testing and diagnostic tools; and

(B) develop and analyze data from the HPV sentinel surveillance system described in subparagraph (A).

(2) REPORT.—The Secretary shall make a progress report to the Congress with respect to paragraph (1) no later than 1 year after the effective date of this section.

(b) PREVENTION ACTIVITIES; EDUCATION PROGRAM.—

(1) IN GENERAL.—The Secretary, acting through the Centers for Disease Control and Prevention, shall conduct prevention research on HPV, including—

(A) behavioral and other research on the impact of HPV-related diagnosis on individuals;

(B) formative research to assist with the development of educational messages and information for the public, for patients, and for their partners about HPV;

(C) surveys of physician and public knowledge, attitudes, and practices about genital HPV infection; and

(D) upon the completion of and based on the findings under subparagraphs (A) through (C), develop and disseminate educational materials for the public and health care providers regarding HPV and its impact and prevention.

(2) REPORT; FINAL PROPOSAL.—The Secretary shall make a progress report to the Congress with respect to paragraph (1) not later than 1 year after the effective date of this section, and shall develop a final report not later than 3 years after such effective date, including a detailed summary of the significant findings and problems and the best strategies to prevent future infections, based on available science.

(c) HPV EDUCATION AND PREVENTION.—

(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 Sec-

retary (including materials prepared through the Food and Drug Administration, the Centers for Disease Control and Prevention, and the Health Resources and Services Administration), or by contractors, grantees, or subgrantees thereof, that are specifically designed to address STDs including HPV shall contain medically accurate information regarding the effectiveness or lack of effectiveness of condoms in preventing the STD the materials are designed to address. Such requirement only applies to materials mass produced for the public and health care providers, and not to routine communications.

(d) JOHANNA'S LAW.—

(1) NATIONAL PUBLIC AWARENESS CAMPAIGN.—

(A) IN GENERAL.—The Secretary shall carry out a national campaign to increase the awareness and knowledge of health care providers and women with respect to gynecologic cancers.

(B) WRITTEN MATERIALS.—Activities under the national campaign under subparagraph (A) shall include—

(i) maintaining a supply of written materials that provide information to the public on gynecologic cancers; and

(ii) distributing the materials to members of the public upon request.

(C) PUBLIC SERVICE ANNOUNCEMENTS.—Activities under the national campaign under subparagraph (A) shall, in accordance with applicable law and regulations, include developing and placing, in telecommunications media, public service announcements intended to encourage women to discuss with their physicians their risks of gynecologic cancers. Such announcements shall inform the public on the manner in which the written materials referred to in subparagraph (B) can be obtained upon request, and shall call attention to early warning signs and risk factors based on the best available medical information.

(2) REPORT AND STRATEGY.—

(A) REPORT.—Not later than 6 months after the date of the enactment of this subsection, the Secretary shall submit to the Congress a report including the following:

(i) A description of the past and present activities of the Department of Health and Human Services to increase awareness and knowledge of the public with respect to different types of cancer, including gynecologic cancers.

(ii) A description of the past and present activities of the Department of Health and Human Services to increase awareness and knowledge of health care providers with respect to different types of cancer, including gynecologic cancers.

(iii) For each activity described pursuant to clause (i) or (ii), a description of the following:

(I) The funding for such activity for fiscal year 2006 and the cumulative funding for such activity for previous fiscal years.

(II) The background and history of such activity, including—

(aa) the goals of such activity;

(bb) the communications objectives of such activity;

(cc) the identity of each agency within the Department of Health and Human Services responsible for any aspect of the activity; and

(dd) how such activity is or was expected to result in change.

(III) How long the activity lasted or is expected to last.

(IV) The outcomes observed and the evaluation methods, if any, that have been, are being, or will be used with respect to such activity.

(V) For each such outcome or evaluation method, a description of the associated results, analyses, and conclusions.

(B) STRATEGY.—

(i) DEVELOPMENT; SUBMISSION TO CONGRESS.—Not later than 3 months after submitting the report required by subparagraph (A), the Secretary shall develop and submit to the Congress a strategy for improving efforts to increase awareness and knowledge of the public and health care providers with respect to different types of cancer, including gynecological cancers.

(ii) CONSULTATION.—In developing the strategy under clause (i), the Secretary should consult with qualified private sector groups, including nonprofit organizations.

(3) FULL COMPLIANCE.—

(A) IN GENERAL.—Not later than March 1, 2008, the Secretary shall ensure that all provisions of this section, including activities directed to be carried out by the Centers for Disease Control and Prevention and the Food and Drug Administration, are fully implemented and being complied with. Not later than April 30, 2008, the Secretary shall submit to Congress a report that certifies compliance with the preceding sentence and that contains a description of all activities undertaken to achieve such compliance.

(B) If the Secretary fails to submit the certification as provided for under subparagraph (A), the Secretary shall, not later than 3 months after the date on which the report is to be submitted under subparagraph (A), and every 3 months thereafter, submit to Congress an explanation as to why the Secretary has not yet complied with the first sentence of subparagraph (A), a detailed description of all actions undertaken within the month for which the report is being submitted to bring the Secretary into compliance with such sentence, and the anticipated date the Secretary expects to be in full compliance with such sentence.

(4) CONSULTATION WITH NONPROFIT GYNECOLOGIC CANCER ORGANIZATIONS.—In carrying out the national campaign under this subsection, the Secretary shall consult with nonprofit gynecologic cancer organizations, with a mission both to conquer ovarian or other gynecologic cancer and to provide outreach to State and local governments and communities, for the purpose of determining the best practices for providing gynecologic cancer information and outreach services to varied populations.

(6)[15] AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this subsection, there is authorized to be appropriated $16,500,000 for the period of fiscal years 2007 through 2009 and $18,000,000 for the period of fiscal years 2012 through 2014.

SEC. 317Q. [247b–18] SURVEILLANCE AND RESEARCH REGARDING MUSCULAR DYSTROPHY.

(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may award grants and cooperative agreements to public or nonprofit private entities (including health departments of States and political subdivisions of States, and including universities and other educational entities) for the collection, analysis, and reporting of data on Duchenne and other forms of muscular dystrophy. In making such awards, the Secretary may provide direct technical assistance in lieu of cash.

(b) NATIONAL MUSCULAR DYSTROPHY EPIDEMIOLOGY PROGRAM.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may award grants to public or nonprofit private entities (including health departments of States and political subdivisions of States, and including universities and other educational entities) for the purpose of carrying out epidemiological activities regarding Duchenne and other forms of muscular dystrophies, including collecting and analyzing information on the number, incidence, correlates, and symptoms of cases. In carrying out the preceding sentence, the Secretary shall provide for a national surveillance program and, to the extent possible, ensure that data be representative of all affected populations and shared in a timely manner. 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) DATA.—In carrying out this section, the Secretary may ensure that any data on patients that is collected as part of the Muscular Dystrophy STARnet (under a grant under this section) is regularly updated to reflect changes in patient condition over time.

(e) REPORTS AND STUDY.—

(1) ANNUAL REPORT.—Not later than 18 months after the date of the enactment of the Paul D. Wellstone Muscular Dystrophy Community Assistance, Research, and Education Amendments of 2008, and annually thereafter, the Director of

[15] So in law. There is no paragraph (5).

the Centers for Disease Control and Prevention shall submit to the appropriate committees of the Congress a report—

(A) concerning the activities carried out by MD STARnet site [16] funded under this section during the year for which the report is prepared;

(B) containing the data collected and findings derived from the MD STARnet sites each fiscal year (as funded under a grant under this section during fiscal years 2008 through 2012); and

(C) that every 2 years outlines prospective data collection objectives and strategies.

(2) TRACKING HEALTH OUTCOMES.—The Secretary may provide health outcome data on the health and survival of people with muscular dystrophy.

(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary to carry out this section.

SEC. 317R. [247b–20] FOOD SAFETY GRANTS.

(a) IN GENERAL.—The Secretary may award grants to States and Indian tribes (as defined in section 4(e) of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450b(e))) to expand participation in networks to enhance Federal, State, and local food safety efforts, including meeting the costs of establishing and maintaining the food safety surveillance, technical, and laboratory capacity needed for such participation.

(b) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $19,500,000 for fiscal year 2010, and such sums as may be necessary for each of the fiscal years 2011 through 2015.

SEC. 317S. [247b–21] MOSQUITO-BORNE DISEASES; COORDINATION GRANTS TO STATES; ASSESSMENT AND CONTROL GRANTS TO POLITICAL SUBDIVISIONS.

(a) COORDINATION GRANTS TO STATES; ASSESSMENT GRANTS TO POLITICAL SUBDIVISIONS.—

(1) IN GENERAL.—With respect to mosquito control programs to prevent and control mosquito-borne diseases (referred 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, including programs to address emerging infectious mosquito-borne diseases, and to develop, on the basis of such assessments, plans for carrying out control programs in the subdivisions or improving existing control programs.

(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 in-

[16] So in law. The term "site" probably should be "sites".

cidence, 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, including improvement, 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;

(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, including an emerging infectious mosquito-borne disease that presents a serious public health threat; or

(iv) a public health emergency due to the incidence or prevalence of a mosquito-borne disease that presents a serious public health threat;

(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)(i) is located in a State that has received a grant under subsection (a); or

(ii) that demonstrates to the Secretary that the control program is consistent with existing State mosquito control plans or policies, or other applicable State preparedness plans.

(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—

(i) extraordinary economic conditions in the political subdivision or consortium of political subdivisions involved justify the waiver; or

(ii) the geographical area covered by a political subdivision or consortium for a grant under paragraph (1) has an extreme mosquito control need due to—

(I) the size or density of the potentially impacted human population;

(II) the size or density of a mosquito population that requires heightened control; or

(III) the severity of the mosquito-borne disease, such that expected serious adverse health outcomes for the human population 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) 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 each of fiscal years 2019 through 2023.

(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 this Act and other medical and public health preparedness and response laws.

(3) FISCAL YEAR 2019 APPROPRIATIONS.—For fiscal year 2019, 50 percent or more of the funds appropriated under paragraph (1) shall be used to award grants to political subdivisions or consortia of political subdivisions under subsection (b).

SEC. 317T. [247b–22] MICROBICIDE RESEARCH.

(a) IN GENERAL.—The Director of the Centers for Disease Control and Prevention is strongly encouraged to fully implement the Centers' microbicide agenda to support research and development of microbicides for use to prevent the transmission of the human immunodeficiency virus.

(b) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary for each of fiscal years 2009 through 2013 to carry out this section.

SEC. 317U. [247b-23] NATIONAL STRATEGY AND REGIONAL CENTERS OF EXCELLENCE IN VECTOR-BORNE DISEASES.

(a) IN GENERAL.—The Secretary shall—

(1)(A) ensure the development and implementation of a national strategy to address vector-borne diseases, including tick-borne diseases, that—

(i) identifies and assesses gaps and any unnecessary duplication in federally-funded programs; and

(ii) identifies strategic goals to address such diseases and appropriate benchmarks to measure progress toward achieving such goals; and

(B) update such strategy, as appropriate; and

(2) coordinate programs and activities, including related to data collection, research, and the development of diagnostics, treatments, vaccines, and other related activities, to address vector-borne diseases, including tick-borne diseases, across the Department of Health and Human Services and with other Federal agencies or departments, as appropriate.

(b) CONSULTATION.—In carrying out subsection (a)(1), the Secretary shall consult with appropriate individuals, such as—

(1) epidemiologists with experience in vector-borne diseases;

(2) representatives of patient advocacy and research organizations that focus on vector-borne diseases, including such organizations that have demonstrated experience in related research, public health, data collection, or patient access to care;

(3) health information technology experts or other information management specialists;

(4) clinicians, entomologists, vector management professionals, public health professionals, and others with expertise in vector-borne diseases; and

(5) researchers, including researchers with experience conducting translational research.

(c) CENTERS OF EXCELLENCE.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall award grants, contracts, or cooperative agreements to institutions of higher education for the establishment or continued support of regional centers of excellence in vector-borne diseases to address vector-borne diseases, including tick-borne diseases, by—

(1) facilitating collaboration between academia and public health organizations for public health surveillance, prevention, and response activities related to vector-borne diseases, including tick-borne diseases;

(2) providing training for public health entomologists and other health care professionals, as appropriate, to address vector-borne diseases, including tick-borne diseases;

(3) conducting research to develop and validate prevention and control tools and methods, including evidence-based and innovative, evidence-informed tools and methods to anticipate and respond to disease outbreaks; or

(4) preparing for and responding to outbreaks of vector-borne diseases, including tick-borne diseases.

(d) ELIGIBILITY.—To be eligible to receive a grant, contract, or cooperative agreement under subsection (c), 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 a description of how the entity will conduct the activities described in such subsection.

(e) REPORTS.—

(1) PROGRAM SUMMARY.—An entity receiving an award under subsection (c) shall, not later than one year after receiving such award, and annually thereafter, submit to the Secretary a summary of programs and activities funded under the award.

(2) PROGRESS REPORT.—Not later than 4 years after the date of enactment of this section, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report on the progress made in addressing vector-borne diseases, including tick-borne diseases, through activities carried out under this section.

(f) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $10,000,000 for each of fiscal years 2026 through 2030.

SEC. 317V. [247b-24] ADDRESSING FACTORS RELATED TO IMPROVING HEALTH OUTCOMES.

(a) IN GENERAL.—The Secretary may, as appropriate, award grants, contracts, or cooperative agreements to eligible entities for the conduct of evidence-based or evidence-informed projects, which may include the development of networks to improve health outcomes by improving the capacity of such entities to address factors that contribute to negative health outcomes in communities.

(b) ELIGIBLE ENTITIES.—To be eligible to receive an award under this section, an entity shall—

(1)(A) be a State, local, or Tribal health department, community-based organization, Indian Tribe or Tribal organization (as such terms are defined in section 4 of the Indian Self-De-

termination and Education Assistance Act), urban Indian organization (as defined in section 4 of the Indian Health Care Improvement Act), or other public or private entity, as the Secretary determines appropriate; or

(B) be a consortia of entities described in subparagraph (A) or a public-private partnership, including a community partnership;

(2) submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary shall require;

(3) in the case of an entity other than a community-based organization, demonstrate a history of successfully working with an established community-based organization to address health outcomes; and

(4) submit a plan to conduct activities described in subsection (a) based on a community needs assessment that takes into account community input.

(c) USE OF FUNDS.—An entity described in subsection (b) shall use funds received under subsection (a), in consultation with State, local, and Tribal health departments, community-based organizations, entities serving medically underserved communities, and other entities, as applicable, for one or more of the following purposes:

(1) Supporting the implementation, evaluation, and dissemination of strategies, through evidence-informed or evidence-based programs and through the support and use of public health and health care professionals to address factors related to health outcomes.

(2) Establishing, maintaining, or improving, in consultation with State, local, or Tribal health departments, technology platforms or networks to support, in a manner that is consistent with applicable Federal and State privacy law—

(A) coordination among appropriate entities, and, as applicable and appropriate, activities to improve such coordination;

(B) information sharing on health and related social services; and

(C) technical assistance and related support for entities participating in the platforms or networks.

(3) Implementing best practices for improving health outcomes and reducing disease among underserved populations.

(4) Supporting consideration of factors related to health outcomes in preparing for, and responding to, public health emergencies, through outreach, education, research, and other relevant activities.

(d) BEST PRACTICES AND TECHNICAL ASSISTANCE.—The Secretary, in consultation with the Director of the Office of Minority Health, the National Coordinator for Health Information Technology, and the Administrator of the Administration for Community Living, may award grants, contracts, and cooperative agreements to public or nonprofit private entities, including minority serving institutions (defined, for purposes of this subsection, as institutions and programs described in section 326(e)(1) of the Higher

Education Act of 1965 and institutions described in section 371(a) of such Act of 1965), to—

(1) identify or facilitate the development of best practices to support improved health outcomes for underserved populations;

(2) provide technical assistance, training, and evaluation assistance to award recipients under subsection (a);

(3) disseminate best practices, including to award recipients under subsection (a); and

(4) leverage, establish, or operate regional centers to develop, evaluate, and disseminate effective strategies on factors related to health outcomes, including supporting research and training related to such strategies.

(e) AWARD PERIODS.—The Secretary shall issue awards under this section for periods of not more than 5 years and may issue extensions of such award periods for an additional period of up to 3 years.

(f) REPORT.—Not later than September 30, 2026, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that includes information on activities funded under this section. Such report shall include a description of—

(1) changes in the capacity of public health entities to address factors related to health outcomes in communities, including any applicable platforms or networks developed or utilized to coordinate health and related social services and any changes in workforce capacity or capabilities;

(2) improvements in health outcomes and in reducing health disparities in medically underserved communities;

(3) activities conducted to support consideration of factors related to health outcomes in preparing for, and responding to, public health emergencies, through outreach, education, and other relevant activities;

(4) communities and populations served by recipients of awards under subsection (a);

(5) activities supported under subsection (e); and

(6) other relevant activities and outcomes, as determined by the Secretary.

(g) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $35,000,000 for each of fiscal years 2023 through 2027. Of the amounts appropriated under this subsection for a fiscal year, 5 percent shall be reserved for awards under subsection (a) to Indian Tribes and Tribal organizations (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act), urban Indian organizations (as defined in section 4 of the Indian Health Care Improvement Act), and Tribal health departments.

PROJECTS AND PROGRAMS FOR THE PREVENTION AND CONTROL OF SEXUALLY TRANSMITTED DISEASES [17]

SEC. 318. [247c] (a) The Secretary may provide technical assistance to appropriate public and non-profit private entities and to scientific institutions for their research in, and training and public health programs for the prevention and control of sexually transmitted diseases.

(b) The Secretary may make grants to States, political subdivisions of States, and any other public and nonprofit private entity for—

(1) research into the prevention and control of sexually transmitted diseases;

(2) demonstration projects for the prevention and control of sexually transmitted diseases;

(3) public information and education programs for the prevention and control of such diseases; and

(4) education, training, and clinical skills improvement activities in the prevention and control of such diseases for health professionals (including allied health personnel).

(c) The Secretary is also authorized to make project grants to States and, in consultation with the State health authority, to political subdivisions of States, for—

(1) sexually transmitted diseases surveillance activities, including the reporting, screening, and followup of diagnostic tests for, and diagnosed cases of, sexually transmitted diseases;

(2) casefinding and case followup activities respecting sexually transmitted diseases, including contact tracing of infectious cases of sexually transmitted diseases and routine testing, including laboratory tests and followup systems;

(3) interstate epidemiologic referral and followup activities respecting sexually transmitted diseases; and

(4) such special studies or demonstrations to evaluate or test sexually transmitted diseases prevention and control strategies and activities as may be prescribed by the Secretary.

(d) The Secretary may make grants to States and political subdivisions of States for the development, implementation, and evaluation of innovative, interdisciplinary approaches to the prevention and control of sexually transmitted diseases.

(e)(1) For the purpose of making grants under subsections (b) through (d), there are authorized to be appropriated $85,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 through 1998.

(2) Each recipient of a grant under this section shall keep such records as the Secretary shall prescribe including records which fully disclose the amount and disposition by such recipient of the

[17] Title II of Public Law 103–333, an appropriations Act, provides (under the heading relating to the Centers for Disease Control and Prevention; see 108 Stat. 2550) in part as follows: "That funds appropriated under this heading for fiscal year 1995 and subsequent fiscal years shall be available for payment of the costs of medical care, related expenses, and burial expenses hereafter incurred by or on behalf of any person who had participated in the study of untreated syphilis initiated in Tuskegee, Alabama, in 1932, in such amounts and subject to such terms and conditions as prescribed by the Secretary of Health and Human Services and for payment, in such amounts and subject to such terms and conditions, of such costs and expenses hereafter incurred by or on behalf of such person's wife or offspring determined by the Secretary to have suffered injury or disease from syphilis contracted from such person".

proceeds of such grant, the total cost of the project or undertaking in connection with which such grant was given or used and the amount of that portion of the cost of the project or undertaking supplied by other sources, and such other records as will facilitate an effective audit.

(3) The Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of the recipients of grants under this section that are pertinent to such grants.

(4) The Secretary, at the request of a recipient of a grant under this section, may reduce such grant by the fair market value of any supplies or equipment furnished to such recipient and by the amount of pay, allowances, travel expenses, and any other costs in connection with the detail of an officer or employee of the United States to the recipient when the furnishing of such supplies or equipment or the detail of such an officer or employee is for the convenience of and at the request of such recipient and for the purpose of carrying out the program with respect to which the grant under this section is made. The amount by which any such grant is so reduced shall be available for payment by the Secretary of the costs incurred in furnishing the supplies, equipment, or personal services on which the reduction of such grant is based.

(5) All information obtained in connection with the examination, care, or treatment of any individual under any program which is being carried out with a grant made under this section shall not, without such individual's consent, be disclosed except as may be necessary to provide service to him or as may be required by a law of a State or political subdivision of a State. Information derived from any such program may be disclosed—

(A) in summary, statistical, or other form; or

(B) for clinical or research purposes;

but only if the identity of the individuals diagnosed or provided care or treatment under such program is not disclosed.

(f) Nothing in this section shall be construed to require any State or any political subdivision of a State to have a sexually transmitted diseases program which would require any person, who objects to any treatment provided under such a program, to be treated under such a program.

INFERTILITY AND SEXUALLY TRANSMITTED DISEASES

SEC. 318A. [247c–1] (a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make grants to States, political subdivisions of States, and other public or nonprofit private entities for the purpose of carrying out the activities described in subsection (c) regarding any treatable sexually transmitted disease that can cause infertility in women if treatment is not received for the disease.

(b) AUTHORITY REGARDING INDIVIDUAL DISEASES.—With respect to diseases described in subsection (a), the Secretary shall, in making a grant under such subsection, specify the particular disease or diseases with respect to which the grant is to be made. The Secretary may not make the grant unless the applicant involved

agrees to carry out this section only with respect to the disease or diseases so specified.

(c) AUTHORIZED ACTIVITIES.—With respect to any sexually transmitted disease described in subsection (a), the activities referred to in such subsection are—

(1) screening women for the disease and for secondary conditions resulting from the disease, subject to compliance with criteria issued under subsection (f);

(2) providing treatment to women for the disease;

(3) providing counseling to women on the prevention and control of the disease (including, in the case of a woman with the disease, counseling on the benefits of locating and providing such counseling to any individual from whom the woman may have contracted the disease and any individual whom the woman may have exposed to the disease);

(4) providing follow-up services;

(5) referrals for necessary medical services for women screened pursuant to paragraph (1), including referrals for evaluation and treatment with respect to acquired immune deficiency syndrome and other sexually transmitted diseases;

(6) in the case of any woman receiving services pursuant to any of paragraphs (1) through (5), providing to the partner of the woman the services described in such paragraphs, as appropriate;

(7) providing outreach services to inform women of the availability of the services described in paragraphs (1) through (6);

(8) providing to the public information and education on the prevention and control of the disease, including disseminating such information; and

(9) providing training to health care providers in carrying out the screenings and counseling described in paragraphs (1) and (3).

(d) REQUIREMENT OF AVAILABILITY OF ALL SERVICES THROUGH EACH GRANTEE.—The Secretary may make a grant under subsection (a) only if the applicant involved agrees that each activity authorized in subsection (c) will be available through the applicant. With respect to compliance with such agreement, the applicant may expend the grant to carry out any of the activities directly, and may expend the grant to enter into agreements with other public or nonprofit private entities under which the entities carry out the activities.

(e) REQUIRED PROVIDERS REGARDING CERTAIN SERVICES.—The Secretary may make a grant under subsection (a) only if the applicant involved agrees that, in expending the grant to carry out activities authorized in subsection (c), the services described in paragraphs (1) through (7) of such subsection will be provided only through entities that are State or local health departments, grantees under section 329, 330, 340A, or 1001, or are other public or nonprofit private entities that provide health services to a significant number of low-income women.

(f) QUALITY ASSURANCE REGARDING SCREENING FOR DISEASES.—For purposes of this section, the Secretary shall establish

criteria for ensuring the quality of screening procedures for diseases described in subsection (a).

(g) CONFIDENTIALITY.—The Secretary may make a grant under subsection (a) only if the applicant involved agrees, subject to applicable law, to maintain the confidentiality of information on individuals with respect to activities carried out under subsection (c).

(h) LIMITATION ON IMPOSITION OF FEES FOR SERVICES.—The Secretary may make a grant under subsection (a) only if the applicant involved agrees that, if a charge is imposed for the provision of services or activities under the grant, such charge—

(1) will be made according to a schedule of charges that is made available to the public;

(2) will be adjusted to reflect the income of the individual involved; and

(3) will not be imposed on any individual with an income of less than 150 percent of the official poverty line, as established by the Director of the Office of Management and Budget and revised by the Secretary in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1981.

(i) LIMITATIONS ON CERTAIN EXPENDITURES.—The Secretary may make a grant under subsection (a) only if the applicant involved agrees that not less than 80 percent of the grant will be expended for the purpose of carrying out paragraphs (1) through (7) of subsection (c).

(j) REPORTS TO SECRETARY.—

(1) COLLECTION OF DATA.—The Secretary may make a grant under subsection (a) only if the applicant involved agrees, with respect to any disease selected under subsection (b) for the applicant, to submit to the Secretary, for each fiscal year for which the applicant receives such a grant, a report providing—

(A) the incidence of the disease among the population of individuals served by the applicant;

(B) the number and demographic characteristics of individuals in such population;

(C) the types of interventions and treatments provided by the applicant, and the health conditions with respect to which referrals have been made pursuant to subsection (c)(5);

(D) an assessment of the extent to which the activities carried pursuant to subsection (a) have reduced the incidence of infertility in the geographic area involved; and

(E) such other information as the Secretary may require with respect to the project carried out with the grant.

(2) UTILITY AND COMPARABILITY OF DATA.—The Secretary shall carry out activities for the purpose of ensuring the utility and comparability of data collected pursuant to paragraph (1).

(k) MAINTENANCE OF EFFORT.—With respect to activities for which a grant under subsection (a) is authorized to be expended, the Secretary may make such a grant only if the applicant involved agrees to maintain expenditures of non-Federal amounts for such activities at a level that is not less than the average level of such expenditures maintained by the applicant for the 2-year period pre-

ceding 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 appro-

priated 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 or if the Secretary determines there is the significant potential for a public health emergency, to allow the Secretary to rapidly respond to the immediate needs resulting from such public health emergency or potential public health emergency. The Secretary shall plan for the expedited distribution of funds to appropriate agencies and entities. There is authorized to be appropriated to the Fund such sums as may be necessary.

(2) USES.—The Secretary may use amounts in the Fund established under paragraph (1), to—

(A) facilitate coordination between and among Federal, State, local, Tribal, and territorial entities and public and

private health care entities that the Secretary determines may be affected by a public health emergency or potential public health emergency referred to in paragraph (1) (including communication of such entities with relevant international entities, as applicable);

(B) make grants, provide for awards, enter into contracts, and conduct supportive investigations pertaining to a public health emergency or potential public health emergency, including further supporting programs under section 319C–1, 319C–2, or 319C–3;

(C) facilitate and accelerate, as applicable, advanced research and development of security countermeasures (as defined in section 319F–2), qualified countermeasures (as defined in section 319F–1), or qualified pandemic or epidemic products (as defined in section 319F–3), that are applicable to the public health emergency or potential public health emergency under paragraph (1);

(D) strengthen biosurveillance capabilities and laboratory capacity to identify, collect, and analyze information regarding such public health emergency or potential public health emergency, including the systems under section 319D;

(E) support initial emergency operations and assets related to preparation and deployment of intermittent disaster response personnel under section 2812 and the Medical Reserve Corps under section 2813;

(F) support the initial deployment and distribution of contents of the Strategic National Stockpile, as appropriate; and

(G) carry out other activities, as the Secretary determines applicable and appropriate.

(3) 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, including—

(i) the amount obligated;

(ii) the recipient or recipients of such obligated funds;

(iii) the specific response activities such obligated funds will support; and

(iv) the declared or potential public health emergency for which such funds were obligated; 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.

(4) REVIEW.—Not later than 2 years after the date of enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019, the Secretary, in coordination with the Assistant Secretary for Preparedness and Re-

sponse, shall conduct a review of the Fund under this section and provide recommendations to the Committee on Health, Education, Labor, and Pensions 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 on policies to improve such Fund for the uses described in paragraph (2).

(5) GAO REPORT.—Not later than 4 years after the date of enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019, the Comptroller General of the United States shall—

(A) conduct a review of the Fund under this section, including its uses and the resources available in the Fund; and

(B) submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on such review, including recommendations related to such review, as applicable.

(c) SUPPLEMENT NOT SUPPLANT.—Funds appropriated under this section shall be used to rapidly respond to public health emergencies or potential public health emergencies and supplement and not supplant other Federal, State, and local public funds provided for activities under this Act or funds otherwise provided for emergency response.

(d) DATA SUBMITTAL AND REPORTING DEADLINES.—In any case in which the Secretary determines that, wholly or partially as a result of a public health emergency that has been determined pursuant to subsection (a), individuals or public or private entities are unable to comply with deadlines for the submission to the Secretary of data or reports required under any law administered by the Secretary, the Secretary may, notwithstanding any other provision of law, grant such extensions of such deadlines as the circumstances reasonably require, and may waive, wholly or partially, any sanctions otherwise applicable to such failure to comply. Before or promptly after granting such an extension or waiver, the Secretary shall notify the Congress of such action and publish in the Federal Register a notice of the extension or waiver.

(e) TEMPORARY REASSIGNMENT OF STATE AND LOCAL PERSONNEL DURING A PUBLIC HEALTH EMERGENCY.—

(1) EMERGENCY REASSIGNMENT OF FEDERALLY FUNDED PERSONNEL.—Notwithstanding any other provision of law, and subject to paragraph (2), upon request by the Governor of a State or a tribal organization or such Governor or tribal organization's designee, the Secretary may authorize the requesting State or Indian tribe to temporarily reassign, for purposes of immediately addressing a public health emergency in the State or Indian tribe, State and local public health department or agency personnel funded in whole or in part through programs authorized under this Act, as appropriate.

(2) ACTIVATION OF EMERGENCY REASSIGNMENT.—

(A) PUBLIC HEALTH EMERGENCY.—The Secretary may authorize a temporary reassignment of personnel under

paragraph (1) only during the period of a public health emergency determined pursuant to subsection (a).

(B) CONTENTS OF REQUEST.—To seek authority for a temporary reassignment of personnel under paragraph (1), the Governor of a State or a tribal organization shall submit to the Secretary a request for such reassignment flexibility and shall include in the request each of the following:

(i) An assurance that the public health emergency in the geographic area of the requesting State or Indian tribe cannot be adequately and appropriately addressed by the public health workforce otherwise available.

(ii) An assurance that the public health emergency would be addressed more efficiently and effectively through the requested temporary reassignment of State and local personnel described in paragraph (1).

(iii) An assurance that the requested temporary reassignment of personnel is consistent with any applicable All-Hazards Public Health Emergency Preparedness and Response Plan under section 319C–1.

(iv) An identification of—

(I) each Federal program from which personnel would be temporarily reassigned pursuant to the requested authority; and

(II) the number of personnel who would be so reassigned from each such program.

(v) Such other information and assurances upon which the Secretary and Governor of a State or tribal organization agree.

(C) CONSIDERATION.—In reviewing a request for temporary reassignment under paragraph (1), the Secretary shall consider the degree to which the program or programs funded in whole or in part by programs authorized under this Act would be adversely affected by the reassignment.

(D) TERMINATION AND EXTENSION.—

(i) TERMINATION.—A State or Indian tribe's temporary reassignment of personnel under paragraph (1) shall terminate upon the earlier of the following:

(I) The Secretary's determination that the public health emergency no longer exists.

(II) Subject to clause (ii), the expiration of the 30-day period following the date on which the Secretary approved the State or Indian tribe's request for such reassignment flexibility.

(ii) EXTENSION OF REASSIGNMENT FLEXIBILITY.—The Secretary may extend reassignment flexibility of personnel under paragraph (1) beyond the date otherwise applicable under clause (i)(II) if the public health emergency still exists as of such date, but only if—

(I) the State or Indian tribe that submitted the initial request for a temporary reassignment

of personnel submits a request for an extension of such temporary reassignment; and

(II) the request for an extension contains the same information and assurances necessary for the approval of an initial request for such temporary reassignment pursuant to subparagraph (B).

(3) VOLUNTARY NATURE OF TEMPORARY REASSIGNMENT OF STATE AND LOCAL PERSONNEL.—

(A) IN GENERAL.—Unless otherwise provided under the law or regulation of the State or Indian tribe that receives authorization for temporary reassignment of personnel under paragraph (1), personnel eligible for reassignment pursuant to such authorization—

(i) shall have the opportunity to volunteer for temporary reassignment; and

(ii) shall not be required to agree to a temporary reassignment.

(B) PROHIBITION ON CONDITIONING FEDERAL AWARDS.—The Secretary may not condition the award of a grant, contract, or cooperative agreement under this Act on the requirement that a State or Indian tribe require that personnel eligible for reassignment pursuant to an authorization under paragraph (1) agree to such reassignment.

(4) NOTICE TO CONGRESS.—The Secretary shall give notice to the Congress in conjunction with the approval under this subsection of—

(A) any initial request for temporary reassignment of personnel; and

(B) any request for an extension of such temporary reassignment.

(5) GUIDANCE.—The Secretary shall—

(A) not later than 6 months after the enactment of this subsection, issue proposed guidance on the temporary reassignment of personnel under this subsection; and

(B) after providing notice and a 60-day period for public comment, finalize such guidance.

(6) REPORT TO CONGRESS.—Not later than 4 years after the date of enactment of the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013, the Comptroller General of the United States shall conduct an independent evaluation, and submit to the appropriate committees of the Congress a report, on temporary reassignment under this subsection, including—

(A) a description of how, and under what circumstances, such temporary reassignment has been used by States and Indian tribes;

(B) an analysis of how such temporary reassignment has assisted States and Indian tribes in responding to public health emergencies;

(C) an evaluation of how such temporary reassignment has improved operational efficiencies in responding to public health emergencies;

(D) an analysis of the extent to which, if any, Federal programs from which personnel have been temporarily reassigned have been adversely affected by the reassignment; and

(E) recommendations on how medical surge capacity could be improved in responding to public health emergencies and the impact of the reassignment flexibility under this section on such surge capacity.

(7) DEFINITIONS.—In this subsection—

(A) the terms "Indian tribe" and "tribal organization" have the meanings given such terms in section 4 of the Indian Self-Determination and Education Assistance Act; and

(B) the term "State" includes, in addition to the entities listed in the definition of such term in section 2, the Freely Associated States.

(8) SUNSET.—This subsection shall terminate on December 31, 2026.

(f) DETERMINATION WITH RESPECT TO PAPERWORK REDUCTION ACT WAIVER DURING A PUBLIC HEALTH EMERGENCY.—

(1) DETERMINATION.—If the Secretary determines, after consultation with such public health officials as may be necessary, that—

(A)(i) the criteria set forth for a public health emergency under paragraph (1) or (2) of subsection (a) has been met; or

(ii) a disease or disorder, including a novel and emerging public health threat, is significantly likely to become a public health emergency; and

(B) the circumstances of such public health emergency, or potential for such significantly likely public health emergency, including the specific preparation for and response to such public health emergency or threat, necessitate a waiver from the requirements of subchapter I of chapter 35 of title 44, United States Code (commonly referred to as the Paperwork Reduction Act),

then the requirements of such subchapter I with respect to voluntary collection of information shall not be applicable during the immediate investigation of, and response to, such public health emergency during the period of such public health emergency or the period of time necessary to determine if a disease or disorder, including a novel and emerging public health threat, will become a public health emergency as provided for in this paragraph. The requirements of such subchapter I with respect to voluntary collection of information shall not be applicable during the immediate postresponse review regarding such public health emergency if such immediate postresponse review does not exceed a reasonable length of time.

(2) TRANSPARENCY.—If the Secretary determines that a waiver is necessary under paragraph (1), the Secretary shall promptly post on the Internet website of the Department of Health and Human Services a brief justification for such waiver, the anticipated period of time such waiver will be in effect,

and the agencies and offices within the Department of Health and Human Services to which such waiver shall apply, and update such information posted on the Internet website of the Department of Health and Human Services, as applicable.

(3) EFFECTIVENESS OF WAIVER.—Any waiver under this subsection shall take effect on the date on which the Secretary posts information on the Internet website as provided for in this subsection.

(4) TERMINATION OF WAIVER.—Upon determining that the circumstances necessitating a waiver under paragraph (1) no longer exist, the Secretary shall promptly update the Internet website of the Department of Health and Human Services to reflect the termination of such waiver.

(5) LIMITATIONS.—

(A) PERIOD OF WAIVER.—The period of a waiver under paragraph (1) shall not exceed the period of time for the related public health emergency, including a public health emergency declared pursuant to subsection (a), and any immediate postresponse review regarding the public health emergency consistent with the requirements of this subsection.

(B) SUBSEQUENT COMPLIANCE.—An initiative subject to a waiver under paragraph (1) that is ongoing after the date on which the waiver expires, shall be subject to the requirements of subchapter I of chapter 35 of title 44, United States Code, and the Secretary shall ensure that compliance with such requirements occurs in as timely a manner as possible based on the applicable circumstances, but not to exceed 30 calendar days after the expiration of the applicable waiver.

(g) CERTAIN APPOINTMENTS TO SUPPORT PUBLIC HEALTH EMERGENCY RESPONSES.—

(1) IN GENERAL.—In order to support the initial response to a public health emergency declared by the Secretary under this section, the Secretary may, subject to paragraph (2) and without regard to sections 3309 through 3318 of title 5, United States Code, appoint individuals directly to positions in the Department of Health and Human Services for which the Secretary has provided public notice in order to—

(A) address a critical hiring need directly related to responding to a public health emergency declared by the Secretary under this section; or

(B) address a severe shortage of candidates that impacts the operational capacity of the Department of Health and Human Services to respond in the event of a public health emergency declared by the Secretary under this section.

(2) NUMBER OF APPOINTMENTS.—Each fiscal year in which the Secretary makes a determination of a public health emergency under subsection (a) (not including a renewal), the Secretary may directly appoint not more than—

(A) 400 individuals under paragraph (1)(A); and

(B) 100 individuals under paragraph (1)(B).

(3) COMPENSATION.—The annual rate of basic pay of an individual appointed under this subsection shall be determined in accordance with chapter 51 and subchapter III of chapter 53 of title 5, United States Code.

(4) REPORTING.—The Secretary shall establish and maintain records regarding the use of the authority under this subsection, including—

(A) the number of positions filled through such authority;

(B) the types of appointments of such positions;

(C) the titles, occupational series, and grades of such positions;

(D) the number of positions publicly noticed to be filled under such authority;

(E) the number of qualified applicants who apply for such positions;

(F) the qualification criteria for such positions; and

(G) the demographic information of individuals appointed to such positions.

(5) NOTIFICATION TO CONGRESS.—In the event the Secretary, within a single fiscal year, directly appoints more than 50 percent of the individuals allowable under either subparagraph (A) or (B) of paragraph (2), the Secretary shall, not later than 15 days after the date of such action, notify the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives. Such notification shall, in a manner that protects personal privacy, to the extent required by applicable Federal and State privacy law, at a minimum, include—

(A) information on each such appointment within such fiscal year;

(B) a description of how each such position relates to the requirements of subparagraph (A) or (B) of paragraph (1); and

(C) the additional number of personnel, if any, the Secretary anticipates to be necessary to adequately support a response to a public health emergency declared under this section using the authorities described in paragraph (1) within such fiscal year.

(6) REPORTS TO CONGRESS.—Not later than September 30, 2023, and annually thereafter for each fiscal year in which the authority under this subsection is used, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report describing the total number of appointments filled under this subsection within the fiscal year and a description of how the positions relate to the requirements of subparagraph (A) or (B) of paragraph (1).

(7) SUNSET.—The authority under this subsection shall expire on September 30, 2028.

(h) STOCKPILE DEPLETION REPORTING.—The Secretary shall, not later than 30 days after the deployment of contents of the Strategic National Stockpile under section 319F–2(a) to respond to a

public health emergency declared by the Secretary under this section or an emergency or major disaster declared by the President under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, and every 30 days thereafter until the expiration or termination of such public health emergency, emergency, or major disaster, submit a report to the Committee on Health, Education, Labor, and Pensions 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 on—

(1) the deployment of the contents of the stockpile in response to State, local, and Tribal requests;

(2) the amount of such products that remain within the stockpile following such deployment; and

(3) plans to replenish such products, as appropriate, including related timeframes and any barriers or limitations to replenishment.

SEC. 319A. [247d–1] VACCINE TRACKING AND DISTRIBUTION.

(a) TRACKING.—The Secretary, together with relevant manufacturers, wholesalers, and distributors as may agree to cooperate, may track the initial distribution of federally purchased influenza vaccine in an influenza pandemic, or other federally purchased vaccine to address another pandemic. Such tracking information shall be used to inform Federal, State, local, and tribal decision makers during an influenza pandemic or other pandemic.

(b) DISTRIBUTION.—The Secretary shall promote communication between State, local, and tribal public health officials and such manufacturers, wholesalers, and distributors as agree to participate, regarding the effective distribution of seasonal influenza vaccine. Such communication shall include estimates of high priority populations, as determined by the Secretary, in State, local, and tribal jurisdictions in order to inform Federal, State, local, and tribal decision makers during vaccine shortages and supply disruptions.

(c) CONFIDENTIALITY.—The information submitted to the Secretary or its contractors, if any, under this section or under any other section of this Act related to vaccine distribution information shall remain confidential in accordance with the exception from the public disclosure of trade secrets, commercial or financial information, and information obtained from an individual that is privileged and confidential, as provided for in section 552(b)(4) of title 5, United States Code, and subject to the penalties and exceptions under sections 1832 and 1833 of title 18, United States Code, relating to the protection and theft of trade secrets, and subject to privacy protections that are consistent with the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996. None of such information provided by a manufacturer, wholesaler, or distributor shall be disclosed without its consent to another manufacturer, wholesaler, or distributor, or shall be used in any manner to give a manufacturer, wholesaler, or distributor a proprietary advantage.

(d) GUIDELINES.—The Secretary, in order to maintain the confidentiality of relevant information and ensure that none of the information contained in the systems involved may be used to pro-

vide proprietary advantage within the vaccine market, while allowing State, local, and tribal health officials access to such information to maximize the delivery and availability of vaccines to high priority populations, during times of influenza pandemics or other pandemics, vaccine shortages, and supply disruptions, in consultation with manufacturers, distributors, wholesalers and State, local, and tribal health departments, shall develop guidelines for subsections (a) and (b).

(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, $30,800,000 for each of fiscal years 2019 through 2023.

(f) REPORT TO CONGRESS.—As part of the National Health Security Strategy described in section 2802, the Secretary shall provide an update on the implementation of subsections (a) through (d).

SEC. 319B. [247d-2] EARLIER DEVELOPMENT OF DIAGNOSTIC TESTS.

The Secretary may contract with public and private entities, as appropriate, to increase capacity in the rapid development, validation, manufacture, and dissemination of diagnostic tests, as appropriate, to State, local, and Tribal health departments and other appropriate entities for immediate public health response activities to address an emerging infectious disease with respect to which a public health emergency is declared under section 319, or that has significant potential to cause such a public health emergency.

SEC. 319C–1. [247d–3a] IMPROVING STATE AND LOCAL PUBLIC HEALTH SECURITY.[18]

(a) IN GENERAL.—To enhance the security of the United States with respect to public health emergencies, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall award cooperative agreements to eligible entities to enable such entities to conduct the activities described in subsection (d).

(b) ELIGIBLE ENTITIES.—To be eligible to receive an award under subsection (a), an entity shall—

(1)(A) be a State;

(B) be a political subdivision determined by the Secretary to be eligible for an award under this section (based on criteria described in subsection (h)(4)); or

(C) be a consortium of States; and

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

(A) an All-Hazards Public Health Emergency Preparedness and Response Plan which shall include—

(i) a description of the activities such entity will carry out under the agreement to meet the goals identified under section 2802, including with respect to chemical, biological, radiological, or nuclear threats, whether naturally occurring, unintentional, or deliberate;

[18] Former sections 319B and 319C were repealed by section 204(b)(1) of Public Law 109–417 (120 Stat. 2951).

(ii) a description of the activities such entity will carry out with respect to pandemic influenza, as a component of the activities carried out under clause (i), and consistent with the requirements of paragraphs (2) and (5) of subsection (g);

(iii) preparedness and response strategies and capabilities that take into account the medical and public health needs of at-risk individuals in the event of a public health emergency;

(iv)[19] a description of the mechanism the entity will implement to utilize the Emergency Management Assistance Compact, or other mutual aid agreement, for medical and public health mutual aid, and, as appropriate, the activities such entity will implement pursuant to section 319I to improve enrollment and coordination of volunteer health care professionals seeking to provide medical services during a public health emergency, which may include—

(I) providing a public method of communication for purposes of volunteer coordination (such as a phone number);

(II) providing for optional registration to participate in volunteer services during processes related to State medical licensing, registration, or certification or renewal of such licensing, registration, or certification; or

(III) other mechanisms as the State determines appropriate;

(v) a description of how the entity will include the State Unit on Aging in public health emergency preparedness;

(vi) a description of how, as appropriate, the entity may partner with relevant public and private stakeholders, including public health agencies with specific expertise that may be relevant to public health security, such as environmental health agencies, in public health emergency preparedness and response;

(vii) a description of how, as applicable, such entity may integrate information to account for individuals with behavioral health needs during and following a public health emergency;

(viii) a description of how the entity, as applicable and appropriate, will coordinate with State emergency preparedness and response plans in public health emergency preparedness, including State education agencies (as defined in section 8101 of the Elementary and Secondary Education Act of 1965), State child care lead agencies (designated under section 658D of the Child Care and Development Block Grant Act of 1990), and other relevant State agencies

(ix) in the case of entities that operate on the United States-Mexico border or the United States-

[19] Margin for clause (iv) is so in law.

Canada border, a description of the activities such entity will carry out under the agreement that are specific to the border area including disease detection, identification, investigation, and preparedness and response activities related to emerging diseases and infectious disease outbreaks whether naturally occurring or due to bioterrorism, consistent with the requirements of this section;

(x) a description of any activities that such entity will use to analyze real-time clinical specimens for pathogens of public health or bioterrorism significance, including any utilization of poison control centers;

(xi) a description of how the entity will partner with health care facilities, including hospitals and nursing homes and other long-term care facilities, to promote and improve public health preparedness and response;

(xii) a description of how the entity will provide technical assistance to improve public health preparedness and response, as appropriate, to agencies or other entities that operate facilities within the entity's jurisdiction in which there is an increased risk of infectious disease outbreaks in the event of a public health emergency declared under section 319, such as residential care facilities, group homes, and other similar settings; and

(xiii) a description of how, as appropriate and practicable, the entity will include critical infrastructure partners, such as utility companies within the entity's jurisdiction, in planning pursuant to this subparagraph to help ensure that critical infrastructure will remain functioning during, or return to function as soon as practicable after, a public health emergency;

(B) an assurance that the entity will report to the Secretary on an annual basis (or more frequently as determined by the Secretary) on the evidence-based benchmarks and objective standards established by the Secretary to evaluate the preparedness and response capabilities of such entity under subsection (g);

(C) an assurance that the entity will conduct, on at least an annual basis, an exercise or drill that meets any criteria established by the Secretary to test the preparedness and response capabilities of such entity, including addressing the needs of at-risk individuals, and that the entity will report back to the Secretary within the application of the following year on the strengths and weaknesses identified through such exercise or drill, and corrective actions taken to address material weaknesses;

(D) an assurance that the entity will require relevant staff to complete relevant preparedness and response trainings, including trainings related to efficient and effective operation during an incident or event within an Incident Command System;

(E) an assurance that the entity will provide to the Secretary the data described under section 319D(c)(3) as determined feasible by the Secretary;

(F) an assurance that the entity will conduct activities to inform and educate the hospitals within the jurisdiction of such entity on the role of such hospitals in the plan required under subparagraph (A);

(G) an assurance that the entity, with respect to the plan described under subparagraph (A), has developed and will implement an accountability system to ensure that such entity makes satisfactory annual improvement and describes such system in the plan under subparagraph (A);

(H) a description of the means by which to obtain public comment and input on the plan described in subparagraph (A) and on the implementation of such plan, that shall include an advisory committee or other similar mechanism for obtaining comment from the public and from other State, local, and tribal stakeholders; and

(I) as relevant, a description of the process used by the entity to consult with local departments of public health to reach consensus, approval, or concurrence on the relative distribution of amounts received under this section.

(c) LIMITATION.—Beginning in fiscal year 2009, the Secretary may not award a cooperative agreement to a State unless such State is a participant in the Emergency System for Advance Registration of Volunteer Health Professionals described in section 319I.

(d) USE OF FUNDS.—

(1) IN GENERAL.—An award under subsection (a) shall be expended for activities to achieve the preparedness goals described under paragraphs (1), (2), (4), (5), and (6) of section 2802(b).

(2) EFFECT OF SECTION.—Nothing in this subsection may be construed as establishing new regulatory authority or as modifying any existing regulatory authority.

(e) COORDINATION WITH LOCAL RESPONSE CAPABILITIES.—An entity shall, to the extent practicable, ensure that activities carried out under an award under subsection (a) are coordinated with activities of relevant Metropolitan Medical Response Systems, local public health departments, the Cities Readiness Initiative, local emergency plans, and any regional health care emergency preparedness and response system established pursuant to the applicable guidelines under section 319C–3.

(f) CONSULTATION WITH HOMELAND SECURITY.—In making awards under subsection (a), the Secretary shall consult with the Secretary of Homeland Security to—

(1) ensure maximum coordination of public health and medical preparedness and response activities with the Metropolitan Medical Response System, and other relevant activities;

(2) minimize duplicative funding of programs and activities; and

(3) analyze activities, including exercises and drills, conducted under this section to develop recommendations and guidance on best practices for such activities.

(g) ACHIEVEMENT OF MEASURABLE EVIDENCE-BASED BENCHMARKS AND OBJECTIVE STANDARDS.—

(1) IN GENERAL.—Not later than 180 days after the date of enactment of the Pandemic and All-Hazards Preparedness Act, the Secretary shall develop or where appropriate adopt, and require the application of, measurable evidence-based benchmarks and objective standards that measure levels of preparedness with respect to the activities described in this section and with respect to activities described in section 319C–2. In developing such benchmarks and standards, the Secretary shall consult with and seek comments from State, local, and tribal officials and private entities, as appropriate. Where appropriate, the Secretary shall incorporate existing objective standards. Such benchmarks and standards shall—

(A) include outcome goals representing operational achievements of the National Preparedness Goals developed under section 2802(b) with respect to all-hazards, including chemical, biological, radiological, or nuclear threats; and

(B) at a minimum, require entities to—

(i) measure progress toward achieving the outcome goals; and

(ii) at least annually, test, exercise, and rigorously evaluate the public health and medical emergency preparedness and response capabilities of the entity, and report to the Secretary on such measured and tested capabilities and measured and tested progress toward achieving outcome goals, based on criteria established by the Secretary.

(2) CRITERIA FOR PANDEMIC INFLUENZA PLANS.—

(A) IN GENERAL.—Not later than 180 days after the date of enactment of the Pandemic and All-Hazards Preparedness Act, the Secretary shall develop and disseminate to the chief executive officer of each State criteria for an effective State plan for responding to pandemic influenza. The Secretary shall periodically update, as necessary and appropriate, such pandemic influenza plan criteria and shall require the integration of such criteria into the benchmarks and standards described in paragraph (1).

(B) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to require the duplication of Federal efforts with respect to the development of criteria or standards, without regard to whether such efforts were carried out prior to or after the date of enactment of this section.

(3) TECHNICAL ASSISTANCE.—The Secretary shall, as determined appropriate by the Secretary, provide to a State, upon request, technical assistance in meeting the requirements of this section, including the provision of advice by experts in the development of high-quality assessments, the setting of State objectives and assessment methods, the development of measures of satisfactory annual improvement that are valid and reliable, and other relevant areas.

(4) NOTIFICATION OF FAILURES.—The Secretary shall develop and implement a process to notify entities that are deter-

mined by the Secretary to have failed to meet the requirements of paragraph (1) or (2). Such process shall provide such entities with the opportunity to correct such noncompliance. An entity that fails to correct such noncompliance shall be subject to paragraph (5).

(5) WITHHOLDING OF AMOUNTS FROM ENTITIES THAT FAIL TO ACHIEVE BENCHMARKS OR SUBMIT INFLUENZA PLAN.—Beginning with fiscal year 2019, and in each succeeding fiscal year, the Secretary shall—

(A) withhold from each entity that has failed substantially to meet the benchmarks and performance measures described in paragraph (1) for either of the 2 immediately preceding fiscal years (beginning with fiscal year 2018), pursuant to the process developed under paragraph (4), the amount described in paragraph (6); and

(B) withhold from each entity that has failed to submit to the Secretary a plan for responding to pandemic influenza that meets the criteria developed under paragraph (2), the amount described in paragraph (6).

(6) AMOUNTS DESCRIBED.—

(A) IN GENERAL.—The amounts described in this paragraph are the following amounts that are payable to an entity for activities described in this section or section 319C–2:

(i) For no more than one of each of the first 2 fiscal years immediately following a fiscal year in which an entity experienced a failure described in subparagraph (A) or (B) of paragraph (5), an amount equal to 10 percent of the amount the entity was eligible to receive for the respective fiscal year.

(ii) For no more than one of the first 2 fiscal years immediately following the third consecutive fiscal year in which an entity experienced such a failure, in lieu of applying clause (i), an amount equal to 15 percent of the amount the entity was eligible to receive for the respective fiscal year.

(B) SEPARATE ACCOUNTING.—Each failure described in subparagraph (A) or (B) of paragraph (5) shall be treated as a separate failure for purposes of calculating amounts withheld under subparagraph (A).

(7) REALLOCATION OF AMOUNTS WITHHELD.—

(A) IN GENERAL.—The Secretary shall make amounts withheld under paragraph (6) available for making awards under section 319C–2 to entities described in subsection (b)(1) of such section.

(B) PREFERENCE IN REALLOCATION.—In making awards under section 319C–2 with amounts described in subparagraph (A), the Secretary shall give preference to eligible entities (as described in section 319C–2(b)(1)) that are located in whole or in part in States from which amounts have been withheld under paragraph (6).

(8) WAIVE OR REDUCE WITHHOLDING.—The Secretary may waive or reduce the withholding described in paragraph (6), for a single entity or for all entities in a fiscal year, if the Sec-

retary determines that mitigating conditions exist that justify the waiver or reduction.

(h) FUNDING.—

(1) AUTHORIZATION OF APPROPRIATIONS.—

(A) IN GENERAL.—For the purpose of carrying out this section, there is authorized to be appropriated $685,000,000 for each of fiscal years 2019 through 2023 for awards pursuant to paragraph (3) (subject to the authority of the Secretary to make awards pursuant to paragraphs (4) and (5)).

(B) REQUIREMENT FOR STATE MATCHING FUNDS.—Beginning in fiscal year 2009, in the case of any State or consortium of two or more States, the Secretary may not award a cooperative agreement under this section unless the State or consortium of States agree that, with respect to the amount of the cooperative agreement awarded by the Secretary, the State or consortium of States will make available (directly or through donations from public or private entities) non-Federal contributions in an amount equal to—

(i) for the first fiscal year of the cooperative agreement, not less than 5 percent of such costs ($1 for each $20 of Federal funds provided in the cooperative agreement); and

(ii) for any second fiscal year of the cooperative agreement, and for any subsequent fiscal year of such cooperative agreement, not less than 10 percent of such costs ($1 for each $10 of Federal funds provided in the cooperative agreement).

(C) DETERMINATION OF AMOUNT OF NON-FEDERAL CONTRIBUTIONS.—As determined by the Secretary, non-Federal contributions required in subparagraph (B) may be provided directly or through donations from public or private entities and may be in cash or in kind, fairly evaluated, including plant, equipment or services. Amounts provided by the Federal government, or services assisted or subsidized to any significant extent by the Federal government, may not be included in determining the amount of such non-Federal contributions.

(2) MAINTAINING STATE FUNDING.—

(A) IN GENERAL.—An entity that receives an award under this section shall maintain expenditures for public health security at a level that is not less than the average level of such expenditures maintained by the entity for the preceding 2 year period.

(B) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to prohibit the use of awards under this section to pay salary and related expenses of public health and other professionals employed by State, local, or tribal public health agencies who are carrying out activities supported by such awards (regardless of whether the primary assignment of such personnel is to carry out such activities).

(3) DETERMINATION OF AMOUNT.—

(A) IN GENERAL.—The Secretary shall award cooperative agreements under subsection (a) to each State or consortium of 2 or more States that submits to the Secretary an application that meets the criteria of the Secretary for the receipt of such an award and that meets other implementation conditions established by the Secretary for such awards

(B) BASE AMOUNT.—In determining the amount of an award pursuant to subparagraph (A) for a State, the Secretary shall first determine an amount the Secretary considers appropriate for the State (referred to in this paragraph as the "base amount"), except that such amount may not be greater than the minimum amount determined under subparagraph (D).

(C) INCREASE ON BASIS OF POPULATION.—After determining the base amount for a State under subparagraph (B), the Secretary shall increase the base amount by an amount equal to the product of—

(i) the amount appropriated under paragraph (1)(A) for the fiscal year, less an amount equal to the sum of all base amounts determined for the States under subparagraph (B), and less the amount, if any, reserved by the Secretary under paragraphs (4) and (5); and

(ii) subject to paragraph (4)(C), the percentage constituted by the ratio of an amount equal to the population of the State over an amount equal to the total population of the States (as indicated by the most recent data collected by the Bureau of the Census).

(D) MINIMUM AMOUNT.—Subject to the amount appropriated under paragraph (1)(A), an award pursuant to subparagraph (A) for a State shall be the greater of the base amount as increased under subparagraph (C), or the minimum amount under this subparagraph. The minimum amount under this subparagraph is—

(i) in the case of each of the several States, the District of Columbia, and the Commonwealth of Puerto Rico, an amount equal to the lesser of—

(I) $5,000,000; or

(II) if the amount appropriated under paragraph (1)(A) is less than $667,000,000, an amount equal to 0.75 percent of the amount appropriated under such paragraph, less the amount, if any, reserved by the Secretary under paragraphs (4) and (5); or

(ii) in the case of each of American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, and the Virgin Islands, an amount determined by the Secretary to be appropriate, except that such amount may not exceed the amount determined under clause (i).

(4) CERTAIN POLITICAL SUBDIVISIONS.—

(A) IN GENERAL.—For fiscal year 2007, the Secretary may, before making awards pursuant to paragraph (3) for

such year, reserve from the amount appropriated under paragraph (1) for the year an amount determined necessary by the Secretary to make awards under subsection (a) to political subdivisions that have a substantial number of residents, have a substantial local infrastructure for responding to public health emergencies, and face a high degree of risk from bioterrorist attacks or other public health emergencies. Not more than three political subdivisions may receive awards pursuant to this subparagraph.

(B) COORDINATION WITH STATEWIDE PLANS.—An award pursuant to subparagraph (A) may not be made unless the application of the political subdivision involved is in coordination with, and consistent with, applicable Statewide plans described in subsection (b).

(C) RELATIONSHIP TO FORMULA GRANTS.—In the case of a State that will receive an award pursuant to paragraph (3), and in which there is located a political subdivision that will receive an award pursuant to subparagraph (A), the Secretary shall, in determining the amount under paragraph (3)(C) for the State, subtract from the population of the State an amount equal to the population of such political subdivision.

(D) CONTINUITY OF FUNDING.—In determining whether to make an award pursuant to subparagraph (A) to a political subdivision, the Secretary may consider, as a factor indicating that the award should be made, that the political subdivision received public health funding from the Secretary for fiscal year 2006.

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

(A) IN GENERAL.—For fiscal year 2007, the Secretary may, before making awards pursuant to paragraph (3) for such year, reserve from the amount appropriated under paragraph (1) for the year an amount determined necessary by the Secretary to make awards under subsection (a) to eligible entities that—

(i) have a significant need for funds to build capacity to identify, detect, monitor, and respond to a bioterrorist or other threat to the public health, which need will not be met by awards pursuant to paragraph (3); and

(ii) face a particularly high degree of risk of such a threat.

(B) RECIPIENTS OF GRANTS.—Awards pursuant to subparagraph (A) may be supplemental awards to States that receive awards pursuant to paragraph (3), or may be awards to eligible entities described in subsection (b)(1)(B) within such States.

(C) FINDING WITH RESPECT TO DISTRICT OF COLUMBIA.—The Secretary shall consider the District of Columbia to have a significant unmet need for purposes of subparagraph (A), and to face a particularly high degree of risk for such purposes, on the basis of the concentration of entities of national significance located within the District.

(6) FUNDING OF LOCAL ENTITIES.—The Secretary shall, in making awards under this section, ensure that with respect to the cooperative agreement awarded, the entity make available appropriate portions of such award to political subdivisions and local departments of public health through a process involving the consensus, approval or concurrence with such local entities.

(7) AVAILABILITY OF COOPERATIVE AGREEMENT FUNDS.—

(A) IN GENERAL.—Amounts provided to an eligible entity under a cooperative agreement under subsection (a) for a fiscal year and remaining unobligated at the end of such year shall remain available to such entity for the next fiscal year for the purposes for which such funds were provided.

(B) FUNDS CONTINGENT ON ACHIEVING BENCHMARKS.—The continued availability of funds under subparagraph (A) with respect to an entity shall be contingent upon such entity achieving the benchmarks and submitting the pandemic influenza plan as described in subsection (g).

(i) ADMINISTRATIVE AND FISCAL RESPONSIBILITY.—

(1) ANNUAL REPORTING REQUIREMENTS.—Each entity shall prepare and submit to the Secretary annual reports on its activities under this section and section 319C–2. Each such report shall be prepared by, or in consultation with, the health department. In order to properly evaluate and compare the performance of different entities assisted under this section and section 319C–2 and to assure the proper expenditure of funds under this section and section 319C–2, such reports shall be in such standardized form and contain such information as the Secretary determines and describes within 180 days of the date of enactment of the Pandemic and All-Hazards Preparedness Act (after consultation with the States) to be necessary to—

(A) secure an accurate description of those activities;

(B) secure a complete record of the purposes for which funds were spent, and of the recipients of such funds;

(C) describe the extent to which the entity has met the goals and objectives it set forth under this section or section 319C–2;

(D) determine the extent to which funds were expended consistent with the entity's application transmitted under this section or section 319C–2; and

(E) publish such information on a Federal Internet website consistent with subsection (j).

(2) AUDITS; IMPLEMENTATION.—

(A) IN GENERAL.—Each entity receiving funds under this section or section 319C–2 shall, not less often than once every 2 years, audit its expenditures from amounts received under this section or section 319C–2. Such audits shall be conducted by an entity independent of the agency administering a program funded under this section or section 319C–2 in accordance with the Comptroller General's standards for auditing governmental organizations, programs, activities, and functions and generally accepted au-

diting standards. Within 30 days following the completion of each audit report, the entity shall submit a copy of that audit report to the Secretary.

(B) REPAYMENT.—Each entity shall repay to the United States amounts found by the Secretary, after notice and opportunity for a hearing to the entity, not to have been expended in accordance with this section or section 319C–2 and, if such repayment is not made, the Secretary may offset such amounts against the amount of any allotment to which the entity is or may become entitled under this section or section 319C–2 or may otherwise recover such amounts.

(C) WITHHOLDING OF PAYMENT.—The Secretary may, after notice and opportunity for a hearing, withhold payment of funds to any entity which is not using its allotment under this section or section 319C–2 in accordance with such section. The Secretary may withhold such funds until the Secretary finds that the reason for the withholding has been removed and there is reasonable assurance that it will not recur.

(j) COMPILATION AND AVAILABILITY OF DATA.—The Secretary shall compile the data submitted under this section and make such data available in a timely manner on an appropriate Internet website in a format that is useful to the public and to other entities and that provides information on what activities are best contributing to the achievement of the outcome goals described in subsection (g).

(k) EVALUATION.—

(1) IN GENERAL.—Not later than 2 years after the date of enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 and every 2 years thereafter, the Secretary shall conduct an evaluation of the evidence-based benchmarks and objective standards required under subsection (g). Such evaluation shall be submitted to the congressional committees of jurisdiction together with the National Health Security Strategy under section 2802, at such time as such strategy is submitted.

(2) CONTENT.—The evaluation under this paragraph shall include—

(A) a review of evidence-based benchmarks and objective standards, and associated metrics and targets;

(B) a discussion of changes to any evidence-based benchmarks and objective standards, and the effect of such changes on the ability to track whether entities are meeting or making progress toward the goals under this section and, to the extent practicable, the applicable goals of the National Health Security Strategy under section 2802;

(C) a description of amounts received by eligible entities described in subsection (b) and section 319C–2(b), and amounts received by subrecipients and the effect of such funding on meeting evidence-based benchmarks and objective standards; and

(D) recommendations, as applicable and appropriate, to improve evidence-based benchmarks and objective

standards to more accurately assess the ability of entities receiving awards under this section to better achieve the goals under this section and section 2802.

SEC. 319C–2. [247d–3b] PARTNERSHIPS FOR STATE AND REGIONAL HOSPITAL PREPAREDNESS TO IMPROVE SURGE CAPACITY.

(a) IN GENERAL.—The Secretary, acting through the Assistant Secretary for Preparedness and Response, shall award competitive grants or cooperative agreements to eligible entities to enable such entities to improve surge capacity and enhance community and hospital preparedness for, and response to, public health emergencies in accordance with subsection (c), including, as appropriate, capacity and preparedness to address the needs of children and other at-risk individuals.

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

(1)(A) be a coalition that includes—

(i) one or more hospitals, at least one of which shall be a designated trauma center, consistent with section 1213(c);

(ii) one or more other local health care facilities, including clinics, health centers, community health centers, primary care facilities, mental health centers, mobile medical assets, or nursing homes;

(iii)(I) one or more political subdivisions;

(II) one or more States; or

(III) one or more States and one or more political subdivisions; and

(iv) one or more emergency medical service organizations or emergency management organizations; and

(B) prepare, in consultation with the Chief Executive Officer and the lead health officials of the State, District, or territory in which the hospital and health care facilities described in subparagraph (A) are located, and submit to the Secretary, an application at such time, in such manner, and containing such information as the Secretary may require; or

(2)(A) be an entity described in section 319C–1(b)(1); and

(B) submit an application at such time, in such manner, and containing such information as the Secretary may require, including the information or assurances required under section 319C–1(b)(2) and an assurance that the State will adhere to any applicable guidelines established by the Secretary.

(c) USE OF FUNDS.—An award under subsection (a) shall be expended for activities to achieve the preparedness goals described under paragraphs (1), (3), (4), (5), and (6) of section 2802(b) with respect to all-hazards, including chemical, biological, radiological, or nuclear threats.

(d) PREFERENCES.—

(1) REGIONAL COORDINATION.—In making awards under subsection (a), the Secretary shall give preference to eligible entities that submit applications that, in the determination of the Secretary—

(A) will enhance coordination—

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

(ii) among one or more facilities in a regional health care emergency system under section 319C–3; and

(iii) between such entities and the entities described in subsection (b)(1)(A)(ii); and

(B) include, in the coalition described in subsection (b)(1)(A), a significant percentage of the hospitals and health care facilities within the geographic area served by such coalition.

(2) OTHER PREFERENCES.—In making awards under subsection (a), the Secretary shall give preference to eligible entities that, in the determination of the Secretary—

(A) include one or more hospitals that are participants in the National Disaster Medical System;

(B) are located in a geographic area that faces a high degree of risk, as determined by the Secretary in consultation with the Secretary of Homeland Security; or

(C) have a significant need for funds to achieve the preparedness and response goals described in section 2802(b)(3).

(e) CONSISTENCY OF PLANNED ACTIVITIES.—The Secretary may not award a cooperative agreement to an eligible entity described in subsection (b)(1) unless the application submitted by the entity is coordinated and consistent with an applicable State All-Hazards Public Health Emergency Preparedness and Response Plan and relevant local plans, as determined by the Secretary in consultation with relevant State health officials.

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

(g) COORDINATION.—

(1) LOCAL RESPONSE CAPABILITIES.—An eligible entity shall, to the extent practicable, ensure that activities carried out under an award under subsection (a) are coordinated with activities of relevant local Metropolitan Medical Response Systems, local Medical Reserve Corps, the local Cities Readiness Initiative, and local emergency plans.

(2) NATIONAL COLLABORATION.—Coalitions consisting of one or more eligible entities under this section may, to the extent practicable, collaborate with other coalitions consisting of one or more eligible entities under this section for purposes of national coordination and collaboration with respect to activities to achieve the preparedness and response goals described under paragraphs (1), (3), (4), (5), and (6) of section 2802(b).

(h) MAINTENANCE OF FUNDING.—

(1) IN GENERAL.—An entity that receives an award under this section shall maintain expenditures for health care preparedness at a level that is not less than the average level of such expenditures maintained by the entity for the preceding 2 year period.

(2) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to prohibit the use of awards under this section

to pay salary and related expenses of public health and other professionals employed by State, local, or tribal agencies who are carrying out activities supported by such awards (regardless of whether the primary assignment of such personnel is to carry out such activities).

(i) PERFORMANCE AND ACCOUNTABILITY.—

(1) IN GENERAL.—The requirements of section 319C–1(g), (i), (j), and (k) shall apply to entities receiving awards under this section (regardless of whether such entities are described under subsection (b)(1)(A) or (b)(2)(A)) in the same manner as such requirements apply to entities under section 319C–1. In submitting reports under this paragraph, a coalition shall include information on the progress that the coalition has made toward the implementation of section 319C–3 (or barriers to progress, if any).A coalition described in subsection (b)(1)(A) shall make such reports available to the lead health official of the State in which such coalition is located.

(2) MEETING GOALS OF NATIONAL HEALTH SECURITY STRATEGY.—The Secretary shall implement objective, evidence-based metrics to ensure that entities receiving awards under this section are meeting, to the extent practicable, the applicable goals of the National Health Security Strategy under section 2802.

(j) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—

(A) AUTHORIZATION OF APPROPRIATIONS.—For purposes of carrying out this section and section 319C–3, in accordance with subparagraph (B), there is authorized to be appropriated $385,000,000 for each of fiscal years 2019 through 2023.

(B) RESERVATION OF AMOUNTS FOR REGIONAL SYSTEMS.—

(i) IN GENERAL.—Subject to clause (ii), of the amount appropriated under subparagraph (A) for a fiscal year, the Secretary may reserve up to 5 percent for the purpose of carrying out section 319C–3.

(ii) RESERVATION CONTINGENT ON CONTINUED APPROPRIATIONS FOR THIS SECTION.—If for fiscal year 2019 or a subsequent fiscal year, the amount appropriated under subparagraph (A) is such that, after application of clause (i), the amount remaining for the purpose of carrying out this section would be less than the amount available for such purpose for the previous fiscal year, the amount that may be reserved under clause (i) shall be reduced such that the amount remaining for the purpose of carrying out this section is not less than the amount available for such purpose for the previous fiscal year.

(iii) SUNSET.—The authority to reserve amounts under clause (i) shall expire on September 30, 2023.

(2) RESERVATION OF AMOUNTS FOR PARTNERSHIPS.—Prior to making awards described in paragraph (3), the Secretary may reserve from the amount appropriated under paragraph (1)(A) for a fiscal year and not reserved for the purpose described in paragraph (1)(B)(i), an amount determined appropriate by the

Secretary for making awards to entities described in subsection (b)(1)(A).

(3) AWARDS TO STATES AND POLITICAL SUBDIVISIONS.—

(A) IN GENERAL.—From amounts appropriated for a fiscal year under paragraph (1)(A) and not reserved under paragraph (1)(B)(i) or (2), the Secretary shall make awards to entities described in subsection (b)(2)(A) that have completed an application as described in subsection (b)(2)(B).

(B) AMOUNT.—The Secretary shall determine the amount of an award to each entity described in subparagraph (A) in the same manner as such amounts are determined under section 319C–1(h).

(4) AVAILABILITY OF COOPERATIVE AGREEMENT FUNDS.—

(A) IN GENERAL.—Amounts provided to an eligible entity under a cooperative agreement under subsection (a) for a fiscal year and remaining unobligated at the end of such year shall remain available to such entity for the next fiscal year for the purposes for which such funds were provided.

(B) FUNDS CONTINGENT ON ACHIEVING BENCHMARKS.—The continued availability of funds under subparagraph (A) with respect to an entity shall be contingent upon such entity achieving the benchmarks and submitting the pandemic influenza plan as required under subsection (i).

SEC. 319C–3. [247d-3c] GUIDELINES FOR REGIONAL HEALTH CARE EMERGENCY PREPAREDNESS AND RESPONSE SYSTEMS.

(a) PURPOSE.—It is the purpose of this section to identify and provide guidelines for regional systems of hospitals, health care facilities, and other public and private sector entities, with varying levels of capability to treat patients and increase medical surge capacity during, in advance of, and immediately following a public health emergency, including threats posed by one or more chemical, biological, radiological, or nuclear agents, including emerging infectious diseases.

(b) GUIDELINES.—The Assistant Secretary for Preparedness and Response, in consultation with the Director of the Centers for Disease Control and Prevention, the Administrator of the Centers for Medicare & Medicaid Services, the Administrator of the Health Resources and Services Administration, the Commissioner of Food and Drugs, the Assistant Secretary for Mental Health and Substance Use, the Assistant Secretary of Labor for Occupational Safety and Health, the Secretary of Veterans Affairs, the heads of such other Federal agencies as the Secretary determines to be appropriate, and State, local, Tribal, and territorial public health officials, shall, not later than 2 years after the date of enactment of this section—

(1) identify and develop a set of guidelines relating to practices and protocols for all-hazards public health emergency preparedness and response for hospitals and health care facilities to provide appropriate patient care during, in advance of, or immediately following, a public health emergency, resulting from one or more chemical, biological, radiological, or nuclear agents, including emerging infectious diseases (which may in-

clude existing practices, such as trauma care and medical surge capacity and capabilities), with respect to—

(A) a regional approach to identifying hospitals and health care facilities based on varying capabilities and capacity to treat patients affected by such emergency, including—

(i) the manner in which the system will coordinate with and integrate the partnerships and health care coalitions established under section 319C–2(b); and

(ii) informing and educating appropriate first responders and health care supply chain partners of the regional emergency preparedness and response capabilities and medical surge capacity of such hospitals and health care facilities in the community;

(B) physical and technological infrastructure, laboratory capacity, staffing, blood supply, and other supply chain needs, taking into account resiliency, geographic considerations, and rural considerations;

(C) protocols or best practices for the safety and personal protection of workers who handle human remains and health care workers (including with respect to protective equipment and supplies, waste management processes, and decontamination), sharing of specialized experience among the health care workforce, behavioral health, psychological resilience, and training of the workforce, as applicable;

(D) in a manner that allows for disease containment (within the meaning of section 2802(b)(2)(B)), coordinated medical triage, treatment, and transportation of patients, based on patient medical need (including patients in rural areas), to the appropriate hospitals or health care facilities within the regional system or, as applicable and appropriate, between systems in different States or regions; and

(E) the needs of children and other at-risk individuals;

(2) make such guidelines available on the internet website of the Department of Health and Human Services in a manner that does not compromise national security; and

(3) update such guidelines as appropriate, including based on input received pursuant to subsections (c) and (e) and information resulting from applicable reports required under the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (including any amendments made by such Act), to address new and emerging public health threats.

(c) CONSIDERATIONS.—In identifying, developing, and updating guidelines under subsection (b), the Assistant Secretary for Preparedness and Response shall—

(1) include input from hospitals and health care facilities (including health care coalitions under section 319C–2), State, local, Tribal, and territorial public health departments, and health care or subject matter experts (including experts with relevant expertise in chemical, biological, radiological, or nuclear threats, including emerging infectious diseases), as the Assistant Secretary determines appropriate, to meet the goals under section 2802(b)(3);

(2) consult and engage with appropriate health care providers and professionals, including physicians, nurses, first responders, health care facilities (including hospitals, primary care clinics, community health centers, mental health facilities, ambulatory care facilities, and dental health facilities), pharmacies, emergency medical providers, trauma care providers, environmental health agencies, public health laboratories, poison control centers, blood banks, tissue banks, and other experts that the Assistant Secretary determines appropriate, to meet the goals under section 2802(b)(3);

(3) consider feedback related to financial implications for hospitals, health care facilities, public health agencies, laboratories, blood banks, tissue banks, and other entities engaged in regional preparedness planning to implement and follow such guidelines, as applicable; and

(4) consider financial requirements and potential incentives for entities to prepare for, and respond to, public health emergencies as part of the regional health care emergency preparedness and response system.

(d) TECHNICAL ASSISTANCE.—The Assistant Secretary for Preparedness and Response, in consultation with the Director of the Centers for Disease Control and Prevention and the Assistant Secretary of Labor for Occupational Safety and Health, may provide technical assistance and consultation toward meeting the guidelines described in subsection (b).

(e) DEMONSTRATION PROJECT FOR REGIONAL HEALTH CARE PREPAREDNESS AND RESPONSE SYSTEMS.—

(1) IN GENERAL.—The Assistant Secretary for Preparedness and Response may establish a demonstration project pursuant to the development and implementation of guidelines under subsection (b) to award grants to improve medical surge capacity for all hazards, build and integrate regional medical response capabilities, improve specialty care expertise for all-hazards response, and coordinate medical preparedness and response across State, local, Tribal, territorial, and regional jurisdictions.

(2) SUNSET.—The authority under this subsection shall expire on September 30, 2023.

SEC. 319D. [247d–4] FACILITIES AND CAPACITIES OF THE CENTERS FOR DISEASE CONTROL AND PREVENTION.

(a) IN GENERAL.—

(1) FINDINGS.—Congress finds that the Centers for Disease Control and Prevention has an essential role in defending against and combatting public health threats domestically and abroad and requires secure and modern facilities, and expanded, improved, and appropriately maintained 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 com-

munication facilities, transshipment complexes, secured and isolated parking structures, office buildings, and other facilities and infrastructure), and upgrade security of such facilities, in order to better conduct the capacities described in section 319A, and for supporting public health activities.

(B) MULTIYEAR CONTRACTING AUTHORITY.—For any project of designing, constructing, equipping, or renovating any facility under subparagraph (A), the Director of the Centers for Disease Control and Prevention may enter into a single contract or related contracts that collectively include the full scope of the project, and the solicitation and contract shall contain the clause "availability of funds" found at section 52.232–18 of title 48, Code of Federal Regulations.

(3) IMPROVING THE CAPACITIES OF THE CENTERS FOR DISEASE CONTROL AND PREVENTION.—The Secretary shall expand, improve, enhance, and appropriately maintain the capabilities of the Centers for Disease Control and Prevention relating to preparedness for and responding effectively to bioterrorism and other public health emergencies, by—

(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, infectious disease outbreaks, and other public health emergencies, including increasing the security of such facilities.

(4) STUDY OF RESOURCES FOR FACILITIES AND CAPACITIES.—Not later than June 1, 2022, the Comptroller General of the United States shall conduct a study on Federal spending in fiscal years 2013 through 2018 for activities authorized under this subsection. Such study shall include a review and assessment of obligations and expenditures directly related to each activity under paragraphs (2) and (3), including a specific accounting of, and delineation between, obligations and expenditures incurred for the construction, renovation, equipping, and security upgrades of facilities and associated contracts under this subsection, and the obligations and expenditures incurred to establish and improve the situational awareness and biosurveillance network under subsection (b), and shall identify the agency or agencies incurring such obligations and expenditures.

(b) ESTABLISHMENT OF SYSTEMS OF PUBLIC HEALTH 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 sys-

tems of public health alert communications and surveillance networks between and among—

(A) Federal, State, local, and Tribal public health officials; and

(B) public and private health-related laboratories, hospitals, poison control centers, immunization information systems, and other health care facilities;

(2) REQUIREMENTS.—The Secretary shall develop a plan to, and ensure that networks under paragraph (1) allow for the timely sharing and discussion, in a secure manner and in a form readily usable for analytical approaches, of essential, deidentified information concerning bioterrorism or another public health emergency, or recommended methods for responding to such an attack or emergency, allowing for coordination to maximize all-hazards medical and public health preparedness and response and to minimize duplication of effort. The Secretary shall ensure that the activities carried out pursuant to the previous sentence are conducted in a manner that protects personal privacy, to the extent required by applicable Federal and State information privacy or security law, at a minimum.

(3) STANDARDS.—

(A) IN GENERAL.—Not later than 1 year after the date of the enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019, the Secretary, in cooperation with health care providers, State, local, Tribal, and territorial public health officials, and relevant Federal agencies (including the Office of the National Coordinator for Health Information Technology and the National Institute of Standards and Technology), shall, as necessary, adopt technical and reporting standards, including standards for interoperability as defined by section 3000, for networks under paragraph (1) and update such standards as necessary. Such standards shall be made available on the internet website of the Department of Health and Human Services, in a manner that does not compromise national security.

(B) DEFERENCE TO STANDARDS DEVELOPMENT ORGANIZATIONS.—In adopting and implementing standards under this subsection and subsection (c), the Secretary shall give deference to standards published by standards development organizations and voluntary consensus-based standards entities.

(c) MODERNIZING PUBLIC HEALTH SITUATIONAL AWARENESS AND BIOSURVEILLANCE.—

(1) IN GENERAL.—The Secretary, in collaboration with State, local, and Tribal public health officials, shall establish, modernize, and improve as applicable and appropriate, a near real-time electronic nationwide public health situational awareness capability through an interoperable network of systems to share data and information that is deidentified, as applicable, to enhance early detection of, rapid response to, and management of, potentially catastrophic infectious disease outbreaks, novel emerging threats, and other public health emer-

gencies that originate domestically or abroad. Such network shall be built on existing State situational awareness systems or enhanced systems that enable such interoperability, to the extent practicable. The Secretary shall ensure that the activities carried out pursuant to this paragraph are conducted in a manner that protects personal privacy, to the extent required by applicable Federal and State information privacy or security law, at a minimum.

(2) COORDINATION AND CONSULTATION.—In establishing and improving the network under paragraph (1), the Secretary shall—

(A) facilitate coordination among agencies within the Department of Health and Human Services that provide, or have the potential to provide, information and data to, and analyses for, the situational awareness and biosurveillance network under paragraph (1), including coordination among relevant agencies related to health care services, the facilitation of health information exchange (including the Office of the National Coordinator for Health Information Technology), and public health emergency preparedness and response; and

(B) consult with the Secretary of Agriculture, the Secretary of Commerce (and the Director of the National Institute of Standards and Technology), the Secretary of Defense, the Secretary of Homeland Security, the Secretary of Veterans Affairs, and the heads of other Federal agencies, as the Secretary determines appropriate.

(3) ELEMENTS.—

(A) IN GENERAL.—The network described in paragraph (1) shall include data and information transmitted in a standardized format from—

(i) State, local, and Tribal public health entities, including public health laboratories;

(ii) Federal health agencies;

(iii) zoonotic disease monitoring systems; and

(iv) public and private sector health care entities, hospitals, pharmacies, poison control centers or professional organizations in the field of poison control, immunization information systems, community health centers, health centers, clinical laboratories, and public environmental health agencies, to the extent practicable and provided that such data are voluntarily provided simultaneously to the Secretary and appropriate State, local, and Tribal public health agencies.

(B) REVIEW.—Not later than 2 years after the date of the enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 and every 6 years thereafter, the Secretary shall conduct a review of the elements described in subparagraph (A). Such review shall include a discussion of the addition of any elements pursuant to clause (v), including elements added to advancing new technologies, and identify any challenges in the incorporation of elements under subparagraph (A), and make recommendations to improve the quality of data col-

lected pursuant to subparagraph (A) to ensure complete, accurate, and timely sharing of such data, as appropriate, across such elements as described in subparagraph (A). The Secretary shall provide such review to the congressional committees of jurisdiction.

(4) RULE OF CONSTRUCTION.—Paragraph (3) shall not be construed as requiring separate reporting of data and information from each source listed.

(5) REQUIRED ACTIVITIES.—

(A) IN GENERAL.—In establishing, operating, and updating, as appropriate, the network described in paragraph (1), the Secretary shall—

(i) utilize applicable interoperability standards as adopted by the Secretary, and in consultation with the Office of the National Coordinator for Health Information Technology and the National Institute of Standards and Technology, through a joint public and private sector process;

(ii) define minimal data elements for such network;

(iii) in collaboration with State, local, and Tribal public health officials, integrate and build upon existing State, local, and Tribal capabilities, ensuring simultaneous sharing of data, information, and analyses that is deidentified, as applicable, from the network described in paragraph (1) with State, local, and Tribal public health agencies in accordance with applicable Federal and State privacy and security law;

(iv) in collaboration with State, local, and Tribal public health officials, develop procedures and standards for the collection, analysis, and interpretation of data that States, regions, or other entities collect and report to the network described in paragraph (1);

(v) pilot test standards and implementation specifications, consistent with the process described in section 3002(b)(3)(C), which State, local, Tribal, and territorial public health entities may utilize, on a voluntary basis, as a part of the network; and

(vi) in collaboration with State, local, and Tribal public health officials, integrate and update applicable existing public health data systems and networks of the Department of Health and Human Services to reflect technological advancements, consistent with section 2823, as applicable.

(B) PUBLIC MEETING.—

(i) IN GENERAL.—Not later than 180 days after the date of enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019, and 180 days after the date of enactment of the PREVENT Pandemics Act, the Secretary shall convene a public meeting for purposes of discussing and providing input on the potential goals, functions, and uses of the network described in paragraph (1) and incorporating the elements described in paragraph (3)(A).

(ii) EXPERTS.—The public meeting shall include representatives of relevant Federal agencies (including representatives from the Office of the National Coordinator for Health Information Technology and the National Institute of Standards and Technology); State, local, Tribal, and territorial public health officials; stakeholders with expertise in biosurveillance and situational awareness; stakeholders with expertise in capabilities relevant to biosurveillance and situational awareness, such as experts in informatics and data analytics (including experts in prediction, modeling, or forecasting); experts in State-based public health data systems; experts in standards and implementation specifications, including transaction standards; and experts in privacy and data security.

(iii) TOPICS.—Such public meeting shall include a discussion of—

(I) data elements, including minimal or essential data elements, that are voluntarily provided for such network, which may include elements from public health and public and private health care entities, to the extent practicable;

(II) standards and implementation specifications that may improve the collection, analysis, and interpretation of data during a public health emergency;

(III) strategies to encourage the access, exchange, and use of information;

(IV) considerations for State, local, Tribal, and territorial capabilities and infrastructure related to data exchange and interoperability, including existing public health data systems;

(V) privacy and security protections provided at the Federal, State, local, Tribal, and territorial levels, and by nongovernmental stakeholders;

(VI) opportunities for the incorporation of innovative technologies to improve the network;

(VII) strategies to integrate laboratory and public health data systems and capabilities to support rapid and accurate reporting of laboratory test results and associated relevant data;

(VIII) strategies to improve the collection, reporting, and dissemination of relevant, aggregated, deidentified demographic data to inform responses to public health emergencies, including identification of at-risk populations and to address potential health disparities; and

(IX) strategies to improve the electronic exchange of health information, as appropriate, between State and local health departments and health care providers and facilities to improve the detection of, and responses to, potentially catastrophic infectious disease outbreaks.

(6) STRATEGY AND IMPLEMENTATION PLAN.—

(A) IN GENERAL.—Not later than 18 months after the date of enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019, and every 5 years thereafter, the Secretary shall submit to the congressional committees of jurisdiction a coordinated strategy and an accompanying implementation plan that—

(i) is informed by the public meeting under paragraph (5)(B);

(ii) includes a review and assessment of existing capabilities of the network and related infrastructure, including input provided by the public meeting under paragraph (5)(B);

(iii) identifies and demonstrates the measurable steps the Secretary will carry out to—

(I) develop, implement, and evaluate the network described in paragraph (1), utilizing elements described in paragraph (3)(A);

(II) modernize and enhance biosurveillance activities, including strategies to include innovative technologies and analytical approaches (including prediction and forecasting for pandemics and all-hazards) from public and private entities;

(III) improve information sharing, coordination, and communication among disparate biosurveillance systems supported by the Department of Health and Human Services, including the identification of methods to improve accountability, better utilize resources and workforce capabilities, and incorporate innovative technologies within and across agencies;

(IV) test and evaluate capabilities of the interoperable network of systems to improve situational awareness and biosurveillance capabilities;

(V) improve coordination and collaboration, as appropriate, with other Federal departments to improve the capabilities of the network and reduce administrative burden on State, local, and Tribal entities; and

(VI) implement applicable lessons learned from recent public health emergencies to address gaps in situational awareness and biosurveillance capabilities;

(iv) includes performance measures and the metrics by which performance measures will be assessed with respect to the measurable steps under clause (iii);

(v) establishes dates by which each measurable step under clause (iii) will be implemented, including a description of how such steps will further the goals of the network, consistent with paragraph (1); and

(vi) identifies and demonstrates measurable steps the Secretary will take to further develop and integrate infectious disease detection, support rapid, accurate, and secure sharing of laboratory test results,

deidentified as appropriate, during a public health emergency, and improve coordination and collaboration with State, local, and Tribal public health officials, clinical laboratories, and other entities with expertise in public health surveillance.

(B) ANNUAL BUDGET PLAN.—Not later than 2 years after the date of enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 and on an annual basis thereafter, in accordance with the strategy and implementation plan under this paragraph, the Secretary shall, taking into account recommendations provided by the National Biodefense Science Board, develop a budget plan based on the strategy and implementation plan under this section. Such budget plan shall include—

(i) a summary of resources previously expended to establish, improve, and utilize the nationwide public health situational awareness and biosurveillance network under paragraph (1);

(ii) estimates of costs and resources needed to establish and improve the network under paragraph (1) according to the strategy and implementation plan under subparagraph (A);

(iii) the identification of gaps and inefficiencies in nationwide public health situational awareness and biosurveillance capabilities, resources, and authorities needed to address such gaps; and

(iv) a strategy to minimize and address such gaps and improve inefficiencies.

(7) CONSULTATION WITH THE NATIONAL BIODEFENSE SCIENCE BOARD.—In carrying out this section and consistent with section 319M, the National Biodefense Science Board shall provide expert advice and guidance, including recommendations, regarding the measurable steps the Secretary should take to modernize and enhance biosurveillance activities pursuant to the efforts of the Department of Health and Human Services to ensure comprehensive, real-time, all-hazards biosurveillance capabilities. In complying with the preceding sentence, the National Biodefense Science Board shall—

(A) identify the steps necessary to achieve a national biosurveillance system for human health (taking into account zoonotic disease, including gaps in scientific understanding of the interactions between human, animal, and environmental health), with international connectivity, where appropriate, that is predicated on State, regional, and community level capabilities and creates a networked system to allow for two-way information flow between and among Federal, State, and local government public health authorities and clinical health care providers;

(B) identify any duplicative surveillance programs and gaps in surveillance programs under the authority of the Secretary, or changes that are necessary to existing programs, in order to enhance and modernize such activities, minimize duplication, strengthen and streamline such ac-

tivities under the authority of the Secretary, and achieve real-time and appropriate data that relate to disease activity, both human and zoonotic;

(C) coordinate with applicable existing advisory committees of the Director of the Centers for Disease Control and Prevention, including such advisory committees consisting of representatives from State, local, and Tribal public health authorities and appropriate public and private sector health care entities, animal health organizations related to zoonotic disease, and academic institutions, in order to provide guidance on public health surveillance activities; and

(D) provide recommendations to the Secretary on policies and procedures to complete the steps described in this paragraph in a manner that is consistent with section 2802.

(8) SITUATIONAL AWARENESS AND BIOSURVEILLANCE AS A NATIONAL SECURITY PRIORITY.—The Secretary, on a periodic basis as applicable and appropriate, shall meet with the Director of National Intelligence to inform the development and capabilities of the nationwide public health situational awareness and biosurveillance network.

(9) RULES OF CONSTRUCTION.—

(A) Nothing in this subsection shall be construed to supplant, in whole or in part, State, local, or Tribal activities or responsibilities related to public health surveillance.

(B) Nothing in this subsection shall be construed to alter the authority of the Secretary with respect to the types of data the Secretary may receive through systems supported or established under this section.

(d) STATE AND REGIONAL SYSTEMS TO ENHANCE SITUATIONAL AWARENESS IN PUBLIC HEALTH EMERGENCIES.—

(1) IN GENERAL.—To implement the network described in subsection (c), the Secretary may award grants to States or consortia of States to enhance the ability of such States or consortia of States to establish or operate a coordinated public health situational awareness system for regional or Statewide early detection of, rapid response to, and management of potentially catastrophic infectious disease outbreaks and public health emergencies, in collaboration with appropriate public health agencies, environmental health agencies, sentinel hospitals, clinical laboratories, pharmacies, poison control centers, immunization programs, other health care organizations, and animal health organizations within such States.

(2) ELIGIBILITY.—To be eligible to receive a grant under paragraph (1), the State or consortium of States shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require, including an assurance that the State or consortium of States will submit to the Secretary—

(A) reports of such deidentified data, information, and metrics as the Secretary may require, in consultation with such State or consortium of States;

(B) a report on the effectiveness of the systems funded under the grant;

(C) a description of the manner in which grant funds will be used to enhance the timelines and comprehensiveness of efforts to detect, respond to, and manage potentially catastrophic infectious disease outbreaks and public health emergencies, including any public-private partnerships or other partnerships entered into to improve such capacity; and

(D) an implementation plan that may include measurable steps to achieve the purposes described in paragraph (1).

(3) USE OF FUNDS.—A State or consortium of States that receives an award under this subsection—

(A) shall establish, enhance, or operate a coordinated public health situational awareness system for regional or Statewide early detection of, rapid response to, and management of potentially catastrophic infectious disease outbreaks and public health emergencies;

(B) may award grants or contracts to entities described in paragraph (1) within or serving such State to assist such entities in improving the operation of information technology systems, facilitating the secure exchange of data and information, and training personnel to enhance the operation of the system described in subparagraph (A); and

(C) may conduct a pilot program for the development of multi-State telehealth network test beds that build on, enhance, and securely link existing State and local telehealth programs to prepare for, monitor, respond to, and manage the events of public health emergencies, facilitate coordination and communication among medical, public health, and emergency response agencies, and provide medical services through telehealth initiatives within the States that are involved in such a multi-State telehealth network test bed.

(4) LIMITATION.—Information technology systems acquired or implemented using grants awarded under this section must be compliant with—

(A) interoperability and other technological standards, as determined by the Secretary; and

(B) data collection and reporting requirements for the network described in subsection (c).

(5) TECHNICAL ASSISTANCE.—The Secretary may provide technical assistance to States, localities, Tribes, and territories or a consortium of States, localities, Tribes, and territories receiving an award under this subsection regarding interoperability and the technical standards set forth by the Secretary.

(6) NON-DUPLICATION OF EFFORT.—The Secretary shall ensure that activities carried out under an award under this subsection do not unnecessarily duplicate efforts of other agencies and offices within the Department of Health and Human Services.

(e) PERSONNEL AUTHORITIES.—

(1) SPECIALLY QUALIFIED PERSONNEL.—In addition to any other personnel authorities, to carry out subsections (b) and (c), the Secretary may—

(A) appoint highly qualified individuals to scientific or professional positions at the Centers for Disease Control and Prevention, not to exceed 30 such employees at any time (specific to positions authorized by this subsection), with expertise in capabilities relevant to biosurveillance and situational awareness, such as experts in informatics and data analytics (including experts in prediction, modeling, or forecasting), and other related scientific or technical fields; and

(B) compensate individuals appointed under subparagraph (A) in the same manner and subject to the same terms and conditions in which individuals appointed under 9903 of title 5, United States Code, are compensated, without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates.

(2) LIMITATIONS.—The Secretary shall exercise the authority under paragraph (1) in a manner that is consistent with the limitations described in section 319F–1(e)(2).

(f) TIMELINE.—The Secretary shall accomplish the purposes under subsections (b) and (c) no later than September 30, 2023, and shall provide a justification to the congressional committees of jurisdiction for any missed or delayed implementation of measurable steps identified under subsection (c)(6)(A)(iii).

(g) INDEPENDENT EVALUATION.—Not later than 3 years after the date of enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019, the Comptroller General of the United States shall conduct an independent evaluation and submit to the Secretary and the congressional committees of jurisdiction a report concerning the activities conducted under subsections (b) and (c), and provide recommendations, as applicable and appropriate, on necessary improvements to the biosurveillance and situational awareness network.

(h) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated—

(1) to carry out subsection (a), $25,000,000 for each of fiscal years 2022 and 2023; and

(2) to carry out subsections (b), (c), and (d), $136,800,000 for each of fiscal years 2022 and 2023.

(i) DEFINITION.—For purposes of this section the term "biosurveillance" means the process of gathering near real-time biological data that relates to human and zoonotic disease activity and threats to human or animal health, in order to achieve early warning and identification of such health threats, early detection and prompt ongoing tracking of health events, and overall situational awareness of disease activity.

SEC. 319D–1. [247d-4b] CHILDREN'S PREPAREDNESS UNIT.

(a) ENHANCING EMERGENCY PREPAREDNESS FOR CHILDREN.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention (referred to in this subsection as the

"Director"), shall maintain an internal team of experts, to be known as the Children's Preparedness Unit (referred to in this subsection as the "Unit"), to work collaboratively to provide guidance on the considerations for, and the specific needs of, children before, during, and after public health emergencies. The Unit shall inform the Director regarding emergency preparedness and response efforts pertaining to children at the Centers for Disease Control and Prevention.

(b) EXPERTISE.—The team described in subsection (a) shall include one or more pediatricians, which may be a developmental-behavioral pediatrician, and may also include behavioral scientists, child psychologists, epidemiologists, biostatisticians, health communications staff, and individuals with other areas of expertise, as the Secretary determines appropriate.

(c) DUTIES.—The team described in subsection (a) may—

(1) assist State, local, Tribal, and territorial emergency planning and response activities related to children, which may include developing, identifying, and sharing best practices;

(2) provide technical assistance, training, and consultation to Federal, State, local, Tribal, and territorial public health officials to improve preparedness and response capabilities with respect to the needs of children, including providing such technical assistance, training, and consultation to eligible entities in order to support the achievement of measurable evidence-based benchmarks and objective standards applicable to sections 319C–1 and 319C–2;

(3) improve the utilization of methods to incorporate the needs of children in planning for and responding to a public health emergency, including public awareness of such methods;

(4) coordinate with, and improve, public-private partnerships, such as health care coalitions pursuant to sections 319C–2 and 319C–3, to address gaps and inefficiencies in emergency preparedness and response efforts for children;

(5) provide expertise and input during the development of guidance and clinical recommendations to address the needs of children when preparing for, and responding to, public health emergencies, including pursuant to section 319C–3; and

(6) carry out other duties related to preparedness and response activities for children, as the Secretary determines appropriate.

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 con-

stituencies, 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) MONITORING AT FEDERAL HEALTH CARE FACILITIES.—The Secretary shall encourage reporting on aggregate antimicrobial drug use and antimicrobial resistance to antimicrobial drugs and the implementation of antimicrobial stewardship programs by health care facilities of the Department of Defense, the Department of Veterans Affairs, and the Indian Health Service and shall provide technical assistance to the Secretary of Defense and the Secretary of Veterans Affairs, as appropriate and upon request.

(g) REPORT ON ANTIMICROBIAL RESISTANCE IN HUMANS AND USE OF ANTIMICROBIAL DRUGS.—Not later than 1 year after the date of enactment of the 21st Century Cures Act, and annually thereafter, the Secretary shall prepare and make publicly available data and information concerning—

(1) aggregate national and regional trends of antimicrobial resistance in humans to antimicrobial drugs, including such drugs approved under section 506(h) of the Federal Food, Drug, and Cosmetic Act;

(2) antimicrobial stewardship, which may include summaries of State efforts to address antimicrobial resistance in humans to antimicrobial drugs and antimicrobial stewardship; and

(3) coordination between the Director of the Centers for Disease Control and Prevention and the Commissioner of Food and Drugs with respect to the monitoring of—

(A) any applicable resistance under paragraph (1); and

(B) drugs approved under section 506(h) of the Federal Food, Drug, and Cosmetic Act.

(h) INFORMATION RELATED TO ANTIMICROBIAL STEWARDSHIP PROGRAMS.—The Secretary shall, as appropriate, disseminate guidance, educational materials, or other appropriate materials related to the development and implementation of evidence-based antimicrobial stewardship programs or practices at health care facilities, such as nursing homes and other long-term care facilities, ambulatory surgical centers, dialysis centers, outpatient clinics, and hospitals, including community and rural hospitals.

(i) SUPPORTING STATE-BASED ACTIVITIES TO COMBAT ANTIMICROBIAL RESISTANCE.—The Secretary shall continue to work with State and local public health departments on statewide or regional programs related to antimicrobial resistance. Such efforts may include activities to related to—

(1) identifying patterns of bacterial and fungal resistance in humans to antimicrobial drugs;

(2) preventing the spread of bacterial and fungal infections that are resistant to antimicrobial drugs; and

(3) promoting antimicrobial stewardship.

(j) ANTIMICROBIAL RESISTANCE AND STEWARDSHIP ACTIVITIES.—

(1) IN GENERAL.—For the purposes of supporting stewardship activities, examining changes in antimicrobial resistance, and evaluating the effectiveness of section 506(h) of the Federal Food, Drug, and Cosmetic Act, the Secretary shall—

(A) provide a mechanism for facilities to report data related to their antimicrobial stewardship activities (including analyzing the outcomes of such activities); and

(B) evaluate—

(i) antimicrobial resistance data using a standardized approach; and

(ii) trends in the utilization of drugs approved under such section 506(h) with respect to patient populations.

(2) USE OF SYSTEMS.—The Secretary shall use available systems, including the National Healthcare Safety Network or other systems identified by the Secretary, to fulfill the requirements or conduct activities under this section.

(k) NETWORK OF ANTIBIOTIC RESISTANCE REGIONAL LABORATORIES.—

(1) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall, as appropriate, maintain a network of antibiotic resistance laboratory sites to ensure the maintenance of appropriate capabilities, within existing laboratory capacity maintained or supported by the Centers for Disease Control and Prevention, to—

(A) identify and monitor the emergence and changes in the patterns of antimicrobial-resistant pathogens;

(B) detect, identify, confirm, and isolate such resistant pathogens, including, as appropriate, performing such activities upon the request of another laboratory and providing related technical assistance, and, as applicable, support efforts to respond to local or regional outbreaks of such resistant pathogens; and

(C) perform activities to support the diagnosis of such resistant pathogens and determine the susceptibility of relevant pathogen samples to applicable treatments.

(2) GEOGRAPHIC DISTRIBUTION.—The Secretary shall ensure that such capacity and capabilities are appropriately distributed among the geographical regions of the United States.

(3) PARTNERSHIPS AND NONDUPLICATION OF CURRENT DOMESTIC CAPACITY.—Activities supported under this subsection may be based in an academic center, a State health department, or other facility operated by a public or private entity that carries out relevant laboratory or public health surveillance activities.

(l) INTERNATIONAL COLLABORATION.—

(1) IN GENERAL.—The Secretary, in coordination with heads of other relevant Federal departments and agencies, shall support activities related to addressing antimicrobial resistance internationally, including by—

(A) supporting basic, translational, epidemiological, and clinical research related to antimicrobial-resistant pathogens, including such pathogens that have not yet been detected in the United States, and improving related public health surveillance systems, and laboratory and other response capacity; and

(B) providing technical assistance related to antimicrobial resistant infection and control activities.

(2) AWARDS.—In carrying out paragraph (1), the Secretary may award grants, contracts, or cooperative agreements to public and private entities, including nongovernmental organizations, with applicable expertise, for purposes of supporting new and innovative approaches to the prevention, detection, and mitigation of antimicrobial-resistant pathogens.

(m) ANTIMICROBIAL.—For purposes of subsections (f) through (j), the term "antimicrobial" includes any antibacterial or antifungal drugs, and may include drugs that eliminate or inhibit the growth of other microorganisms, as appropriate.

(n) 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.

(o) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, $40,000,000 for fiscal year 2001, $25,000,000 for each of the fiscal years 2002 and 2003, and such sums as may be necessary for each of the fiscal years 2004 through 2006.

SEC. 319F. [247d–6] PUBLIC HEALTH COUNTERMEASURES TO A BIOTERRORIST ATTACK.

(a) ALL-HAZARDS PUBLIC HEALTH AND MEDICAL RESPONSE CURRICULA AND TRAINING.—

(1) IN GENERAL.—The Secretary, in collaboration with the Secretary of Defense, and in consultation with relevant public and private entities, shall develop core health and medical response curricula and trainings by adapting applicable existing curricula and training programs to improve responses to public health emergencies.

(2) CURRICULUM.—The public health and medical response training program may include course work related to—

(A) medical management of casualties, taking into account the needs of at-risk individuals;

(B) public health aspects of public health emergencies;

(C) mental health aspects of public health emergencies;

(D) national incident management, including coordination among Federal, State, local, tribal, international agencies, and other entities; and

(E) protecting health care workers and health care first responders from workplace exposures during a public health emergency.

(3) PEER REVIEW.—On a periodic basis, products prepared as part of the program shall be rigorously tested and peer-reviewed by experts in the relevant fields.

(4) CREDIT.—The Secretary and the Secretary of Defense shall—

(A) take into account continuing professional education requirements of public health and healthcare professions; and

(B) cooperate with State, local, and tribal accrediting agencies and with professional associations in arranging for students enrolled in the program to obtain continuing professional education credit for program courses.

(5) DISSEMINATION AND TRAINING.—

(A) IN GENERAL.—The Secretary may provide for the dissemination and teaching of the materials described in paragraphs (1) and (2) by appropriate means, as determined by the Secretary.

(B) CERTAIN ENTITIES.—The education and training activities described in subparagraph (A) may be carried out by Federal public health, medical, or dental entities, appropriate educational entities, professional organizations and societies, private accrediting organizations, and other nonprofit institutions or entities meeting criteria established by the Secretary.

(C) GRANTS AND CONTRACTS.—In carrying out this subsection, the Secretary may carry out activities directly or through the award of grants and contracts, and may enter into interagency agreements with other Federal agencies.

(b) ADVICE TO THE FEDERAL GOVERNMENT.—

(1) REQUIRED ADVISORY COMMITTEES.—In coordination with the working group under subsection (a), the Secretary shall establish advisory committees in accordance with paragraphs (2) and (3) to provide expert recommendations to assist such working groups in carrying out their respective responsibilities under subsections (a) and (b)[20].

(2) NATIONAL ADVISORY COMMITTEE ON CHILDREN AND TERRORISM[21].—

(A) IN GENERAL.—For purposes of paragraph (1), the Secretary shall establish an advisory committee to be known as the National Advisory Committee on At-Risk Individuals and Public Health Emergencies (referred to in this paragraph as the "Advisory Committee").

(B) DUTIES.—The Advisory Committee shall provide recommendations regarding—

(i) the preparedness of the health care (including mental health care) system to respond to public health emergencies as they relate to at-risk individuals;

(ii) needed changes to the health care and emergency medical service systems and emergency medical services protocols to meet the special needs of at-risk individuals; and

(iii) changes, if necessary, to the national stockpile under section 121 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 to meet the emergency health security of at-risk individuals.

(C) COMPOSITION.—The Advisory Committee shall be composed of such Federal officials as may be appropriate

[20] Probably should be "to assist such working group in carrying out its responsibilities under subsection (a)". Formerly there were two working groups, one under subsection (a) and one under subsection (b). Now there is only the working group under subsection (a). See the amendments made by sections 104(a) and 108 of Public Law 107–188 (116 Stat. 605, 609).

[21] The heading for subsection (b)(2) probably should read "NATIONAL ADVISORY COMMITTEE ON AT-RISK INDIVIDUALS AND PUBLIC HEALTH EMERGENCIES". The amendment made by section 301(d)(1) of Public Law 109–417 (120 Stat. 2854) to strike "CHILDREN AND TERRORISM" and insert "AT-RISK INDIVIDUALS AND PUBLIC HEALTH EMERGENCIES" could not be executed due to incorrect capitalization of the word "Children" in the matter to be struck. Also the letter "A" in the word "At-risk" in the inserted text probably should be lowercase type.

to address the special needs of the diverse population groups of at-risk populations.

(D) TERMINATION.—The Advisory Committee terminates six years after the date of the enactment of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

(3) EMERGENCY PUBLIC INFORMATION AND COMMUNICATIONS ADVISORY COMMITTEE.—

(A) IN GENERAL.—For purposes of paragraph (1), the Secretary shall establish an advisory committee to be known as the Emergency Public Information and Communications Advisory Committee (referred to in this paragraph as the "EPIC Advisory Committee").

(B) DUTIES.—The EPIC Advisory Committee shall make recommendations to the Secretary and report on appropriate ways to communicate public health information regarding bioterrorism and other public health emergencies to the public.

(C) COMPOSITION.—The EPIC Advisory Committee shall be composed of individuals representing a diverse group of experts in public health, medicine, communications, behavioral psychology, and other areas determined appropriate by the Secretary.

(D) DISSEMINATION.—The Secretary shall review the recommendations of the EPIC Advisory Committee and ensure that appropriate information is disseminated to the public.

(E) TERMINATION.—The EPIC Advisory Committee terminates one year after the date of the enactment of Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

(c) EXPANSION OF EPIDEMIC INTELLIGENCE SERVICE PROGRAM.—The Secretary may establish 20 officer positions in the Epidemic Intelligence Service Program, in addition to the number of the officer positions offered under such Program in 2006, for individuals who agree to participate, for a period of not less than 2 years, in the Career Epidemiology Field Officer program in a State, local, or tribal health department that serves a health professional shortage area (as defined under section 332(a)), a medically underserved population (as defined under section 330(b)(3)), or a medically underserved area or area at high risk of a public health emergency as designated by the Secretary.

(d) CENTERS FOR PUBLIC HEALTH PREPAREDNESS AND RESPONSE.—

(1) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may award grants, contracts, or cooperative agreements to institutions of higher education, including accredited schools of public health, or other nonprofit private entities to establish or maintain a network of Centers for Public Health Preparedness and Response (referred to in this subsection as "Centers").

(2) ELIGIBILITY.—To be eligible to receive an award under this subsection, an entity shall submit to the Secretary an ap-

plication containing such information as the Secretary may require, including a description of how the entity will—

(A) coordinate relevant activities with applicable State, local, and Tribal health departments and officials, health care facilities, and health care coalitions to improve public health preparedness and response, as informed by the public health preparedness and response needs of the community, or communities, involved;

(B) prioritize efforts to implement evidence-informed or evidence-based practices to improve public health preparedness and response, including by helping to reduce the transmission of emerging infectious diseases; and

(C) use funds awarded under this subsection, including by carrying out any activities described in paragraph (3).

(3) USE OF FUNDS.—The Centers established or maintained under this subsection shall use funds awarded under this subsection to carry out activities to advance public health preparedness and response capabilities, which may include—

(A) identifying, translating, and disseminating promising research findings or strategies into evidence-informed or evidence-based practices to inform preparedness for, and responses to, chemical, biological, radiological, or nuclear threats, including emerging infectious diseases, and other public health emergencies, which may include conducting research related to public health preparedness and response systems;

(B) improving awareness of such evidence-informed or evidence-based practices and other relevant scientific or public health information among health care professionals, public health professionals, other stakeholders, and the public, including through the development, evaluation, and dissemination of trainings and training materials, consistent with section 2802(b)(2), as applicable and appropriate, and with consideration given to existing training materials, to support preparedness for, and responses to, such threats;

(C) utilizing and expanding relevant technological and analytical capabilities to inform public health and medical preparedness and response efforts;

(D) expanding activities, including through public-private partnerships, related to public health preparedness and response, including participation in drills and exercises and training public health experts, as appropriate; and

(E) providing technical assistance and expertise that relies on evidence-based practices, as applicable, related to responses to public health emergencies, as appropriate, to State, local, and Tribal health departments and other entities pursuant to paragraph (2)(A).

(4) DISTRIBUTION OF AWARDS.—In awarding grants, contracts, or cooperative agreements under this subsection, the Secretary shall support not fewer than 10 Centers, subject to the availability of appropriations, and ensure that such awards

are equitably distributed among the geographical regions of the United States.

(e) ACCELERATED RESEARCH AND DEVELOPMENT ON PRIORITY PATHOGENS AND COUNTERMEASURES.—

(1) IN GENERAL.—With respect to pathogens of potential use in a bioterrorist attack, and other agents that may cause a public health emergency, the Secretary, taking into consideration any recommendations of the working group under subsection (a), shall conduct, and award grants, contracts, or cooperative agreements for, research, investigations, experiments, demonstrations, and studies in the health sciences relating to—

(A) the epidemiology and pathogenesis of such pathogens;

(B) the sequencing of the genomes, or other DNA analysis, or other comparative analysis, of priority pathogens (as determined by the Director of the National Institutes of Health in consultation with the working group established in subsection (a)), in collaboration and coordination with the activities of the Department of Defense and the Joint Genome Institute of the Department of Energy;

(C) the development of priority countermeasures; and

(D) other relevant areas of research;

with consideration given to the needs of children and other vulnerable populations.

(2) PRIORITY.—The Secretary shall give priority under this section to the funding of research and other studies related to priority countermeasures.

(3) ROLE OF DEPARTMENT OF VETERANS AFFAIRS.—In carrying out paragraph (1), the Secretary shall consider using the biomedical research and development capabilities of the Department of Veterans Affairs, in conjunction with that Department's affiliations with health-professions universities. When advantageous to the Government in furtherance of the purposes of such paragraph, the Secretary may enter into cooperative agreements with the Secretary of Veterans Affairs to achieve such purposes.

(4) PRIORITY COUNTERMEASURES.—For purposes of this section, the term "priority countermeasure" means a drug, biological product, device, vaccine, vaccine adjuvant, antiviral, or diagnostic test that the Secretary determines to be—

(A) a priority to treat, identify, or prevent infection by a biological agent or toxin listed pursuant to section 351A(a)(1), or harm from any other agent that may cause a public health emergency; or

(B) a priority to treat, identify, or prevent conditions that may result in adverse health consequences or death and may be caused by the administering of a drug, biological product, device, vaccine, vaccine adjuvant, antiviral, or diagnostic test that is a priority under subparagraph (A).

(f) AUTHORIZATION OF APPROPRIATIONS.—

(1) FISCAL YEAR 2007.—There are authorized to be appropriated to carry out this section for fiscal year 2007—

(A) to carry out subsection (a)—

(i) $5,000,000 to carry out paragraphs (1) through (4); and

(ii) $7,000,000 to carry out paragraph (5);

(B) to carry out subsection (c), $3,000,000; and

(C) to carry out subsection (d), $31,000,000.

(2) SUBSEQUENT FISCAL YEARS.—There are authorized to be appropriated such sums as may be necessary to carry out this section for fiscal year 2008 and each subsequent fiscal year.

SEC. 319F–1. [247d–6a] AUTHORITY FOR USE OF CERTAIN PROCEDURES REGARDING QUALIFIED COUNTERMEASURE RESEARCH AND DEVELOPMENT ACTIVITIES.[22]

(a) IN GENERAL.—

(1) AUTHORITY.—In conducting and supporting research and development activities regarding countermeasures under section 319F(e), the Secretary may conduct and support such activities in accordance with this section and, in consultation with the Director of the National Institutes of Health, as part of the program under section 446, if the activities concern qualified countermeasures.

(2) DEFINITIONS.—In this section:

(A) QUALIFIED COUNTERMEASURE.—The term "qualified countermeasure" means a drug (as that term is defined by section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1))), biological product (as that term is defined by section 351(i) of this Act (42 U.S.C. 262(i))), or device (as that term is defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h))), that the Secretary determines to be a priority (consistent with sections 302(2) and 304(a) of the Homeland Security Act of 2002)—

(i) to diagnose, mitigate, prevent, or treat harm from any biological agent (including organisms that cause an infectious disease) or toxin, chemical, radiological, or nuclear agent that may cause a public health emergency affecting national security;

(ii) to diagnose, mitigate, prevent, or treat harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, biological product, or device that is used as described in this subparagraph; or

(iii) is a product or technology intended to enhance the use or effect of a drug, biological product, or device described in clause (i) or (ii).

(B) INFECTIOUS DISEASE.—The term "infectious disease" means a disease potentially caused by a pathogenic organism (including a bacteria, virus, fungus, or parasite) that is acquired by a person and that reproduces in that person.

(3) INTERAGENCY COOPERATION.—

(A) IN GENERAL.—In carrying out activities under this section, the Secretary is authorized, subject to subpara-

[22] Section 5 of Public Law 108–276 (118 Stat. 860) requires various reports regarding section 319F–1 and related provisions of law. Section 5 is included in the appendix to this compilation.

graph (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(e) 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 proce-

dures that would be required under sections 301(a)(3), 405(b)(1)(B), 405(b)(2), 406(a)(3)(A), 492, and 494, as applicable to a grant, contract, or cooperative agreement—

(A) that is for performing, administering, or supporting qualified countermeasure research and development activities; and

(B) the amount of which is not greater than $1,500,000.

(2) SUBSEQUENT PHASES OF RESEARCH.—The Secretary's determination of whether to employ expedited peer review with respect to any subsequent phases of a research grant, contract, or cooperative agreement under this section shall be determined without regard to the peer review procedures used for any prior peer review of that same grant, contract, or cooperative agreement. Nothing in the preceding sentence may be construed to impose any requirement with respect to peer review not otherwise required under any other law or regulation.

(d) AUTHORITY FOR PERSONAL SERVICES CONTRACTS.—

(1) IN GENERAL.—For the purpose of performing, administering, or supporting qualified countermeasure research and development activities, the Secretary may, as the Secretary determines necessary to respond to pressing qualified countermeasure research and development needs under this section, obtain by contract (in accordance with section 3109 of title 5, United States Code, but without regard to the limitations in such section on the period of service and on pay) the personal services of experts or consultants who have scientific or other professional qualifications, except that in no case shall the compensation provided to any such expert or consultant exceed the daily equivalent of the annual rate of compensation for the President.

(2) FEDERAL TORT CLAIMS ACT COVERAGE.—

(A) IN GENERAL.—A person carrying out a contract under paragraph (1), and an officer, employee, or governing board member of such person, shall, subject to a determination by the Secretary, be deemed to be an employee of the Department of Health and Human Services for purposes of claims under sections 1346(b) and 2672 of title 28, United States Code, for money damages for personal injury, including death, resulting from performance of functions under such contract.

(B) EXCLUSIVITY OF REMEDY.—The remedy provided by subparagraph (A) shall be exclusive of any other civil action or proceeding by reason of the same subject matter against the entity involved (person, officer, employee, or governing board member) for any act or omission within the scope of the Federal Tort Claims Act.

(C) RECOURSE IN CASE OF GROSS MISCONDUCT OR CONTRACT VIOLATION.—

(i) IN GENERAL.—Should payment be made by the United States to any claimant bringing a claim under this paragraph, either by way of administrative determination, settlement, or court judgment, the United States shall have, notwithstanding any provision of

State law, the right to recover against any entity identified in subparagraph (B) for that portion of the damages so awarded or paid, as well as interest and any costs of litigation, resulting from the failure of any such entity to carry out any obligation or responsibility assumed by such entity under a contract with the United States or from any grossly negligent or reckless conduct or intentional or willful misconduct on the part of such entity.

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

(3) INTERNAL CONTROLS TO BE INSTITUTED.—

(A) IN GENERAL.—The Secretary shall institute appropriate internal controls for contracts under this subsection, including procedures for the Secretary to make a determination of whether a person, or an officer, employee, or governing board member of a person, is deemed to be an employee of the Department of Health and Human Services pursuant to paragraph (2).

(B) DETERMINATION OF EMPLOYEE STATUS TO BE FINAL.—A determination by the Secretary under subparagraph (A) that a person, or an officer, employee, or 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 AND SECURITY COUNTERMEASURE PROCUREMENTS.[23]

(a) STRATEGIC NATIONAL STOCKPILE.—

(1) IN GENERAL.—The Secretary, in collaboration with the Assistant Secretary for Preparedness and Response and the Director of the Centers for Disease Control and Prevention, and 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 (including personal protective equipment, ancillary medical supplies, and other applicable supplies required for the administration of drugs, vaccines and other biological products, medical devices, and diagnostic tests in the stockpile) in such numbers, types, and amounts as are determined consistent with section 2811 by the Secretary to be appropriate and practicable, taking into account other available sources, to provide for and optimize 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 and, as informed by existing recommendations of, or consultations with, the Public Health Emergency Medical Countermeasure Enterprise established under section 2811–1, make necessary additions or modifications to the contents of such stockpile or stockpiles based on the review conducted under paragraph (2).

(2) THREAT-BASED REVIEW.—

(A) IN GENERAL.—The Secretary shall conduct an annual threat-based review (taking into account at-risk individuals) of the contents of the stockpile under paragraph (1), including non-pharmaceutical supplies, and, in consultation with the Public Health Emergency Medical Countermeasures Enterprise established under section 2811–1, review contents within the stockpile and assess whether such contents are consistent with the recommendations made pursuant to section 2811–1(c)(1)(A). Such review

[23] Section 5 of Public Law 108–276 (118 Stat. 860) requires various reports regarding section 319F–2 and related provisions of law. Section 5 is included in the appendix to this compilation.

shall be submitted on June 15, 2019, and on March 15 of each year thereafter, to the Committee on Health, Education, Labor, and Pensions 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, in a manner that does not compromise national security.

(B) ADDITIONS, MODIFICATIONS, AND REPLENISHMENTS.—Each annual threat-based review under subparagraph (A) shall, for each new or modified countermeasure procurement or replenishment, provide—

(i) information regarding—

(I) the quantities of the additional or modified countermeasure procured for, or contracted to be procured for, the stockpile;

(II) planning considerations for appropriate manufacturing capacity and capability to meet the goals of such additions or modifications (without disclosing proprietary information), including—

(aa) consideration of the effect such additions or modifications may have on the availability of such products and ancillary medical supplies on the health care system; and

(bb) an assessment of the current supply chain for such products, including information on supply chain redundancies, any known domestic manufacturing capacity for such products, and any related vulnerabilities;

(III) the presence or lack of a commercial market for the countermeasure at the time of procurement;

(IV) the emergency health security threat or threats such countermeasure procurement is intended to address, including whether such procurement is consistent with meeting emergency health security needs associated with such threat or threats;

(V) an assessment of whether the emergency health security threat or threats described in subclause (IV) could be addressed in a manner that better utilizes the resources of the stockpile and permits the greatest possible increase in the level of emergency preparedness to address such threats;

(VI) whether such countermeasure is replenishing an expiring or expired countermeasure, is a different countermeasure with the same indication that is replacing an expiring or expired countermeasure, or is a new addition to the stockpile;

(VII) a description of how such additions or modifications align with projected investments under previous countermeasures budget plans under section 2811(b)(7), including expected lifecycle costs, expenditures related to counter-

measure procurement to address the threat or threats described in subclause (IV), replenishment dates (including the ability to extend the maximum shelf life of a countermeasure), and the manufacturing capacity required to replenish such countermeasure; and

(VIII) appropriate protocols and processes for the deployment, distribution, or dispensing of the countermeasure at the State and local level, including plans for relevant capabilities of State and local entities to dispense, distribute, and administer the countermeasure; and

(ii) an assurance, which need not be provided in advance of procurement, that for each countermeasure procured or replenished under this subsection, the Secretary completed a review addressing each item listed under this subsection in advance of such procurement or replenishment.

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

(A) consult with the working group under section 319F(a) and the Public Health Emergency Medical Countermeasures Enterprise established under section 2811–1;

(B) ensure that adequate procedures are followed, regularly reviewed, and updated with respect to such stockpile for inventory management and accounting, and for the physical security of the stockpile;

(C) in consultation with Federal, State, local, and Tribal officials, take into consideration the timing and location of special events, and the availability, deployment, dispensing, and administration of countermeasures;

(D) review and revise, as appropriate, the contents of the stockpile on a regular basis to ensure that—

(i) emerging threats, advanced technologies, and new countermeasures are adequately considered;

(ii) the potential depletion of countermeasures currently in the stockpile is identified and appropriately addressed, including through necessary replenishment; and

(iii) such contents are in working condition or usable, as applicable, and are ready for deployment, which may include conducting maintenance services on such contents of the stockpile and disposing of such contents that are no longer in working condition, or usable, as applicable;

(E) devise plans for effective and timely supply-chain management of the stockpile, in consultation with the Director of the Centers for Disease Control and Prevention, the Assistant Secretary for Preparedness and Response, the Secretary of Transportation, the Secretary of Homeland Security, the Secretary of Veterans Affairs, and the heads of other appropriate Federal agencies; State, local, Tribal, and territorial agencies; and the public and private health care infrastructure, as applicable, taking into ac-

count the manufacturing capacity and other available sources of products and appropriate alternatives to supplies in the stockpile;

(F) deploy the stockpile at the discretion of the Secretary, in consultation with, or at the request of, 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;

(H) ensure the adequate physical security of the stockpile;

(I) ensure that each countermeasure or product under consideration for procurement pursuant to this subsection receives the same consideration regardless of whether such countermeasure or product receives or had received funding under section 319L, including with respect to whether the countermeasure or product is most appropriate to meet the emergency health security needs of the United States;

(J) provide assistance, including technical assistance, to maintain and improve State local, and Tribal public health preparedness capabilities to distribute and dispense medical countermeasures and products from the stockpile, as appropriate; and

(K) convene meetings, not less than once per year, with representatives from State, local, and Tribal health departments or officials, relevant industries, other Federal agencies, and other appropriate stakeholders, in a manner that does not compromise national security, to coordinate and share information related to maintenance and use of the stockpile, including a description of future countermeasure needs and additions, modifications, and replenishments of the contents of the stockpile, and considerations related to the manufacturing and procurement of products consistent with the requirements of the with the requirements of chapter 83 of title 41, United States Code (commonly referred to as the "Buy American Act"), as appropriate.

(4) UTILIZATION GUIDELINES.—The Secretary shall ensure timely and accurate recommended utilization guidelines for qualified countermeasures (as defined in section 319F–1), qualified pandemic and epidemic products (as defined in section 319F–3), and security countermeasures (as defined in subsection (c)), including for such products in the stockpile.

(5) VENDOR-MANAGED INVENTORY AND WARM-BASE SURGE CAPACITY.—

(A) IN GENERAL.—For the purposes of maintaining the stockpile under paragraph (1) and carrying out procedures under paragraph (3), the Secretary may enter into contracts or cooperative agreements with vendors, which may include manufacturers or distributors of medical products, with respect to medical products intended to be delivered to the ownership of the Federal Government. Each such

contract or cooperative agreement shall be subject to such terms and conditions as the Secretary may specify, including terms and conditions with respect to—

(i) procurement, maintenance, storage, and delivery of products, in alignment with inventory management and other applicable best practices, under such contract or cooperative agreement, which may consider, as appropriate, costs of transporting and handling such products; or

(ii) maintenance of domestic manufacturing capacity and capabilities of such products to ensure additional reserved production capacity and capabilities are available, and that such capacity and capabilities are able to support the rapid manufacture, purchase, storage, and delivery of such products, as required by the Secretary to prepare for, or respond to, an existing or potential public health emergency.

(B) REPORT.—Not later than 2 years after the date of enactment of the PREVENT Pandemics Act, and annually thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions 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 a report on any contracts or cooperative agreements entered into under subparagraph (A) for purposes of establishing and maintaining vendor-managed inventory or reserve manufacturing capacity and capabilities for products intended for the stockpile, including a description of—

(i) the amount of each award;

(ii) the recipient of each award;

(iii) the product or products covered through each award; and

(iv) how the Secretary works with each recipient to ensure situational awareness related to the manufacturing capacity for, or inventory of, such products and coordinates the distribution and deployment of such products, as appropriate and applicable.

(6) GAO REPORT.—

(A) IN GENERAL.—Not later than 3 years after the date of enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019, and every 5 years thereafter, the Comptroller General of the United States shall conduct a review of any changes to the contents or management of the stockpile since January 1, 2015. Such review shall include—

(i) an assessment of the comprehensiveness and completeness of each annual threat-based review under paragraph (2), including whether all newly procured or replenished countermeasures within the stockpile were described in each annual review, and whether, consistent with paragraph (2)(B), the Secretary conducted the necessary internal review in advance of such procurement or replenishment;

(ii) an assessment of whether the Secretary established health security and science-based justifications, and a description of such justifications for procurement decisions related to health security needs with respect to the identified threat, for additions or modifications to the stockpile based on the information provided in such reviews under paragraph (2)(B), including whether such review was conducted prior to procurement, modification, or replenishment;

(iii) an assessment of the plans developed by the Secretary for the deployment, distribution, and dispensing of countermeasures procured, modified, or replenished under paragraph (1), including whether such plans were developed prior to procurement, modification, or replenishment;

(iv) an accounting of countermeasures procured, modified, or replenished under paragraph (1) that received advanced research and development funding from the Biomedical Advanced Research and Development Authority;

(v) an analysis of how such procurement decisions made progress toward meeting emergency health security needs related to the identified threats for countermeasures added, modified, or replenished under paragraph (1);

(vi) a description of the resources expended related to the procurement of countermeasures (including additions, modifications, and replenishments) in the stockpile, and how such expenditures relate to the ability of the stockpile to meet emergency health security needs;

(vii) an assessment of the extent to which additions, modifications, and replenishments reviewed under paragraph (2) align with previous relevant reports or reviews by the Secretary or the Comptroller General;

(viii) with respect to any change in the Federal organizational management of the stockpile, an assessment and comparison of the processes affected by such change, including planning for potential countermeasure deployment, distribution, or dispensing capabilities and processes related to procurement decisions, use of stockpiled countermeasures, and use of resources for such activities;

(ix) an assessment of whether the processes and procedures described by the Secretary pursuant to section 403(b) of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 are sufficient to ensure countermeasures and products under consideration for procurement pursuant to subsection (a) receive the same consideration regardless of whether such countermeasures and products receive or had received funding under section 319L, including with respect to whether such countermeasures and

products are most appropriate to meet the emergency health security needs of the United States; and

(x) with respect to reports issued in 2027 or any subsequent year, an assessment of selected contracts or cooperative agreements entered into pursuant to paragraph (5).

(B) SUBMISSION.—Not later than 6 months after completing a classified version of the review under subparagraph (A), the Comptroller General shall submit an unclassified version of the review to the congressional committees of jurisdiction.

(7) REIMBURSEMENT FOR CERTAIN SUPPLIES.—

(A) IN GENERAL.—The Secretary may, at appropriate intervals, make available for purchase excess contents procured for, and maintained within, the stockpile under paragraph (1) to any Federal agency or State, local, or Tribal government. The Secretary shall make such contents available for purchase only if—

(i) such contents are in excess of what is required for appropriate maintenance of such stockpile;

(ii) the Secretary determines that the costs for maintaining such excess contents are not appropriate to expend to meet the needs of the stockpile; and

(iii) the Secretary determines that such action does not compromise national security and is in the national interest.

(B) REIMBURSEMENT AND COLLECTION.—The Secretary may require reimbursement for contents that are made available under subparagraph (A), in an amount that reflects the cost of acquiring and maintaining such contents and the costs incurred to make available such contents in the time and manner specified by the Secretary. Amounts collected under this subsection shall be credited to the appropriations account or fund that incurred the costs to procure such contents, and shall remain available, without further appropriation, until expended, for the purposes of the appropriation account or fund so credited.

(C) RULE OF CONSTRUCTION.—This paragraph shall not be construed to preclude transfers of contents in the stockpile under other authorities.

(D) REPORT.—Not later than 2 years after the date of enactment of the PREVENT Pandemics Act, and annually thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions 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 a report on the use of the authority provided under this paragraph, including details of each action taken pursuant to this paragraph, the account or fund to which any collected amounts have been credited, and how the Secretary has used such amounts.

(E) SUNSET.—The authority under this paragraph shall terminate on September 30, 2028.

(b) SMALLPOX VACCINE DEVELOPMENT.—

(1) IN GENERAL.—The Secretary shall award contracts, enter into cooperative agreements, or carry out such other activities as may reasonably be required in order to ensure that the stockpile under subsection (a) includes an amount of vaccine against smallpox as determined by such Secretary to be sufficient to meet the health security needs of the United States.

(2) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to limit the private distribution, purchase, or sale of vaccines from sources other than the stockpile described in subsection (a).

(c) ADDITIONAL AUTHORITY REGARDING PROCUREMENT OF CERTAIN COUNTERMEASURES; AVAILABILITY OF SPECIAL RESERVE FUND.—

(1) IN GENERAL.—

(A) USE OF FUND.—A security countermeasure may, in accordance with this subsection, be procured with amounts in the special reserve fund as defined in subsection (h).

(B) SECURITY COUNTERMEASURE.—For purposes of this subsection, the term "security countermeasure" means a drug (as that term is defined by section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1))), biological product (as that term is defined by section 351(i) of this Act (42 U.S.C. 262(i))), or device (as that term is defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h))) that—

(i)(I) the Secretary determines to be a priority (consistent with sections 302(2) and 304(a) of the Homeland Security Act of 2002) to diagnose, mitigate, prevent, or treat harm from any biological, chemical, radiological, or nuclear agent identified as a material threat under paragraph (2)(A)(ii), or to diagnose, mitigate, prevent, or treat harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, biological product, or device against such an agent;

(II) the Secretary determines under paragraph (2)(B)(ii) to be a necessary countermeasure; and

(III)(aa) is approved or cleared under chapter V of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of this Act; or

(bb) is a countermeasure for which the Secretary determines that sufficient and satisfactory clinical experience or research data (including data, if available, from pre-clinical and clinical trials) support a reasonable conclusion that the countermeasure will qualify for approval or licensing within 10 years after the date of a determination under paragraph (5); or

(ii) is authorized for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act.

(2) DETERMINATION OF MATERIAL THREATS.—

(A) MATERIAL THREAT.—The Homeland Security Secretary, in consultation with the Secretary and the heads of other agencies as appropriate, shall on an ongoing basis—

(i) assess current and emerging threats of chemical, biological, radiological, and nuclear agents; and

(ii) determine which of such agents present a material threat against the United States population sufficient to affect national security.

(B) PUBLIC HEALTH IMPACT; NECESSARY COUNTERMEASURES.—The Secretary shall on an ongoing basis—

(i) assess the potential public health consequences for the United States population of exposure to agents identified under subparagraph (A)(ii); and

(ii) determine, on the basis of such assessment, the agents identified under subparagraph (A)(ii) for which countermeasures are necessary to protect the public health.

(C) NOTICE TO CONGRESS.—The Secretary and the Secretary of Homeland Security shall send to Congress, not later than March 15 of each year, all current material threat determinations and shall promptly notify the Committee on Health, Education, Labor, and Pensions and the Committee on Homeland Security and Governmental Affairs of the Senate and the Committee on Energy and Commerce and the Committee on Homeland Security of the House of Representatives that a determination has been made pursuant to subparagraph (A) or (B).

(D) ASSURING ACCESS TO THREAT INFORMATION.—In making the assessment and determination required under subparagraph (A), the Homeland Security Secretary shall use all relevant information to which such Secretary is entitled under section 202 of the Homeland Security Act of 2002, including but not limited to information, regardless of its level of classification, relating to current and emerging threats of chemical, biological, radiological, and nuclear agents.

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

(A) IN GENERAL.—The Secretary, in consultation with the Homeland Security Secretary, shall assess on an ongoing basis the availability and appropriateness of specific countermeasures to address specific threats identified under paragraph (2).

(B) INFORMATION.—The Secretary shall institute a process for making publicly available the results of assessments under subparagraph (A) while withholding such information as—

(i) would, in the judgment of the Secretary, tend to reveal public health vulnerabilities; or

(ii) would otherwise be exempt from disclosure under section 552 of title 5, United States Code.

(4) CALL FOR DEVELOPMENT OF COUNTERMEASURES; COMMITMENT FOR RECOMMENDATION FOR PROCUREMENT.—

(A) PROPOSAL TO THE PRESIDENT.—If, pursuant to an assessment under paragraph (3), the Homeland Security Secretary and the Secretary make a determination that a countermeasure would be appropriate but is either currently not developed or unavailable for procurement as a security countermeasure or is approved, licensed, or cleared only for alternative uses, such Secretaries may jointly submit to the President a proposal to—

(i) issue a call for the development of such countermeasure; and

(ii) make a commitment that, upon the first development of such countermeasure that meets the conditions for procurement under paragraph (5), the Secretaries will, based in part on information obtained pursuant to such call, and subject to the availability of appropriations, make available the special reserve fund as defined in subsection (h) for procurement of such countermeasure, as applicable.

(B) COUNTERMEASURE SPECIFICATIONS.—The Homeland Security Secretary and the Secretary shall, to the extent practicable, include in the proposal under subparagraph (A)—

(i) estimated quantity of purchase (in the form of number of doses or number of effective courses of treatments regardless of dosage form);

(ii) necessary measures of minimum safety and effectiveness;

(iii) estimated price for each dose or effective course of treatment regardless of dosage form; and

(iv) other information that may be necessary to encourage and facilitate research, development, and manufacture of the countermeasure or to provide specifications for the countermeasure.

(C) PRESIDENTIAL APPROVAL.—If the President approves a proposal under subparagraph (A), the Homeland Security Secretary and the Secretary shall make known to persons who may respond to a call for the countermeasure involved—

(i) the call for the countermeasure;

(ii) specifications for the countermeasure under subparagraph (B); and

(iii) the commitment described in subparagraph (A)(ii).

(5) SECRETARY'S DETERMINATION OF COUNTERMEASURES APPROPRIATE FOR FUNDING FROM SPECIAL RESERVE FUND.—

(A) IN GENERAL.—The Secretary, in accordance with the provisions of this paragraph, shall identify specific security countermeasures that the Secretary determines, in consultation with the Homeland Security Secretary, to be appropriate for inclusion in the stockpile under subsection (a) pursuant to procurements made with amounts in the special reserve fund as defined in subsection (h) (referred to in this subsection individually as a "procurement under this subsection").

(B) REQUIREMENTS.—In making a determination under subparagraph (A) with respect to a security countermeasure, the Secretary shall determine and consider the following:

(i) The quantities of the product that will be needed to meet the stockpile needs.

(ii) The feasibility of production and delivery within 10 years of sufficient quantities of the product.

(iii) Whether there is a lack of a significant commercial market for the product at the time of procurement, other than as a security countermeasure.

(6) RECOMMENDATIONS FOR PROCUREMENT.—

(A) NOTICE TO APPROPRIATE CONGRESSIONAL COMMITTEES.—The Secretary shall notify the Committee on Appropriations and the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Appropriations and the Committee on Energy and Commerce of the House of Representatives of each decision to make available the special reserve fund as defined in subsection (h) for procurement of a security countermeasure, including, where available, the number of, the 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 for each such rejection.

(B) SUBSEQUENT SPECIFIC COUNTERMEASURES.—Procurement under this subsection of a security countermeasure for a particular purpose does not preclude the subsequent procurement under this subsection of any other security countermeasure for such purpose if the Secretary has determined under paragraph (5)(A) that such countermeasure is appropriate for inclusion in the stockpile and if, as determined by the Secretary, such countermeasure provides improved safety or effectiveness, or for other reasons enhances preparedness to respond to threats of use of a biological, chemical, radiological, or nuclear agent. Such a determination by the Secretary is committed to agency discretion.

(7) PROCUREMENT.—

(A) PAYMENTS FROM SPECIAL RESERVE FUND.—The special reserve fund as defined in subsection (h) shall be available for payments made by the Secretary to a vendor for procurement of a security countermeasure in accordance with the provisions of this paragraph.

(B) PROCUREMENT.—

(i) IN GENERAL.—The Secretary shall be responsible for—

(I) arranging for procurement of a security countermeasure, including negotiating terms (including quantity, production schedule, and price) of, and entering into, contracts and cooperative agreements, and for carrying out such other activities as may reasonably be required, including

advanced research and development, in accordance with the provisions of this subparagraph; and

(II) promulgating such regulations as the Secretary determines necessary to implement the provisions of this subsection.

(ii) CONTRACT TERMS.—A contract for procurements under this subsection shall (or, as specified below, may) include the following terms:

(I) PAYMENT CONDITIONED ON DELIVERY.—The contract shall provide that no payment may be made until delivery of a portion, acceptable to the Secretary, of the total number of units contracted for, except that, notwithstanding any other provision of law, the contract may provide that, if the Secretary determines (in the Secretary's discretion) that an advance payment, partial payment for significant milestones, or payment to increase manufacturing capacity is necessary to ensure success of a project, the Secretary shall pay an amount, not to exceed 10 percent of the contract amount, in advance of delivery. The Secretary shall, to the extent practicable, make the determination of advance payment at the same time as the issuance of a solicitation. The contract shall provide that such advance payment is required to be repaid if there is a failure to perform by the vendor under the contract. The contract may also provide for additional advance payments of 5 percent each for meeting the milestones specified in such contract, except that such payments shall not exceed 50 percent of the total contract amount. If the specified milestones are reached, the advanced payments of 5 percent shall not be required to be repaid. Nothing in this subclause shall be construed as affecting the rights of vendors under provisions of law or regulation (including the Federal Acquisition Regulation) relating to the termination of contracts for the convenience of the Government.

(II) DISCOUNTED PAYMENT.—The contract may provide for a discounted price per unit of a product that is not licensed, cleared, or approved as described in paragraph (1)(B)(i)(III)(aa) at the time of delivery, and may provide for payment of an additional amount per unit if the product becomes so licensed, cleared, or approved before the expiration date of the contract (including an additional amount per unit of product delivered before the effective date of such licensing, clearance, or approval).

(III) CONTRACT DURATION.—The contract shall be for a period not to exceed five years, except that, in first awarding the contract, the Secretary

may provide for a longer duration, not exceeding 10 years, if the Secretary determines that complexities or other difficulties in performance under the contract justify such a period. The contract shall be renewable for additional periods, none of which shall exceed five years. The Secretary shall notify the vendor within 90 days of a determination by the Secretary to renew, extend, or terminate such contract.

(IV) STORAGE BY VENDOR.—The contract may provide that the vendor will provide storage for stocks of a product delivered to the ownership of the Federal Government under the contract, for such period and under such terms and conditions as the Secretary may specify, and in such case amounts from the special reserve fund as defined in subsection (h) shall be available for costs of shipping, handling, storage, and related costs for such product.

(V) PRODUCT APPROVAL.—The contract shall provide that the vendor seek approval, clearance, or licensing of the product from the Secretary; for a timetable for the development of data and other information to support such approval, clearance, or licensing; and that the Secretary may waive part or all of this contract term on request of the vendor or on the initiative of the Secretary.

(VI) NON-STOCKPILE TRANSFERS OF SECURITY COUNTERMEASURES.—The contract shall provide that the vendor will comply with all applicable export-related controls with respect to such countermeasure.

(VII) SALES EXCLUSIVITY.—The contract may provide that the vendor is the exclusive supplier of the product to the Federal Government for a specified period of time, not to exceed the term of the contract, on the condition that the vendor is able to satisfy the needs of the Government. During the agreed period of sales exclusivity, the vendor shall not assign its rights of sales exclusivity to another entity or entities without approval by the Secretary. Such a sales exclusivity provision in such a contract shall constitute a valid basis for a sole source procurement under section 303(c)(1) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(c)(1)).

(VIII) WARM BASED SURGE CAPACITY.—The contract may provide that the vendor establish domestic manufacturing capacity of the product to ensure that additional production of the product is available in the event that the Secretary determines that there is a need to quickly purchase additional quantities of the product. Such contract may provide a fee to the vendor for establishing

and maintaining such capacity in excess of the initial requirement for the purchase of the product. Additionally, the cost of maintaining the domestic manufacturing capacity shall be an allowable and allocable direct cost of the contract.

(IX) CONTRACT TERMS.—The Secretary, in any contract for procurement under this section—

(aa) may specify—

(AA) the dosing and administration requirements for the countermeasure to be developed and procured;

(BB) the amount of funding that will be dedicated by the Secretary for advanced research, development, and procurement of the countermeasure; and

(CC) the specifications the countermeasure must meet to qualify for procurement under a contract under this section; and

(bb) shall provide a clear statement of defined Government purpose limited to uses related to a security countermeasure, as defined in paragraph (1)(B).

(iii) AVAILABILITY OF SIMPLIFIED ACQUISITION PROCEDURES.—

(I) IN GENERAL.—If the Secretary determines that there is a pressing need for a procurement of a specific countermeasure, the amount of the procurement under this subsection shall be deemed to be below the threshold amount specified in section 4(11) of the Office of Federal Procurement Policy Act (41 U.S.C. 403(11)), for purposes of application to such procurement, pursuant to section 302A(a) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 252a(a)), of—

(aa) section 303(g)(1)(A) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(g)(1)(A)) and its implementing regulations; and

(bb) section 302A(b) of such Act (41 U.S.C. 252a(b)) and its implementing regulations.

(II) APPLICATION OF CERTAIN PROVISIONS.—Notwithstanding subclause (I) and the provision of law and regulations referred to in such clause, each of the following provisions shall apply to procurements described in this clause to the same extent that such provisions would apply to such procurements in the absence of subclause (I):

(aa) Chapter 37 of title 40, United States Code (relating to contract work hours and safety standards).

(bb) Subsections (a) and (b) of section 7 of the Anti-Kickback Act of 1986 (41 U.S.C. 57(a) and (b)).

(cc) Section 304C of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 254d) (relating to the examination of contractor records).

(dd) Section 3131 of title 40, United States Code (relating to bonds of contractors of public buildings or works).

(ee) Subsection (a) of section 304 of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 254(a)) (relating to contingent fees to middlemen).

(ff) Section 6002 of the Solid Waste Disposal Act (42 U.S.C. 6962).

(gg) Section 1354 of title 31, United States Code (relating to the limitation on the use of appropriated funds for contracts with entities not meeting veterans employment reporting requirements).

(III) INTERNAL CONTROLS TO BE ESTABLISHED.—The Secretary shall establish appropriate internal controls for procurements made under this clause, including requirements with respect to documentation of the justification for the use of the authority provided under this paragraph with respect to the procurement involved.

(IV) AUTHORITY TO LIMIT COMPETITION.—In conducting a procurement under this subparagraph, the Secretary may not use the authority provided for under subclause (I) to conduct a procurement on a basis other than full and open competition unless the Secretary determines that the mission of the BioShield Program under the Project BioShield Act of 2004 would be seriously impaired without such a limitation.

(iv) PROCEDURES OTHER THAN FULL AND OPEN COMPETITION.—

(I) IN GENERAL.—In using the authority provided in section 303(c)(1) of title III of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(c)(1)) to use procedures other than competitive procedures in the case of a 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.

(viii) FLEXIBILITY.—In carrying out this section, the Secretary may, consistent with the applicable provisions of this section, enter into contracts and other agreements that are in the best interest of the Government in meeting identified security countermeasure needs, including with respect to reimbursement of the cost of advanced research and development as a reasonable, allowable, and allocable direct cost of the contract involved.

(8) INTERAGENCY COOPERATION.—

(A) IN GENERAL.—In carrying out activities under this section, the Homeland Security Secretary and the Secretary are authorized, subject to subparagraph (B), to enter into interagency agreements and other collaborative undertakings with other agencies of the United States Government. Such agreements may allow other executive agencies to order qualified and security countermeasures under procurement contracts or other agreements established by the Secretary. Such ordering process (including transfers of appropriated funds between an agency and the Department of Health and Human Services as reimbursements for such orders for countermeasures) may be conducted under the authority of section 1535 of title 31, United States Code, except that all such orders shall be processed under the terms established under this subsection for the procurement of countermeasures.

(B) LIMITATION.—An agreement or undertaking under this paragraph shall not authorize another agency to exercise the authorities provided by this section to the Homeland Security Secretary or to the Secretary.

(d) DISCLOSURES.—No Federal agency may disclose under section 552 of title 5, United States Code any information identifying the location at which materials in the stockpile described in subsection (a) are stored, or other information regarding the contents or deployment capability of the stockpile that could compromise national security.

(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 $610,000,000 for each of fiscal years 2019 through 2021, and $750,000,000 for each of fiscal years 2022 and 2023, to remain available until expended. Such authorization is in addition to amounts in the special reserve fund referred to in subsection (h).

(2) SMALLPOX VACCINE DEVELOPMENT.—For the purpose of carrying out subsection (b), there are authorized to be appro-

priated $509,000,000 for fiscal year 2002, and such sums as may be necessary for each of fiscal years 2003 through 2006.

(g) SPECIAL RESERVE FUND.—

(1) AUTHORIZATION OF APPROPRIATIONS.—In addition to amounts appropriated to the special reserve fund prior to the date of the enactment of this subsection, there is authorized to be appropriated, for the procurement of security countermeasures under subsection (c) and for carrying out section 319L (relating to the Biomedical Advanced Research and Development Authority), $7,100,000,000 for the period of fiscal years 2019 through 2028, to remain available until expended.

(2) USE OF SPECIAL RESERVE FUND FOR ADVANCED RESEARCH AND DEVELOPMENT.—The Secretary may utilize not more than 50 percent of the amounts authorized to be appropriated under paragraph (1) to carry out section 319L (related to the Biomedical Advanced Research and Development Authority). Amounts authorized to be appropriated under this subsection to carry out section 319L are in addition to amounts otherwise authorized to be appropriated to carry out such section.

(3) RESTRICTIONS ON USE OF FUNDS.—Amounts in the special reserve fund shall not be used to pay costs other than payments made by the Secretary to a vendor for advanced development (under section 319L) or for procurement of a security countermeasure under subsection (c)(7).

(4) REPORT ON SECURITY COUNTERMEASURE PROCUREMENT.—Not later than March 1 of each year in which the Secretary determines that the amount of funds available for procurement of security countermeasures is less than $1,500,000,000, the Secretary shall submit to the Committee on Appropriations and the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Appropriations and the Committee on Energy and Commerce of the House of Representatives a report detailing the amount of such funds available for procurement and the impact such amount of funding will have—

(A) in meeting the security countermeasure needs identified under this section; and

(B) on the annual Public Health Emergency Medical Countermeasures Enterprise and Strategy Implementation Plan (pursuant to section 2811(d)).

(5) CLARIFICATION ON CONTRACTING AUTHORITY.—The Secretary, acting through the Director of the Biomedical Advanced Research and Development Authority, shall carry out the programs funded by the special reserve fund (for the procurement of security countermeasures under subsection (c) and for carrying out section 319L), including the execution of procurement contracts, grants, and cooperative agreements pursuant to this section and section 319L.

(h) DEFINITIONS.—In this section:

(1) The term "advanced research and development" has the meaning given such term in section 319L(a).

(2) The term "special reserve fund" means the "Biodefense Countermeasures" appropriations account, any appropriation

made available pursuant to section 521(a) of the Homeland Security Act of 2002, and any appropriation made available pursuant to subsection (g)(1).

(i) PILOT PROGRAM TO SUPPORT STATE MEDICAL STOCKPILES.—

(1) IN GENERAL.—The Secretary, in consultation with the Assistant Secretary for Preparedness and Response and the Director of the Centers for Disease Control and Prevention, shall award grants or cooperative agreements to not fewer than 5 States, or consortia of States, with consideration given to distribution among the geographical regions of the United States, to establish, expand, or maintain a stockpile of appropriate drugs, vaccines and other biological products, medical devices, and other medical supplies determined by the State to be necessary to respond to a public health emergency declared by the Governor of a State or by the Secretary under section 319, or a major disaster or emergency declared by the President under section 401 or 501, respectively, of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, in order to support the preparedness goals described in paragraphs (2) through (6) and (8) of section 2802(b). A recipient of such an award may not use award funds to support the stockpiling of security countermeasures (as defined in subsection (c)(1), unless the eligible entity provides justification for maintaining such countermeasures and the Secretary determines such justification is appropriate and applicable.

(2) REQUIREMENTS.—

(A) APPLICATION.—To be eligible to receive an award under paragraph (1), an entity shall prepare, in consultation with appropriate health care entities and health officials within the jurisdiction of such State or States, and submit to the Secretary an application that contains such information as the Secretary may require, including—

(i) a plan for such stockpile, consistent with paragraph (4), including—

(I) a description of the activities such entity will carry out under the agreement;

(II) an assurance that such entity will use funds under such award in alignment with the requirements of chapter 83 of title 41, United States Code (commonly referred to as the "Buy American Act"); and

(III) an outline of proposed expenses; and

(ii) a description of how such entity will coordinate with relevant entities in receipt of an award under section 319C–1 or 319C–2 pursuant to paragraph (4), including through promoting alignment between the stockpile plan established pursuant to clause (i) and applicable plans that are established by such entity pursuant to section 319C–1 or 319C–2.

(B) MATCHING FUNDS.—

(i) Subject to clause (ii), the Secretary may not make an award under this subsection unless the applicant agrees, with respect to the costs to be incurred by the applicant in carrying out the purpose described in

this subsection, to make available non-Federal contributions toward such costs in an amount equal to—

(I) for each of fiscal years 2023 and 2024, not less than $1 for each $20 of Federal funds provided in the award; and

(II) for fiscal year 2025 and each fiscal year thereafter, not less than $1 for each $10 of Federal funds provided in the award.

(ii) WAIVER.—The Secretary may, upon the request of a State, waive the requirement under clause (i), in whole or in part, if the Secretary determines that extraordinary economic conditions in the State in the fiscal year involved or in the previous fiscal year justify the waiver. A waiver provided by the Secretary under this subparagraph shall apply only to the fiscal year involved.

(C) ADMINISTRATIVE EXPENSES.—Not more than 10 percent of amounts received by an entity pursuant to an award under this subsection may be used for administrative expenses.

(3) LEAD ENTITY.—An entity in receipt of an award under paragraph (1) may designate a lead entity, which may be a public or private entity, as appropriate, to manage the stockpile at the direction of the State or consortium of States.

(4) USE OF FUNDS.—An entity in receipt of an award under paragraph (1) shall use such funds to—

(A) purchase, store, and maintain a stockpile of appropriate drugs, vaccines and other biological products, medical devices, and other medical supplies to be used during a public health emergency, major disaster, or emergency described in paragraph (1), in such numbers, types, and amounts as the entity determines necessary, consistent with such entity's stockpile plan established pursuant to paragraph (2)(A)(i);

(B) deploy the stockpile as required by the entity to respond to an actual or potential public health emergency, major disaster, or other emergency described in paragraph (1);

(C) replenish and make necessary additions or modifications to the contents of such stockpile, including to address potential depletion;

(D) in consultation with Federal, State, and local officials, take into consideration the availability, deployment, dispensing, and administration requirements of medical products within the stockpile;

(E) ensure that procedures are followed for inventory management and accounting, and for the physical security of the stockpile, as appropriate;

(F) review and revise, as appropriate, the contents of the stockpile on a regular basis to ensure that, to the extent practicable, new technologies and medical products are considered;

(G) carry out exercises, drills, and other training for purposes of stockpile deployment, dispensing, and adminis-

tration of medical products, and for purposes of assessing the capability of such stockpile to address the medical supply needs of public health emergencies, major disasters, or other emergencies described in paragraph (1) of varying types and scales, which may be conducted in accordance with requirements related to exercises, drills, and other training for recipients of awards under section 319C–1 or 319C–2, as applicable; and

(H) carry out other activities related to the State strategic stockpile as the entity determines appropriate, to support State efforts to prepare for, and respond to, public health threats.

(5) SUPPLEMENT NOT SUPPLANT.—Awards under paragraph (1) shall supplement, not supplant, the maintenance and use of the Strategic National Stockpile by the Secretary under subsection (a).

(6) GUIDANCE FOR STATES.—Not later than 180 days after the date of enactment of this subsection, the Secretary, in consultation with States, health officials, and other relevant stakeholders, as appropriate, shall issue guidance, and update such guidance as appropriate, for States related to maintaining and replenishing a stockpile of medical products, which may include strategies and best practices related to—

(A) types of medical products and medical supplies that are critical to respond to public health emergencies, and may be appropriate for inclusion in a stockpile by States, with consideration of threats that require the large-scale and simultaneous deployment of stockpiles, including the stockpile maintained by the Secretary pursuant to subsection (a), and long-term public health and medical response needs;

(B) appropriate management of the contents of a stockpile, including management by vendors of reserve amounts of medical products and supplies intended to be delivered to the ownership of the State and appropriate disposition of excess products, as applicable; and

(C) the procurement of medical products and medical supplies consistent with the requirements of chapter 83 of title 41, United States Code (commonly referred to as the "Buy American Act").

(7) TECHNICAL ASSISTANCE.—The Secretary shall provide assistance to States, including technical assistance, as appropriate, in establishing, maintaining, improving, and utilizing a medical stockpile, including appropriate inventory management and disposition of products.

(8) REPORTING.—

(A) STATE REPORTS.—Each entity receiving an award under paragraph (1) shall update, as appropriate, the plan established pursuant to paragraph (2)(A)(i) and submit to the Secretary an annual report on implementation of such plan, including any changes to the contents of the stockpile supported under such award. The Secretary shall use information obtained from such reports to inform the main-

tenance and management of the Strategic National Stockpile pursuant to subsection (a).

(B) REPORTS TO CONGRESS.—Not later than 1 year after the initial issuance of awards pursuant to paragraph (1), and annually thereafter for the duration of the program established under this subsection, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions 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 a report on such program, including—

(i) Federal and State expenditures to support stockpiles under such program;

(ii) activities conducted pursuant to paragraph (4); and

(iii) any additional information from the States that the Secretary determines relevant.

(9) AUTHORIZATION OF APPROPRIATIONS.—To carry out this subsection, there is authorized to be appropriated $3,500,000,000 for each of fiscal years 2023 and 2024, to remain available until expended.

SEC. 319F–3. [247d–6d] TARGETED LIABILITY PROTECTIONS FOR PANDEMIC AND EPIDEMIC PRODUCTS AND SECURITY COUNTERMEASURES.

(a) LIABILITY PROTECTIONS.—

(1) IN GENERAL.—Subject to the other provisions of this section, a covered person shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure if a declaration under subsection (b) has been issued with respect to such countermeasure.

(2) SCOPE OF CLAIMS FOR LOSS.—

(A) LOSS.—For purposes of this section, the term "loss" means any type of loss, including—

(i) death;

(ii) physical, mental, or emotional injury, illness, disability, or condition;

(iii) fear of physical, mental, or emotional injury, illness, disability, or condition, including any need for medical monitoring; and

(iv) loss of or damage to property, including business interruption loss.

Each of clauses (i) through (iv) applies without regard to the date of the occurrence, presentation, or discovery of the loss described in the clause.

(B) SCOPE.—The immunity under paragraph (1) applies to any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure, including a causal relationship with the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dis-

pensing, prescribing, administration, licensing, or use of such countermeasure.

(3) CERTAIN CONDITIONS.—Subject to the other provisions of this section, immunity under paragraph (1) with respect to a covered countermeasure applies only if—

(A) the countermeasure was administered or used during the effective period of the declaration that was issued under subsection (b) with respect to the countermeasure;

(B) the countermeasure was administered or used for the category or categories of diseases, health conditions, or threats to health specified in the declaration; and

(C) in addition, in the case of a covered person who is a program planner or qualified person with respect to the administration or use of the countermeasure, the countermeasure was administered to or used by an individual who—

(i) was in a population specified by the declaration; and

(ii) was at the time of administration physically present in a geographic area specified by the declaration or had a connection to such area specified in the declaration.

(4) APPLICABILITY OF CERTAIN CONDITIONS.—With respect to immunity under paragraph (1) and subject to the other provisions of this section:

(A) In the case of a covered person who is a manufacturer or distributor of the covered countermeasure involved, the immunity applies without regard to whether such countermeasure was administered to or used by an individual in accordance with the conditions described in paragraph (3)(C).

(B) In the case of a covered person who is a program planner or qualified person with respect to the administration or use of the covered countermeasure, the scope of immunity includes circumstances in which the countermeasure was administered to or used by an individual in circumstances in which the covered person reasonably could have believed that the countermeasure was administered or used in accordance with the conditions described in paragraph (3)(C).

(5) EFFECT OF DISTRIBUTION METHOD.—The provisions of this section apply to a covered countermeasure regardless of whether such countermeasure is obtained by donation, commercial sale, or any other means of distribution, except to the extent that, under paragraph (2)(E) of subsection (b), the declaration under such subsection provides that subsection (a) applies only to covered countermeasures obtained through a particular means of distribution.

(6) REBUTTABLE PRESUMPTION.—For purposes of paragraph (1), there shall be a rebuttable presumption that any administration or use, during the effective period of the emergency declaration by the Secretary under subsection (b), of a covered countermeasure shall have been for the category or categories

of diseases, health conditions, or threats to health with respect to which such declaration was issued.

(b) DECLARATION BY SECRETARY.—

(1) AUTHORITY TO ISSUE DECLARATION.—Subject to paragraph (2), if the Secretary makes a determination that a disease or other health condition or other threat to health constitutes a public health emergency, or that there is a credible risk that the disease, condition, or threat may in the future constitute such an emergency, the Secretary may make a declaration, through publication in the Federal Register, recommending, under conditions as the Secretary may specify, the manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures, and stating that subsection (a) is in effect with respect to the activities so recommended.

(2) CONTENTS.—In issuing a declaration under paragraph (1), the Secretary shall identify, for each covered countermeasure specified in the declaration—

(A) the category or categories of diseases, health conditions, or threats to health for which the Secretary recommends the administration or use of the countermeasure;

(B) the period or periods during which, including as modified by paragraph (3), subsection (a) is in effect, which period or periods may be designated by dates, or by milestones or other description of events, including factors specified in paragraph (6);

(C) the population or populations of individuals for which subsection (a) is in effect with respect to the administration or use of the countermeasure (which may be a specification that such subsection applies without geographic limitation to all individuals);

(D) the geographic area or areas for which subsection (a) is in effect with respect to the administration or use of the countermeasure (which may be a specification that such subsection applies without geographic limitation), including, with respect to individuals in the populations identified under subparagraph (C), a specification, as determined appropriate by the Secretary, of whether the declaration applies only to individuals physically present in such areas or whether in addition the declaration applies to individuals who have a connection to such areas, which connection is described in the declaration; and

(E) whether subsection (a) is effective only to a particular means of distribution as provided in subsection (a)(5) for obtaining the countermeasure, and if so, the particular means to which such subsection is effective.

(3) EFFECTIVE PERIOD OF DECLARATION.—

(A) FLEXIBILITY OF PERIOD.—The Secretary may, in describing periods under paragraph (2)(B), have different periods for different covered persons to address different logistical, practical or other differences in responsibilities.

(B) ADDITIONAL TIME TO BE SPECIFIED.—In each declaration under paragraph (1), the Secretary, after consulting, to the extent the Secretary deems appropriate,

with the manufacturer of the covered countermeasure, shall also specify a date that is after the ending date specified under paragraph (2)(B) and that allows what the Secretary determines is—

(i) a reasonable period for the manufacturer to arrange for disposition of the covered countermeasure, including the return of such product to the manufacturer; and

(ii) a reasonable period for covered persons to take such other actions as may be appropriate to limit administration or use of the covered countermeasure.

(C) ADDITIONAL PERIOD FOR CERTAIN STRATEGIC NATIONAL STOCKPILE COUNTERMEASURES.—With respect to a covered countermeasure that is in the stockpile under section 319F-2, if such countermeasure was the subject of a declaration under paragraph (1) at the time that it was obtained for the stockpile, the effective period of such declaration shall include a period when the countermeasure is administered or used pursuant to a distribution or release from the stockpile.

(4) AMENDMENTS TO DECLARATION.—The Secretary may through publication in the Federal Register amend any portion of a declaration under paragraph (1). Such an amendment shall not retroactively limit the applicability of subsection (a) with respect to the administration or use of the covered countermeasure involved.

(5) CERTAIN DISCLOSURES.—In publishing a declaration under paragraph (1) in the Federal Register, the Secretary is not required to disclose any matter described in section 552(b) of title 5, United States Code.

(6) FACTORS TO BE CONSIDERED.—In deciding whether and under what circumstances or conditions to issue a declaration under paragraph (1) with respect to a covered countermeasure, the Secretary shall consider the desirability of encouraging the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of such countermeasure.

(7) JUDICIAL REVIEW.—No court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary under this subsection.

(8) PREEMPTION OF STATE LAW.—During the effective period of a declaration under subsection (b), or at any time with respect to conduct undertaken in accordance with such declaration, no State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that—

(A) is different from, or is in conflict with, any requirement applicable under this section; and

(B) relates to the design, development, clinical testing or investigation, formulation, manufacture, distribution, sale, donation, purchase, marketing, promotion, packaging, labeling, licensing, use, any other aspect of safety or effi-

cacy, or the prescribing, dispensing, or administration by qualified persons of the covered countermeasure, or to any matter included in a requirement applicable to the covered countermeasure under this section or any other provision of this Act, or under the Federal Food, Drug, and Cosmetic Act.

(9) REPORT TO CONGRESS.—Within 30 days after making a declaration under paragraph (1), the Secretary shall submit to the appropriate committees of the Congress a report that provides an explanation of the reasons for issuing the declaration and the reasons underlying the determinations of the Secretary with respect to paragraph (2). Within 30 days after making an amendment under paragraph (4), the Secretary shall submit to such committees a report that provides the reasons underlying the determination of the Secretary to make the amendment.

(c) DEFINITION OF WILLFUL MISCONDUCT.—

(1) DEFINITION.—

(A) IN GENERAL.—Except as the meaning of such term is further restricted pursuant to paragraph (2), the term "willful misconduct" shall, for purposes of subsection (d), denote an act or omission that is taken—

(i) intentionally to achieve a wrongful purpose;

(ii) knowingly without legal or factual justification; and

(iii) in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit.

(B) RULE OF CONSTRUCTION.—The criterion stated in subparagraph (A) shall be construed as establishing a standard for liability that is more stringent than a standard of negligence in any form or recklessness.

(2) AUTHORITY TO PROMULGATE REGULATORY DEFINITION.—

(A) IN GENERAL.—The Secretary, in consultation with the Attorney General, shall promulgate regulations, which may be promulgated through interim final rules, that further restrict the scope of actions or omissions by a covered person that may qualify as "willful misconduct" for purposes of subsection (d).

(B) FACTORS TO BE CONSIDERED.—In promulgating the regulations under this paragraph, the Secretary, in consultation with the Attorney General, shall consider the need to define the scope of permissible civil actions under subsection (d) in a way that will not adversely affect the public health.

(C) TEMPORAL SCOPE OF REGULATIONS.—The regulations under this paragraph may specify the temporal effect that they shall be given for purposes of subsection (d).

(D) INITIAL RULEMAKING.—Within 180 days after the enactment of the Public Readiness and Emergency Preparedness Act, the Secretary, in consultation with the Attorney General, shall commence and complete an initial rulemaking process under this paragraph.

(3) PROOF OF WILLFUL MISCONDUCT.—In an action under subsection (d), the plaintiff shall have the burden of proving by clear and convincing evidence willful misconduct by each covered person sued and that such willful misconduct caused death or serious physical injury.

(4) DEFENSE FOR ACTS OR OMISSIONS TAKEN PURSUANT TO SECRETARY'S DECLARATION.—Notwithstanding any other provision of law, a program planner or qualified person shall not have engaged in "willful misconduct" as a matter of law where such program planner or qualified person acted consistent with applicable directions, guidelines, or recommendations by the Secretary regarding the administration or use of a covered countermeasure that is specified in the declaration under subsection (b), provided either the Secretary, or a State or local health authority, was provided with notice of information regarding serious physical injury or death from the administration or use of a covered countermeasure that is material to the plaintiff's alleged loss within 7 days of the actual discovery of such information by such program planner or qualified person.

(5) EXCLUSION FOR REGULATED ACTIVITY OF MANUFACTURER OR DISTRIBUTOR.—

(A) IN GENERAL.—If an act or omission by a manufacturer or distributor with respect to a covered countermeasure, which act or omission is alleged under subsection (e)(3)(A) to constitute willful misconduct, is subject to regulation by this Act or by the Federal Food, Drug, and Cosmetic Act, such act or omission shall not constitute "willful misconduct" for purposes of subsection (d) if—

(i) neither the Secretary nor the Attorney General has initiated an enforcement action with respect to such act or omission; or

(ii) such an enforcement action has been initiated and the action has been terminated or finally resolved without a covered remedy.

Any action or proceeding under subsection (d) shall be stayed during the pendency of such an enforcement action.

(B) DEFINITIONS.—For purposes of this paragraph, the following terms have the following meanings:

(i) ENFORCEMENT ACTION.—The term "enforcement action" means a criminal prosecution, an action seeking an injunction, a seizure action, a civil monetary proceeding based on willful misconduct, a mandatory recall of a product because voluntary recall was refused, a proceeding to compel repair or replacement of a product, a termination of an exemption under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act, a debarment proceeding, an investigator disqualification proceeding where an investigator is an employee or agent of the manufacturer, a revocation, based on willful misconduct, of an authorization under section 564 of such Act, or a suspension or withdrawal, based on willful misconduct, of an approval or clearance under chapter V of such Act or of a licensure under section 351 of this Act.

(ii) COVERED REMEDY.—The term "covered remedy" means an outcome—

(I) that is a criminal conviction, an injunction, or a condemnation, a civil monetary payment, a product recall, a repair or replacement of a product, a termination of an exemption under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act, a debarment, an investigator disqualification, a revocation of an authorization under section 564 of such Act, or a suspension or withdrawal of an approval or clearance under chapter 5 of such Act or of a licensure under section 351 of this Act; and

(II) that results from a final determination by a court or from a final agency action.

(iii) FINAL.—The terms "final" and "finally"—

(I) with respect to a court determination, or to a final resolution of an enforcement action that is a court determination, mean a judgment from which an appeal of right cannot be taken or a voluntary or stipulated dismissal; and

(II) with respect to an agency action, or to a final resolution of an enforcement action that is an agency action, mean an order that is not subject to further review within the agency and that has not been reversed, vacated, enjoined, or otherwise nullified by a final court determination or a voluntary or stipulated dismissal.

(C) RULES OF CONSTRUCTION.—

(i) IN GENERAL.—Nothing in this paragraph shall be construed—

(I) to affect the interpretation of any provision of the Federal Food, Drug, and Cosmetic Act, of this Act, or of any other applicable statute or regulation; or

(II) to impair, delay, alter, or affect the authority, including the enforcement discretion, of the United States, of the Secretary, of the Attorney General, or of any other official with respect to any administrative or court proceeding under this Act, under the Federal Food, Drug, and Cosmetic Act, under title 18 of the United States Code, or under any other applicable statute or regulation.

(ii) MANDATORY RECALLS.—A mandatory recall called for in the declaration is not a Food and Drug Administration enforcement action.

(d) EXCEPTION TO IMMUNITY OF COVERED PERSONS.—

(1) IN GENERAL.—Subject to subsection (f), the sole exception to the immunity from suit and liability of covered persons set forth in subsection (a) shall be for an exclusive Federal cause of action against a covered person for death or serious physical injury proximately caused by willful misconduct, as defined pursuant to subsection (c), by such covered person. For

purposes of section 2679(b)(2)(B) of title 28, United States Code, such a cause of action is not an action brought for violation of a statute of the United States under which an action against an individual is otherwise authorized.

(2) PERSONS WHO CAN SUE.—An action under this subsection may be brought for wrongful death or serious physical injury by any person who suffers such injury or by any representative of such a person.

(e) PROCEDURES FOR SUIT.—

(1) EXCLUSIVE FEDERAL JURISDICTION.—Any action under subsection (d) shall be filed and maintained only in the United States District Court for the District of Columbia.

(2) GOVERNING LAW.—The substantive law for decision in an action under subsection (d) shall be derived from the law, including choice of law principles, of the State in which the alleged willful misconduct occurred, unless such law is inconsistent with or preempted by Federal law, including provisions of this section.

(3) PLEADING WITH PARTICULARITY.—In an action under subsection (d), the complaint shall plead with particularity each element of the plaintiff's claim, including—

(A) each act or omission, by each covered person sued, that is alleged to constitute willful misconduct relating to the covered countermeasure administered to or used by the person on whose behalf the complaint was filed;

(B) facts supporting the allegation that such alleged willful misconduct proximately caused the injury claimed; and

(C) facts supporting the allegation that the person on whose behalf the complaint was filed suffered death or serious physical injury.

(4) VERIFICATION, CERTIFICATION, AND MEDICAL RECORDS.—

(A) IN GENERAL.—In an action under subsection (d), the plaintiff shall verify the complaint in the manner stated in subparagraph (B) and shall file with the complaint the materials described in subparagraph (C). A complaint that does not substantially comply with subparagraphs (B) and (C) shall not be accepted for filing and shall not stop the running of the statute of limitations.

(B) VERIFICATION REQUIREMENT.—

(i) IN GENERAL.—The complaint shall include a verification, made by affidavit of the plaintiff under oath, stating that the pleading is true to the knowledge of the deponent, except as to matters specifically identified as being alleged on information and belief, and that as to those matters the plaintiff believes it to be true.

(ii) IDENTIFICATION OF MATTERS ALLEGED UPON INFORMATION AND BELIEF.—Any matter that is not specifically identified as being alleged upon the information and belief of the plaintiff, shall be regarded for all purposes, including a criminal prosecution, as having been made upon the knowledge of the plaintiff.

(C) MATERIALS REQUIRED.—In an action under subsection (d), the plaintiff shall file with the complaint—

(i) an affidavit, by a physician who did not treat the person on whose behalf the complaint was filed, certifying, and explaining the basis for such physician's belief, that such person suffered the serious physical injury or death alleged in the complaint and that such injury or death was proximately caused by the administration or use of a covered countermeasure; and

(ii) certified medical records documenting such injury or death and such proximate causal connection.

(5) THREE-JUDGE COURT.—Any action under subsection (d) shall be assigned initially to a panel of three judges. Such panel shall have jurisdiction over such action for purposes of considering motions to dismiss, motions for summary judgment, and matters related thereto. If such panel has denied such motions, or if the time for filing such motions has expired, such panel shall refer the action to the chief judge for assignment for further proceedings, including any trial. Section 1253 of title 28, United States Code, and paragraph (3) of subsection (b) of section 2284 of title 28, United States Code, shall not apply to actions under subsection (d).

(6) CIVIL DISCOVERY.—

(A) TIMING.—In an action under subsection (d), no discovery shall be allowed—

(i) before each covered person sued has had a reasonable opportunity to file a motion to dismiss;

(ii) in the event such a motion is filed, before the court has ruled on such motion; and

(iii) in the event a covered person files an interlocutory appeal from the denial of such a motion, before the court of appeals has ruled on such appeal.

(B) STANDARD.—Notwithstanding any other provision of law, the court in an action under subsection (d) shall permit discovery only with respect to matters directly related to material issues contested in such action, and the court shall compel a response to a discovery request (including a request for admission, an interrogatory, a request for production of documents, or any other form of discovery request) under Rule 37, Federal Rules of Civil Procedure, only if the court finds that the requesting party needs the information sought to prove or defend as to a material issue contested in such action and that the likely benefits of a response to such request equal or exceed the burden or cost for the responding party of providing such response.

(7) REDUCTION IN AWARD OF DAMAGES FOR COLLATERAL SOURCE BENEFITS.—

(A) IN GENERAL.—In an action under subsection (d), the amount of an award of damages that would otherwise be made to a plaintiff shall be reduced by the amount of collateral source benefits to such plaintiff.

(B) PROVIDER OF COLLATERAL SOURCE BENEFITS NOT TO HAVE LIEN OR SUBROGATION.—No provider of collateral source benefits shall recover any amount against the plaintiff or receive any lien or credit against the plaintiff's recovery or be equitably or legally subrogated to the right of the plaintiff in an action under subsection (d).

(C) COLLATERAL SOURCE BENEFIT DEFINED.—For purposes of this paragraph, the term "collateral source benefit" means any amount paid or to be paid in the future to or on behalf of the plaintiff, or any service, product, or other benefit provided or to be provided in the future to or on behalf of the plaintiff, as a result of the injury or wrongful death, pursuant to—

(i) any State or Federal health, sickness, income-disability, accident, or workers' compensation law;

(ii) any health, sickness, income-disability, or accident insurance that provides health benefits or income-disability coverage;

(iii) any contract or agreement of any group, organization, partnership, or corporation to provide, pay for, or reimburse the cost of medical, hospital, dental, or income disability benefits; or

(iv) any other publicly or privately funded program.

(8) NONECONOMIC DAMAGES.—In an action under subsection (d), any noneconomic damages may be awarded only in an amount directly proportional to the percentage of responsibility of a defendant for the harm to the plaintiff. For purposes of this paragraph, the term "noneconomic damages" means damages for losses for physical and emotional pain, suffering, inconvenience, physical impairment, mental anguish, disfigurement, loss of enjoyment of life, loss of society and companionship, loss of consortium, hedonic damages, injury to reputation, and any other nonpecuniary losses.

(9) RULE 11 SANCTIONS.—Whenever a district court of the United States determines that there has been a violation of Rule 11 of the Federal Rules of Civil Procedure in an action under subsection (d), the court shall impose upon the attorney, law firm, or parties that have violated Rule 11 or are responsible for the violation, an appropriate sanction, which may include an order to pay the other party or parties for the reasonable expenses incurred as a direct result of the filing of the pleading, motion, or other paper that is the subject of the violation, including a reasonable attorney's fee. Such sanction shall be sufficient to deter repetition of such conduct or comparable conduct by others similarly situated, and to compensate the party or parties injured by such conduct.

(10) INTERLOCUTORY APPEAL.—The United States Court of Appeals for the District of Columbia Circuit shall have jurisdiction of an interlocutory appeal by a covered person taken within 30 days of an order denying a motion to dismiss or a motion for summary judgment based on an assertion of the immunity from suit conferred by subsection (a) or based on an assertion of the exclusion under subsection (c)(5).

(f) ACTIONS BY AND AGAINST THE UNITED STATES.—Nothing in this section shall be construed to abrogate or limit any right, remedy, or authority that the United States or any agency thereof may possess under any other provision of law or to waive sovereign immunity or to abrogate or limit any defense or protection available to the United States or its agencies, instrumentalities, officers, or employees under any other law, including any provision of chapter 171 of title 28, United States Code (relating to tort claims procedure).

(g) SEVERABILITY.—If any provision of this section, or the application of such provision to any person or circumstance, is held to be unconstitutional, the remainder of this section and the application of such remainder to any person or circumstance shall not be affected thereby.

(h) RULE OF CONSTRUCTION CONCERNING NATIONAL VACCINE INJURY COMPENSATION PROGRAM.—Nothing in this section, or any amendment made by the Public Readiness and Emergency Preparedness Act, shall be construed to affect the National Vaccine Injury Compensation Program under title XXI of this Act.

(i) DEFINITIONS.—In this section:

(1) COVERED COUNTERMEASURE.—The term "covered countermeasure" means—

(A) a qualified pandemic or epidemic product (as defined in paragraph (7));

(B) a security countermeasure (as defined in section 319F–2(c)(1)(B));

(C) a drug (as such term is defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)), biological product (as such term is defined by section 351(i) of this Act), or device (as such term is defined by section 201(h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321(h)) that is authorized for emergency use in accordance with section 564, 564A, or 564B of the Federal Food, Drug, and Cosmetic Act; or

(D) a respiratory protective device that is approved by the National Institute for Occupational Safety and Health under part 84 of title 42, Code of Federal Regulations (or any successor regulations), and that the Secretary determines to be a priority for use during a public health emergency declared under section 319.

(2) COVERED PERSON.—The term "covered person", when used with respect to the administration or use of a covered countermeasure, means—

(A) the United States; or

(B) a person or entity that is—

(i) a manufacturer of such countermeasure;

(ii) a distributor of such countermeasure;

(iii) a program planner of such countermeasure;

(iv) a qualified person who prescribed, administered, or dispensed such countermeasure; or

(v) an official, agent, or employee of a person or entity described in clause (i), (ii), (iii), or (iv).

(3) DISTRIBUTOR.—The term "distributor" means a person or entity engaged in the distribution of drugs, biologics, or de-

vices, including but not limited to manufacturers; repackers; common carriers; contract carriers; air carriers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies.

(4) MANUFACTURER.—The term "manufacturer" includes—

(A) a contractor or subcontractor of a manufacturer;

(B) a supplier or licenser of any product, intellectual property, service, research tool, or component or other article used in the design, development, clinical testing, investigation, or manufacturing of a covered countermeasure; and

(C) any or all of the parents, subsidiaries, affiliates, successors, and assigns of a manufacturer.

(5) PERSON.—The term "person" includes an individual, partnership, corporation, association, entity, or public or private corporation, including a Federal, State, or local government agency or department.

(6) PROGRAM PLANNER.—The term "program planner" means a State or local government, including an Indian tribe, a person employed by the State or local government, or other person who supervised or administered a program with respect to the administration, dispensing, distribution, provision, or use of a security countermeasure or a qualified pandemic or epidemic product, including a person who has established requirements, provided policy guidance, or supplied technical or scientific advice or assistance or provides a facility to administer or use a covered countermeasure in accordance with a declaration under subsection (b).

(7) QUALIFIED PANDEMIC OR EPIDEMIC PRODUCT.—The term "qualified pandemic or epidemic product" means a drug (as such term is defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)), biological product (as such term is defined by section 351(i) of this Act), or device (as such term is defined by section 201(h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321(h)) that is—

(A)(i) a product manufactured, used, designed, developed, modified, licensed, or procured—

(I) to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic; or

(II) to limit the harm such pandemic or epidemic might otherwise cause;

(ii) a product manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a serious or life-threatening disease or condition caused by a product described in clause (i); or

(iii)[24] a product or technology intended to enhance the use or effect of a drug, biological product, or device described in clause (i) or (ii); and

(B)(i) approved or cleared under chapter V of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of this Act;

[24] Margin of clause (iii) so in law.

(ii) the object of research for possible use as described by subparagraph (A) and is the subject of an exemption under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act; or

(iii) authorized for emergency use in accordance with section 564, 564A, or 564B of the Federal Food, Drug, and Cosmetic Act.

(8) QUALIFIED PERSON.—The term "qualified person", when used with respect to the administration or use of a covered countermeasure, means—

(A) a licensed health professional or other individual who is authorized to prescribe, administer, or dispense such countermeasures under the law of the State in which the countermeasure was prescribed, administered, or dispensed; or

(B) a person within a category of persons so identified in a declaration by the Secretary under subsection (b).

(9) SECURITY COUNTERMEASURE.—The term "security countermeasure" has the meaning given such term in section 319F–2(c)(1)(B).

(10) SERIOUS PHYSICAL INJURY.—The term "serious physical injury" means an injury that—

(A) is life threatening;

(B) results in permanent impairment of a body function or permanent damage to a body structure; or

(C) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

SEC. 319F–4. [247d–6e] COVERED COUNTERMEASURE PROCESS.

(a) ESTABLISHMENT OF FUND.—Upon the issuance by the Secretary of a declaration under section 319F–3(b), there is hereby established in the Treasury an emergency fund designated as the "Covered Countermeasure Process Fund" for purposes of providing timely, uniform, and adequate compensation to eligible individuals for covered injuries directly caused by the administration or use of a covered countermeasure pursuant to such declaration, which Fund shall consist of such amounts designated as emergency appropriations under section 402 of H. Con. Res. 95 of the 109th Congress, this emergency designation shall remain in effect through October 1, 2006.

(b) PAYMENT OF COMPENSATION.—

(1) IN GENERAL.—If the Secretary issues a declaration under 319F–3(b), the Secretary shall, after amounts have by law been provided for the Fund under subsection (a), provide compensation to an eligible individual for a covered injury directly caused by the administration or use of a covered countermeasure pursuant to such declaration.

(2) ELEMENTS OF COMPENSATION.—The compensation that shall be provided pursuant to paragraph (1) shall have the same elements, and be in the same amount, as is prescribed by sections 264, 265, and 266 in the case of certain individuals injured as a result of administration of certain counter-

measures against smallpox, except that section 266(a)(2)(B) shall not apply.

(3) RULE OF CONSTRUCTION.—Neither reasonable and necessary medical benefits nor lifetime total benefits for lost employment income due to permanent and total disability shall be limited by section 266.

(4) DETERMINATION OF ELIGIBILITY AND COMPENSATION.—Except as provided in this section, the procedures for determining, and for reviewing a determination of, whether an individual is an eligible individual, whether such individual has sustained a covered injury, whether compensation may be available under this section, and the amount of such compensation shall be those stated in section 262 (other than in subsection (d)(2) of such section), in regulations issued pursuant to that section, and in such additional or alternate regulations as the Secretary may promulgate for purposes of this section. In making determinations under this section, other than those described in paragraph (5)(A) as to the direct causation of a covered injury, the Secretary may only make such determination based on compelling, reliable, valid, medical and scientific evidence.

(5) COVERED COUNTERMEASURE INJURY TABLE.—

(A) IN GENERAL.—The Secretary shall by regulation establish a table identifying covered injuries that shall be presumed to be directly caused by the administration or use of a covered countermeasure and the time period in which the first symptom or manifestation of onset of each such adverse effect must manifest in order for such presumption to apply. The Secretary may only identify such covered injuries, for purpose of inclusion on the table, where the Secretary determines, based on compelling, reliable, valid, medical and scientific evidence that administration or use of the covered countermeasure directly caused such covered injury.

(B) AMENDMENTS.—The provisions of section 263 (other than a provision of subsection (a)(2) of such section that relates to accidental vaccinia inoculation) shall apply to the table established under this section.

(C) JUDICIAL REVIEW.—No court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary under this paragraph.

(6) MEANINGS OF TERMS.—In applying sections 262, 263, 264, 265, and 266 for purposes of this section—

(A) the terms "vaccine" and "smallpox vaccine" shall be deemed to mean a covered countermeasure;

(B) the terms "smallpox vaccine injury table" and "table established under section 263" shall be deemed to refer to the table established under paragraph (4); and

(C) other terms used in those sections shall have the meanings given to such terms by this section.

(c) VOLUNTARY PROGRAM.—The Secretary shall ensure that a State, local, or Department of Health and Human Services plan to administer or use a covered countermeasure is consistent with any

declaration under 319F–3 and any applicable guidelines of the Centers for Disease Control and Prevention and that potential participants are educated with respect to contraindications, the voluntary nature of the program, and the availability of potential benefits and compensation under this part.

(d) EXHAUSTION; EXCLUSIVITY; ELECTION.—

(1) EXHAUSTION.—Subject to paragraph (5), a covered individual may not bring a civil action under section 319F–3(d) against a covered person (as such term is defined in section 319F–3(i)(2)) unless such individual has exhausted such remedies as are available under subsection (a), except that if amounts have not by law been provided for the Fund under subsection (a), or if the Secretary fails to make a final determination on a request for benefits or compensation filed in accordance with the requirements of this section within 240 days after such request was filed, the individual may seek any remedy that may be available under section 319F–3(d).

(2) TOLLING OF STATUTE OF LIMITATIONS.—The time limit for filing a civil action under section 319F–3(d) for an injury or death shall be tolled during the pendency of a claim for compensation under subsection (a).

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

(4) EXCLUSIVITY.—The remedy provided by subsection (a) shall be exclusive of any other civil action or proceeding for any claim or suit this section encompasses, except for a proceeding under section 319F–3.

(5) ELECTION.—If under subsection (a) the Secretary determines that a covered individual qualifies for compensation, the individual has an election to accept the compensation or to bring an action under section 319F–3(d). If such individual elects to accept the compensation, the individual may not bring such an action.

(e) DEFINITIONS.—For purposes of this section, the following terms shall have the following meanings:

(1) COVERED COUNTERMEASURE.—The term "covered countermeasure" has the meaning given such term in section 319F–3.

(2) COVERED INDIVIDUAL.—The term "covered individual", with respect to administration or use of a covered countermeasure pursuant to a declaration, means an individual—

(A) who is in a population specified in such declaration, and with respect to whom the administration or use of the covered countermeasure satisfies the other specifications of such declaration; or

(B) who uses the covered countermeasure, or to whom the covered countermeasure is administered, in a good faith belief that the individual is in the category described by subparagraph (A).

(3) COVERED INJURY.—The term "covered injury" means serious physical injury or death.

(4) DECLARATION.—The term "declaration" means a declaration under section 319F–3(b).

(5) ELIGIBLE INDIVIDUAL.—The term "eligible individual" means an individual who is determined, in accordance with subsection (b), to be a covered individual who sustains a covered injury.

SEC. 319F–5. [247d-6f] PROVISION OF MEDICAL COUNTERMEASURES TO INDIAN PROGRAMS AND FACILITIES.

In the event that the Secretary deploys the contents of the Strategic National Stockpile under section 319F–2(a), or otherwise distributes medical countermeasures to States to respond to a public health emergency declared by the Secretary under section 319, the Secretary shall, in consultation with the applicable States, make such contents or countermeasures directly available to Indian Tribes and Tribal organizations (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304), which may include through health programs or facilities operated by the Indian Health Service, that are affected by such public health emergency.

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 VOLUNTEER HEALTH PROFESSIONAL.

(a) IN GENERAL.—Not later than 12 months after the date of enactment of the Pandemic and All-Hazards Preparedness Act, the Secretary shall link existing State verification systems to maintain a single national interoperable network of systems, each system being maintained by a State or group of States, for the purpose of verifying the credentials and licenses of health care professionals who volunteer to provide health services during a public health emergency. Such health care professionals may include members of the National Disaster Medical System, members of the Medical Reserve Corps, and individual health care professionals.

(b) REQUIREMENTS.—The interoperable network of systems established under subsection (a) (referred to in this section as the "verification network") shall include—

(1) with respect to each volunteer health professional included in the verification network—

(A) information necessary for the rapid identification of, and communication with, such professionals; and

(B) the credentials, certifications, licenses, and relevant training of such individuals; and

(2) the name of each member of the Medical Reserve Corps, the National Disaster Medical System, and any other relevant federally-sponsored or administered programs determined necessary by the Secretary.

(c) OTHER ASSISTANCE.—The Secretary may make grants and provide technical assistance to States and other public or nonprofit private entities for activities relating to the verification network developed under subsection (a).

(d) ACCESSIBILITY.—The Secretary shall ensure that the verification network is electronically accessible by State, local, and tribal health departments and can be linked with the identification cards under section 2813.

(e) CONFIDENTIALITY.—The Secretary shall establish and require the application of and compliance with measures to ensure the effective security of, integrity of, and access to the data included in the verification network.

(f) COORDINATION.—The Secretary shall coordinate with the Secretary of Veterans Affairs and the Secretary of Homeland Security to assess the feasibility of integrating the verification network under this section with the VetPro system of the Department of Veterans Affairs and the National Emergency Responder Credentialing System of the Department of Homeland Security. The Secretary shall, if feasible, integrate the verification network under this section with such VetPro system and the National Emergency Responder Credentialing System.

(g) UPDATING OF INFORMATION.—The States that are participants in the verification network shall, on at least a quarterly basis, work with the Director to provide for the updating of the information contained in the verification network.

(h) CLARIFICATION.—Inclusion of a health professional in the verification network shall not constitute appointment of such individual as a Federal employee for any purpose, either under section 2812(c) or otherwise. Such appointment may only be made under section 2812 or 2813.

(i) HEALTH CARE PROVIDER LICENSES.—The Secretary shall encourage States to establish and implement mechanisms to waive the application of licensing requirements applicable to health professionals, who are seeking to provide medical services (within their scope of practice), during a national, State, local, or tribal public health emergency upon verification that such health professionals are licensed and in good standing in another State and have not been disciplined by any State health licensing or disciplinary board. In order to inform the development of such mechanisms by States, the Secretary shall make available information and material provided by States that have developed mechanisms

to waive the application of licensing requirements to applicable health professionals seeking to provide medical services during a public health emergency. Such information shall be made publicly available in a manner that does not compromise national security.

(j) RULE OF CONSTRUCTION.—This section may not be construed as authorizing the Secretary to issue requirements regarding the provision by the States of credentials, licenses, accreditations, or hospital privileges.

(k) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $5,000,000 for each of fiscal years 2019 through 2023.

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(e)(4)).

(b) GUIDELINES.—The Secretary may develop guidelines to enable entities eligible to receive assistance under subsection (a) to secure their facilities against potential terrorist attack.

SEC. 319L. [247d–7e] BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY.

(a) DEFINITIONS.—In this section:

(1) BARDA.—The term "BARDA" means the Biomedical Advanced Research and Development Authority.

(2) FUND.—The term "Fund" means the Biodefense Medical Countermeasure Development Fund established under subsection (d).

(3) OTHER TRANSACTIONS.—The term "other transactions" means transactions, other than procurement contracts, grants, and cooperative agreements.

(4) QUALIFIED COUNTERMEASURE.—The term "qualified countermeasure" has the meaning given such term in section 319F–1.

(5) QUALIFIED PANDEMIC OR EPIDEMIC PRODUCT.—The term "qualified pandemic or epidemic product" has the meaning given the term in section 319F–3.

(6) ADVANCED RESEARCH AND DEVELOPMENT.—

(A) IN GENERAL.—The term "advanced research and development" means, with respect to a product that is or may become a qualified countermeasure or a qualified pandemic or epidemic product, activities that predominantly—

(i) are conducted after basic research and preclinical development of the product; and

(ii) are related to manufacturing the product on a commercial scale and in a form that satisfies the regulatory requirements under the Federal Food, Drug, and Cosmetic Act or under section 351 of this Act.

(B) ACTIVITIES INCLUDED.—The term under subparagraph (A) includes—

(i) testing of the product to determine whether the product may be approved, cleared, or licensed under the Federal Food, Drug, and Cosmetic Act or under section 351 of this Act for a use that is or may be the basis for such product becoming a qualified countermeasure or qualified pandemic or epidemic product, or to help obtain such approval, clearance, or license;

(ii) design and development of tests or models, including animal models, for such testing;

(iii) activities to facilitate manufacture of the product on a commercial scale with consistently high quality, as well as to improve and make available new technologies to increase manufacturing surge capacity;

(iv) activities to support, maintain, and improve domestic manufacturing surge capacity and capabilities, as appropriate, including through the utilization of advanced manufacturing and platform technologies, to increase the availability of products that are or may become qualified countermeasures or qualified pandemic or epidemic products;

(v) activities to improve the shelf-life of the product or technologies for administering the product; and

(vi) such other activities as are part of the advanced stages of testing, refinement, improvement, manufacturing, or preparation of the product for such use and as are specified by the Secretary.

(7) SECURITY COUNTERMEASURE.—The term "security countermeasure" has the meaning given such term in section 319F–2.

(8) RESEARCH TOOL.—The term "research tool" means a device, technology, biological material (including a cell line or an antibody), reagent, animal model, computer system, computer software, or analytical technique that is developed to assist in the discovery, development, or manufacture of qualified countermeasures or qualified pandemic or epidemic products.

(9) PROGRAM MANAGER.—The term "program manager" means an individual appointed to carry out functions under

this section and authorized to provide project oversight and management of strategic initiatives.

(10) PERSON.—The term "person" includes an individual, partnership, corporation, association, entity, or public or private corporation, and a Federal, State, or local government agency or department.

(b) STRATEGIC PLAN FOR COUNTERMEASURE RESEARCH, DEVELOPMENT, AND PROCUREMENT.—

(1) IN GENERAL.—Not later than 6 months after the date of enactment of the Pandemic and All-Hazards Preparedness Act, the Secretary shall develop and make public a strategic plan to integrate biodefense and emerging infectious disease requirements with the advanced research and development, strategic initiatives for innovation, support for domestic manufacturing surge capacity and capabilities, and the procurement of qualified countermeasures and qualified pandemic or epidemic products. The Secretary shall carry out such activities as may be practicable to disseminate the information contained in such plan to persons who may have the capacity to substantially contribute to the activities described in such strategic plan. The Secretary shall update and incorporate such plan as part of the National Health Security Strategy described in section 2802.

(2) CONTENT.—The strategic plan under paragraph (1) shall guide—

(A) research and development, conducted or supported by the Department of Health and Human Services, of qualified countermeasures and qualified pandemic or epidemic products against possible biological, chemical, radiological, and nuclear agents and to emerging infectious diseases;

(B) innovation in technologies that may assist advanced research and development of qualified countermeasures and qualified pandemic or epidemic products (such research and development referred to in this section as "countermeasure and product advanced research and development");

(C) activities to support, maintain, and improve domestic manufacturing surge capacity and capabilities, as appropriate, including through the utilization of advanced manufacturing and platform technologies, to increase the availability of products that are or may become qualified countermeasures or qualified pandemic or epidemic products; and

(D) procurement of such qualified countermeasures and qualified pandemic or epidemic products by such Department.

(c) BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY.—

(1) ESTABLISHMENT.—There is established within the Department of Health and Human Services the Biomedical Advanced Research and Development Authority.

(2) IN GENERAL.—Based upon the strategic plan described in subsection (b), the Secretary shall coordinate the accelera-

tion of countermeasure and product advanced research and development by—

(A) facilitating collaboration between the Department of Health and Human Services and other Federal agencies, relevant industries, academia, and other persons, with respect to such advanced research and development;

(B) promoting countermeasure and product advanced research and development, including through the establishment and maintenance of domestic manufacturing surge capacity and capabilities, consistent with subsection (a)(6)(B)(iv);

(C) facilitating contacts between interested persons and the offices or employees authorized by the Secretary to advise such persons regarding requirements under the Federal Food, Drug, and Cosmetic Act and under section 351 of this Act; and

(D) promoting innovation to reduce the time and cost of countermeasure and product advanced research and development.

(3) DIRECTOR.—The BARDA shall be headed by a Director (referred to in this section as the "Director") who shall be appointed by the Secretary and to whom the Secretary shall delegate such functions and authorities as necessary to implement this section, including the execution of procurement contracts, grants, and cooperative agreements pursuant to this section.

(4) DUTIES.—

(A) COLLABORATION.—To carry out the purpose described in paragraph (2)(A), the Secretary shall—

(i) facilitate and increase the expeditious and direct communication between the Department of Health and Human Services and relevant persons with respect to countermeasure and product advanced research and development, including by—

(I) facilitating such communication regarding the processes for procuring such advanced research and development with respect to qualified countermeasures and qualified pandemic or epidemic products of interest;

(II) soliciting information about and data from research on potential qualified countermeasures and qualified pandemic or epidemic products and related technologies;

(III) facilitating such communication, as appropriate, regarding manufacturing surge capacity and capabilities with respect to qualified countermeasures and qualified pandemic or epidemic products to prepare for, or respond to, a public health emergency or potential public health emergency; and

(IV) facilitating such communication, as appropriate and in a manner that does not compromise national security, with respect to potential eligibility for the material threat medical countermeasure priority review voucher program

under section 565A of the Federal Food, Drug, and Cosmetic Act;

(ii) at least annually—

(I) convene meetings with representatives from relevant industries, academia, other Federal agencies, international agencies as appropriate, and other interested persons;

(II) sponsor opportunities to demonstrate the operation and effectiveness of relevant biodefense countermeasure technologies; and

(III) convene such working groups on countermeasure and product advanced research and development as the Secretary may determine are necessary to carry out this section;

(iii) communicate regularly with entities in receipt of an award pursuant to subparagraph (B)(v), and facilitate communication between such entities and other entities in receipt of an award pursuant to subparagraph (B)(iv), as appropriate, for purposes of planning and response regarding the availability of countermeasures and the maintenance of domestic manufacturing surge capacity and capabilities, including any planned uses of such capacity and capabilities in the near- and mid-term, and identification of any significant challenges related to the long-term maintenance of such capacity and capabilities; and

(iv) carry out the activities described in section 319L–1.

(B) SUPPORT ADVANCED RESEARCH AND DEVELOPMENT.—To carry out the purpose described in paragraph (2)(B), the Secretary shall—

(i) conduct ongoing searches for, and support calls for, potential qualified countermeasures and qualified pandemic or epidemic products;

(ii) direct and coordinate the countermeasure and product advanced research and development activities of the Department of Health and Human Services;

(iii) establish strategic initiatives to accelerate countermeasure and product advanced research and development (which may include advanced research and development for purposes of fulfilling requirements under the Federal Food, Drug, and Cosmetic Act or section 351 of this Act) and innovation in such areas as the Secretary may identify as priority unmet need areas;

(iv) award contracts, grants, cooperative agreements, and enter into other transactions, for countermeasure and product advanced research and development; and

(v) award contracts, grants, and cooperative agreements and enter into other transactions to support, maintain, and improve domestic manufacturing surge capacity and capabilities, including through supporting flexible or advanced manufacturing, to ensure

that additional capacity is available to rapidly manufacture products that are or may become qualified countermeasures or qualified pandemic or epidemic products in the event of a public health emergency declaration or significant potential for a public health emergency.

(C) FACILITATING ADVICE.—To carry out the purpose described in paragraph (2)(C) the Secretary shall—

(i) connect interested persons with the offices or employees authorized by the Secretary to advise such persons regarding the regulatory requirements under the Federal Food, Drug, and Cosmetic Act and under section 351 of this Act related to the approval, clearance, or licensure of qualified countermeasures or qualified pandemic or epidemic products;

(ii) with respect to persons performing countermeasure and product advanced research and development funded under this section, enable such offices or employees to provide to the extent practicable such advice in a manner that is ongoing and that is otherwise designed to facilitate expeditious development of qualified countermeasures and qualified pandemic or epidemic products that may achieve such approval, clearance, or licensure; and

(iii) consult with the Commissioner of Food and Drugs, pursuant to section 565(b)(2) of the Federal Food, Drug, and Cosmetic Act, to ensure that facilities performing manufacturing, pursuant to an award under subparagraph (B)(v), are in compliance with applicable requirements under such Act and this Act, as appropriate, including current good manufacturing practice pursuant to section 501(a)(2)(B) of the Food, Drug, and Cosmetic Act; and

(D) SUPPORTING INNOVATION.—To carry out the purpose described in paragraph (2)(D), the Secretary may award contracts, grants, and cooperative agreements, or enter into other transactions, such as prize payments, to promote—

(i) innovation in technologies that may assist countermeasure and product advanced research and development, including to improve manufacturing capacities and capabilities for medical countermeasures;

(ii) research on and development of research tools and other devices and technologies; and

(iii) research to promote strategic initiatives, such as rapid diagnostics, broad spectrum antimicrobials, vaccine-manufacturing technologies, dose-sparing technologies, efficacy-increasing technologies, platform technologies, technologies to administer countermeasures, and technologies to improve storage and transportation of countermeasures.

(E) MEDICAL COUNTERMEASURES INNOVATION PARTNER.—

(i) IN GENERAL.—To support the purposes described in paragraph (2), the Secretary, acting through the Director of BARDA, may enter into an agreement (including through the use of grants, contracts, cooperative agreements, or other transactions as described in paragraph (5)) with an independent, nonprofit entity to—

(I) foster and accelerate the development and innovation of medical countermeasures and technologies that may assist advanced research and the development of qualified countermeasures and qualified pandemic or epidemic products, including through the use of strategic venture capital practices and methods;

(II) promote the development of new and promising technologies that address urgent medical countermeasure needs, as identified by the Secretary;

(III) address unmet public health needs that are directly related to medical countermeasure requirements, such as novel antimicrobials for multidrug resistant organisms and multiuse platform technologies for diagnostics, prophylaxis, vaccines, and therapeutics; and

(IV) provide expert consultation and advice to foster viable medical countermeasure innovators, including helping qualified countermeasure innovators navigate unique industry challenges with respect to developing chemical, biological, radiological, and nuclear countermeasure products.

(ii) ELIGIBILITY.—

(I) IN GENERAL.—To be eligible to enter into an agreement under clause (i) an entity shall—

(aa) be an independent, nonprofit entity;

(bb) have a demonstrated record of being able to create linkages between innovators and investors and leverage such partnerships and resources for the purpose of addressing identified strategic needs of the Federal Government;

(cc) have experience in promoting novel technology innovation;

(dd) be problem-driven and solution-focused based on the needs, requirements, and problems identified by the Secretary under clause (iv);

(ee) demonstrate the ability, or the potential ability, to promote the development of medical countermeasure products;

(ff) demonstrate expertise, or the capacity to develop or acquire expertise, related to technical and regulatory considerations with respect to medical countermeasures; and

(gg) not be within the Department of Health and Human Services.

(II) PARTNERING EXPERIENCE.—In selecting an entity with which to enter into an agreement under clause (i), the Secretary shall place a high value on the demonstrated experience of the entity in partnering with the Federal Government to meet identified strategic needs.

(iii) NOT AGENCY.—An entity that enters into an agreement under clause (i) shall not be deemed to be a Federal agency for any purpose, including for any purpose under title 5, United States Code.

(iv) DIRECTION.—Pursuant to an agreement entered into under this subparagraph, the Secretary, acting through the Director of BARDA, shall provide direction to the entity that enters into an agreement under clause (i). As part of this agreement the Director of BARDA shall—

(I) communicate the medical countermeasure needs, requirements, and problems to be addressed by the entity under the agreement;

(II) develop a description of work to be performed by the entity under the agreement;

(III) provide technical feedback and appropriate oversight over work carried out by the entity under the agreement, including subsequent development and partnerships consistent with the needs and requirements set forth in this subparagraph;

(IV) ensure fair consideration of products developed under the agreement in order to maintain competition to the maximum practical extent, as applicable and appropriate under applicable provisions of this section; and

(V) ensure, as a condition of the agreement that the entity—

(aa) has in place a comprehensive set of policies that demonstrate a commitment to transparency and accountability;

(bb) protects against conflicts of interest through a comprehensive set of policies that address potential conflicts of interest, ethics, disclosure, and reporting requirements;

(cc) provides monthly accounting on the use of funds provided under such agreement; and

(dd) provides on a quarterly basis, reports regarding the progress made toward meeting the identified needs set forth in the agreement.

(v) SUPPLEMENT NOT SUPPLANT.—Activities carried out under this subparagraph shall supplement, and not supplant, other activities carried out under this section.

(vi) NO ESTABLISHMENT OF ENTITY.—To prevent unnecessary duplication and target resources effectively, nothing in this subparagraph shall be construed to authorize the Secretary to establish within the Department of Health and Human Services an entity for the purposes of carrying out this subparagraph.

(vii) TRANSPARENCY AND OVERSIGHT.—Upon request, the Secretary shall provide to Congress the information provided to the Secretary under clause (iv)(V)(dd).

(viii) INDEPENDENT EVALUATION.—Not later than 4 years after the date of enactment of the 21st Century Cures Act, the Comptroller General of the United States shall conduct an independent evaluation, and submit to the Secretary and the appropriate committees of Congress a report, concerning the activities conducted under this subparagraph. Such report shall include recommendations with respect to any agreement or activities carried out pursuant to this subparagraph.

(ix) SUNSET.—This subparagraph shall have no force or effect after September 30, 2028.

(F) STRATEGIC INITIATIVES.—The Secretary, acting through the Director of BARDA, may implement strategic initiatives, including by building on existing programs and by awarding contracts, grants, and cooperative agreements, or entering into other transactions, to support innovative candidate products in preclinical and clinical development that address priority, naturally occurring and man-made threats that, as determined by the Secretary, pose a significant level of risk to national security based on the characteristics of a chemical, biological, radiological or nuclear threat, or existing capabilities to respond to such a threat (including medical response and treatment capabilities and manufacturing infrastructure). Such initiatives shall accelerate and support the advanced research, development, and procurement of countermeasures and products, as applicable, to address areas including—

(i) chemical, biological, radiological, or nuclear threats, including emerging infectious diseases, for which insufficient approved, licensed, or authorized countermeasures exist, or for which such threat, or the result of an exposure to such threat, may become resistant to countermeasures or existing countermeasures may be rendered ineffective;

(ii) threats that consistently exist or continually circulate and have a significant potential to become a pandemic, such as pandemic influenza, which may include the advanced research and development, manufacturing, and appropriate stockpiling of qualified pandemic or epidemic products, and products, technologies, or processes to support the advanced research and development of such countermeasures (including multiuse platform technologies for diagnostics,

vaccines, and therapeutics; virus seeds; clinical trial lots; novel virus strains; and antigen and adjuvant material); and

(iii) threats that may result primarily or secondarily from a chemical, biological, radiological, or nuclear agent, or emerging infectious diseases, and which may present increased treatment complications such as the occurrence of resistance to available countermeasures or potential countermeasures, including antimicrobial resistant pathogens.

(G) ANNUAL REPORTS BY AWARD RECIPIENTS.—As a condition of receiving an award under subparagraph (B)(v), a recipient shall develop and submit to the Secretary annual reports related to the maintenance of such capacity and capabilities, including ensuring that such capacity and capabilities are able to support the rapid manufacture of countermeasures as required by the Secretary.

(5) TRANSACTION AUTHORITIES.—

(A) OTHER TRANSACTIONS.—

(i) IN GENERAL.—The Secretary shall have the authority to enter into other transactions (as defined in subsection (a)(3)) under this subsection.

(ii) LIMITATIONS ON AUTHORITY.—

(I) IN GENERAL.—To the maximum extent practicable, competitive procedures shall be used when entering into transactions to carry out projects under this subsection.

(II) WRITTEN DETERMINATIONS REQUIRED.—The authority of this subparagraph may be exercised for a project that is expected to cost the Department of Health and Human Services in excess of $100,000,000 only upon a written determination by the Assistant Secretary for Financial Resources, that the use of such authority is essential to promoting the success of the project. The authority of the Assistant Secretary for Financial Resources under this subclause may not be delegated.

(iii) AUTHORITY DURING A PUBLIC HEALTH EMERGENCY.—

(I) IN GENERAL.—Notwithstanding clause (ii), the Secretary, shall, to the maximum extent practicable, use competitive procedures when entering into transactions to carry out projects under this subsection for purposes of a public health emergency declared by the Secretary under section 319. Any such transactions entered into during such public health emergency shall not be terminated solely due to the expiration of such public health emergency, if such public health emergency ends before the completion of the terms of such agreement.

(II) REPORT.—After the expiration of the public health emergency declared by the Secretary

under section 319, the Secretary shall provide a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives regarding the use of any funds pursuant to the authority under subclause (I), including any outcomes, benefits, and risks associated with the use of such funds, and a description of the reasons for the use of such authority for the project or projects.

(iv) GUIDELINES.—The Secretary shall establish guidelines regarding the use of the authority under clause (i). Such guidelines shall include auditing requirements.

(B) EXPEDITED AUTHORITIES.—

(i) IN GENERAL.—In awarding contracts, grants, and cooperative agreements, and in entering into other transactions under subparagraph (B) or (D) of paragraph (4), the Secretary shall have the expedited procurement authorities, the authority to expedite peer review, and the authority for personal services contracts, supplied by subsections (b), (c), and (d) of section 319F–1.

(ii) APPLICATION OF PROVISIONS.—Provisions in such section 319F–1 that apply to such authorities and that require institution of internal controls, limit review, provide for Federal Tort Claims Act coverage of personal services contractors, and commit decisions to the discretion of the Secretary shall apply to the authorities as exercised pursuant to this paragraph.

(iii) AUTHORITY TO LIMIT COMPETITION.—For purposes of applying section 319F–1(b)(1)(D) to this paragraph, the phrase "BioShield Program under the Project BioShield Act of 2004" shall be deemed to mean the countermeasure and product advanced research and development program under this section.

(iv) AVAILABILITY OF DATA.—The Secretary shall require that, as a condition of being awarded a contract, grant, cooperative agreement, or other transaction under subparagraph (B) or (D) of paragraph (4), a person make available to the Secretary on an ongoing basis, and submit upon request to the Secretary, all data related to or resulting from countermeasure and product advanced research and development carried out pursuant to this section.

(C) ADVANCE PAYMENTS; ADVERTISING.—The Secretary may waive the requirements of section 3324(a) of title 31, United States Code, or section 3709 of the Revised Statutes of the United States (41 U.S.C. 5) upon the determination by the Secretary that such waiver is necessary to obtain countermeasures or products under this section.

(D) MILESTONE-BASED PAYMENTS ALLOWED.—In awarding contracts, grants, and cooperative agreements, and in

entering into other transactions, under this section, the Secretary may use milestone-based awards and payments.

(E) FOREIGN NATIONALS ELIGIBLE.—The Secretary may under this section award contracts, grants, and cooperative agreements to, and may enter into other transactions with, highly qualified foreign national persons outside the United States, alone or in collaboration with American participants, when such transactions may inure to the benefit of the American people.

(F) ESTABLISHMENT OF RESEARCH CENTERS.—The Secretary may assess the feasibility and appropriateness of establishing, through contract, grant, cooperative agreement, or other transaction, an arrangement with an existing research center in order to achieve the goals of this section. If such an agreement is not feasible and appropriate, the Secretary may establish one or more federally-funded research and development centers, or university-affiliated research centers, in accordance with section 303(c)(3) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(c)(3)).

(G) GOVERNMENT PURPOSE.—In awarding contracts, grants, and cooperative agreements under this section, the Secretary shall provide a clear statement of defined Government purpose related to activities included in subsection (a)(6)(B) for a qualified countermeasure or qualified pandemic or epidemic product.

(H) SUPPORTING WARM-BASE AND SURGE CAPACITY AND CAPABILITIES.—Pursuant to an award under subparagraph (B)(v), the Secretary may make payments for activities necessary to maintain domestic manufacturing surge capacity and capabilities supported under such award to ensure that such capacity and capabilities are able to support the rapid manufacture of countermeasures as required by the Secretary to prepare for, or respond to, an existing or potential public health emergency or otherwise address threats that pose a significant level of risk to national security. The Secretary may support the utilization of such capacity and capabilities under awards for countermeasure and product advanced research and development, as appropriate, to provide for the maintenance of such capacity and capabilities.

(6) AT-RISK INDIVIDUALS.—In carrying out the functions under this section, the Secretary may give priority to the advanced research and development of qualified countermeasures and qualified pandemic or epidemic products that are likely to be safe and effective with respect to children, pregnant women, older adults, and other at-risk individuals with relevant characteristics that warrant consideration during the process of researching and developing such countermeasures and products.

(7) PERSONNEL AUTHORITIES.—

(A) SPECIALLY QUALIFIED SCIENTIFIC AND PROFESSIONAL PERSONNEL.—

(i) IN GENERAL.—In addition to any other personnel authorities, the Secretary may—

(I) without regard to those provisions of title 5, United States Code, governing appointments in the competitive service, appoint highly qualified individuals to scientific or professional positions in BARDA, such as program managers, to carry out this section; and

(II) compensate them in the same manner and subject to the same terms and conditions in which individuals appointed under section 9903 of such title are compensated, without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates.

(ii) MANNER OF EXERCISE OF AUTHORITY.—The authority provided for in this subparagraph shall be exercised subject to the same limitations described in section 319F–1(e)(2).

(iii) TERM OF APPOINTMENT.—The term limitations described in section 9903(c) of title 5, United States Code, shall apply to appointments under this subparagraph, except that the references to the "Secretary" and to the "Department of Defense's national security missions" shall be deemed to be to the Secretary of Health and Human Services and to the mission of the Department of Health and Human Services under this section.

(B) SPECIAL CONSULTANTS.—In carrying out this section, the Secretary may appoint special consultants pursuant to section 207(f).

(C) LIMITATION.—

(i) IN GENERAL.—The Secretary may hire up to 100 highly qualified individuals, or up to 50 percent of the total number of employees, whichever is less, under the authorities provided for in subparagraphs (A) and (B).

(ii) REPORT.—The Secretary shall report to Congress on a biennial basis on the implementation of this subparagraph.

(d) FUND.—

(1) ESTABLISHMENT.—There is established the Biodefense Medical Countermeasure Development Fund, which shall be available to carry out this section in addition to such amounts as are otherwise available for this purpose.

(2) FUNDING.—To carry out the purposes of this section, there is authorized to be appropriated to the Fund $611,700,000 for each of fiscal years 2019 through 2023, such amounts to remain available until expended.

(e) INAPPLICABILITY OF CERTAIN PROVISIONS.—

(1) DISCLOSURE.—

(A) NONDISCLOSURE OF INFORMATION.—

(i) IN GENERAL.—Information described in clause (ii) shall be deemed to be information described in section 552(b)(3) of title 5, United States Code.

(ii) INFORMATION DESCRIBED.—The information described in this clause is information relevant to programs of the Department of Health and Human Services that could compromise national security and reveal significant and not otherwise publicly known vulnerabilities of existing medical or public health defenses against chemical, biological, radiological, or nuclear threats, and is comprised of—

(I) specific technical data or scientific information that is created or obtained during the countermeasure and product advanced research and development carried out under subsection (c);

(II) information pertaining to the location security, personnel, and research materials and methods of high-containment laboratories conducting research with select agents, toxins, or other agents with a material threat determination under section 319F–2(c)(2); or

(III) security and vulnerability assessments.

(B) REVIEW.—Information subject to nondisclosure under subparagraph (A) shall be reviewed by the Secretary every 5 years, or more frequently as determined necessary by the Secretary, to determine the relevance or necessity of continued nondisclosure.

(C) REPORTING.—One year after the date of enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019, and annually thereafter, the Secretary shall report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives on the number of instances in which the Secretary has used the authority under this subsection to withhold information from disclosure, as well as the nature of any request under section 552 of title 5, United States Code that was denied using such authority.

(D) SUNSET.—This paragraph shall cease to have force or effect after December 31, 2026.

(2) REVIEW.—Notwithstanding section 1013 of title 5, United States Code, a working group of BARDA under this section and the National Biodefense Science Board under section 319M shall each terminate on the date that is 5 years after the date on which each such group or Board, as applicable, was established. Such 5-year period may be extended by the Secretary for one or more additional 5-year periods if the Secretary determines that any such extension is appropriate.

(f) INDEPENDENT EVALUATION.—

(1) IN GENERAL.—Not later than 180 days after the date of enactment of the PREVENT Pandemics Act, the Comptroller General of the United States shall conduct an independent evaluation of the activities carried out to facilitate flexible manufacturing capacity pursuant to this section.

(2) REPORT.—Not later than 1 year after the date of enactment of the PREVENT Pandemics Act, the Comptroller General of the United States shall submit to the appropriate com-

mittees of Congress a report concerning the results of the evaluation conducted under paragraph (1). Such report shall review and assess—

(A) the extent to which flexible manufacturing capacity under this section is dedicated to chemical, biological, radiological, and nuclear threats;

(B) the activities supported by flexible manufacturing initiatives;

(C) the ability of flexible manufacturing activities carried out under this section to—

(i) secure and leverage leading technical expertise with respect to countermeasure advanced research, development, and manufacturing processes; and

(ii) meet the surge manufacturing capacity needs presented by novel and emerging threats, including chemical, biological, radiological, and nuclear agents; and

(D) plans for the near-, mid-, and long-term sustainment of manufacturing activities carried out under this section, including such activities pursuant to subsection (c)(5)(H), specific actions to regularly assess the ability of recipients of an award under subsection (c)(4)(B)(v) to rapidly manufacture countermeasures as required by the Secretary, and recommendations to address challenges, if any, related to such activities.

SEC. 319L–1. [247d–7f] COLLABORATION AND COORDINATION

(a) LIMITED ANTITRUST EXEMPTION.—

(1) MEETINGS AND CONSULTATIONS TO DISCUSS SECURITY COUNTERMEASURES, QUALIFIED COUNTERMEASURES, OR QUALIFIED PANDEMIC OR EPIDEMIC PRODUCT DEVELOPMENT.—

(A) AUTHORITY TO CONDUCT MEETINGS AND CONSULTATIONS.—The Secretary, in coordination with the Attorney General and the Secretary of Homeland Security, may conduct meetings and consultations with persons engaged in the development of a security countermeasure (as defined in section 319F-2), a qualified countermeasure (as defined in section 319F-1), or a qualified pandemic or epidemic product (as defined in section 319F-3) for the purpose of the development, manufacture, distribution, purchase, or storage of a countermeasure or product. The Secretary may convene such meeting or consultation at the request of the Secretary of Homeland Security, the Attorney General, the Chairman of the Federal Trade Commission (referred to in this section as the "Chairman"), or any interested person, or upon initiation by the Secretary. The Secretary shall give prior notice of any such meeting or consultation, and the topics to be discussed, to the Attorney General, the Chairman, and the Secretary of Homeland Security.

(B) MEETING AND CONSULTATION CONDITIONS.—A meeting or consultation conducted under subparagraph (A) shall—

(i) be chaired or, in the case of a consultation, facilitated by the Secretary;

(ii) be open to persons involved in the development, manufacture, distribution, purchase, or storage of a countermeasure or product, as determined by the Secretary;

(iii) be open to the Attorney General, the Secretary of Homeland Security, and the Chairman;

(iv) be limited to discussions involving covered activities; and

(v) be conducted in such manner as to ensure that no national security, confidential commercial, or proprietary information is disclosed outside the meeting or consultation.

(C) LIMITATION.—The Secretary may not require participants to disclose confidential commercial or proprietary information.

(D) TRANSCRIPT.—The Secretary shall maintain a complete verbatim transcript of each meeting or consultation conducted under this subsection. Such transcript (or a portion thereof) shall not be disclosed under section 552 of title 5, United States Code, to the extent that the Secretary, in consultation with the Attorney General and the Secretary of Homeland Security, determines that disclosure of such transcript (or portion thereof) would pose a threat to national security. The transcript (or portion thereof) with respect to which the Secretary has made such a determination shall be deemed to be information described in subsection (b)(3) of such section 552.

(E) EXEMPTION.—

(i) IN GENERAL.—Subject to clause (ii), it shall not be a violation of the antitrust laws for any person to participate in a meeting or consultation conducted in accordance with this paragraph.

(ii) LIMITATION.—Clause (i) shall not apply to any agreement or conduct that results from a meeting or consultation and that is not covered by an exemption granted under paragraph (4).

(2) SUBMISSION OF WRITTEN AGREEMENTS.—The Secretary shall submit each written agreement regarding covered activities that is made pursuant to meetings or consultations conducted under paragraph (1) to the Attorney General and the Chairman for consideration. In addition to the proposed agreement itself, any submission shall include—

(A) an explanation of the intended purpose of the agreement;

(B) a specific statement of the substance of the agreement;

(C) a description of the methods that will be utilized to achieve the objectives of the agreement;

(D) an explanation of the necessity for a cooperative effort among the particular participating persons to achieve the objectives of the agreement; and

(E) any other relevant information determined necessary by the Attorney General, in consultation with the Chairman and the Secretary.

(3) EXEMPTION FOR CONDUCT UNDER APPROVED AGREEMENT.—It shall not be a violation of the antitrust laws for a person to engage in conduct in accordance with a written agreement to the extent that such agreement has been granted an exemption under paragraph (4), during the period for which the exemption is in effect.

(4) ACTION ON WRITTEN AGREEMENTS.—

(A) IN GENERAL.—The Attorney General, in consultation with the Chairman, shall grant, deny, grant in part and deny in part, or propose modifications to an exemption request regarding a written agreement submitted under paragraph (2), in a written statement to the Secretary, within 15 business days of the receipt of such request. An exemption granted under this paragraph shall take effect immediately.

(B) EXTENSION.—The Attorney General may extend the 15-day period referred to in subparagraph (A) for an additional period of not to exceed 10 business days.

(C) DETERMINATION.—An exemption shall be granted regarding a written agreement submitted in accordance with paragraph (2) only to the extent that the Attorney General, in consultation with the Chairman and the Secretary, finds that the conduct that will be exempted will not have any substantial anticompetitive effect that is not reasonably necessary for ensuring the availability of the countermeasure or product involved.

(5) LIMITATION ON AND RENEWAL OF EXEMPTIONS.—An exemption granted under paragraph (4) shall be limited to covered activities, and such exemption shall be renewed (with modifications, as appropriate, consistent with the finding described in paragraph (4)(C)), on the date that is 3 years after the date on which the exemption is granted unless the Attorney General in consultation with the Chairman determines that the exemption should not be renewed (with modifications, as appropriate) considering the factors described in paragraph (4).

(6) AUTHORITY TO OBTAIN INFORMATION.—Consideration by the Attorney General for granting or renewing an exemption submitted under this section shall be considered an antitrust investigation for purposes of the Antitrust Civil Process Act (15 U.S.C. 1311 et seq.).

(7) LIMITATION ON PARTIES.—The use of any information acquired under an agreement for which an exemption has been granted under paragraph (4), for any purpose other than specified in the exemption, shall be subject to the antitrust laws and any other applicable laws.

(8) REPORT.—Not later than one year after the date of enactment of this Act and biannually thereafter, the Attorney General and the Chairman shall report to Congress on the use of the exemption from the antitrust laws provided by this subsection.

(b) SUNSET.—The applicability of this section shall expire after December 31, 2026.

(c) DEFINITIONS.—In this section:

(1) ANTITRUST LAWS.—The term "antitrust laws"—

(A) has the meaning given such term in subsection (a) of the first section of the Clayton Act (15 U.S.C. 12(a)), except that such term includes section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent such section 5 applies to unfair methods of competition; and

(B) includes any State law similar to the laws referred to in subparagraph (A).

(2) COUNTERMEASURE OR PRODUCT.—The term "countermeasure or product" refers to a security countermeasure, qualified countermeasure, or qualified pandemic or epidemic product (as those terms are defined in subsection (a)(1)).

(3) COVERED ACTIVITIES.—

(A) IN GENERAL.—Except as provided in subparagraph (B), the term "covered activities" includes any activity relating to the development, manufacture, distribution, purchase, or storage of a countermeasure or product.

(B) EXCEPTION.—The term "covered activities" shall not include, with respect to a meeting or consultation conducted under subsection (a)(1) or an agreement for which an exemption has been granted under subsection (a)(4), the following activities involving 2 or more persons:

(i) Exchanging information among competitors relating to costs, profitability, or distribution of any product, process, or service if such information is not reasonably necessary to carry out covered activities—

(I) with respect to a countermeasure or product regarding which such meeting or consultation is being conducted; or

(II) that are described in the agreement as exempted.

(ii) Entering into any agreement or engaging in any other conduct—

(I) to restrict or require the sale, licensing, or sharing of inventions, developments, products, processes, or services not developed through, produced by, or distributed or sold through such covered activities; or

(II) to restrict or require participation, by any person participating in such covered activities, in other research and development activities, except as reasonably necessary to prevent the misappropriation of proprietary information contributed by any person participating in such covered activities or of the results of such covered activities.

(iii) Entering into any agreement or engaging in any other conduct allocating a market with a competitor that is not expressly exempted from the antitrust laws under subsection (a)(4).

(iv) Exchanging information among competitors relating to production (other than production by such

covered activities) of a product, process, or service if such information is not reasonably necessary to carry out such covered activities.

(v) Entering into any agreement or engaging in any other conduct restricting, requiring, or otherwise involving the production of a product, process, or service that is not expressly exempted from the antitrust laws under subsection (a)(4).

(vi) Except as otherwise provided in this subsection, entering into any agreement or engaging in any other conduct to restrict or require participation by any person participating in such covered activities, in any unilateral or joint activity that is not reasonably necessary to carry out such covered activities.

(vii) Entering into any agreement or engaging in any other conduct restricting or setting the price at which a countermeasure or product is offered for sale, whether by bid or otherwise.

SEC. 319M. [247d–f] NATIONAL BIODEFENSE SCIENCE BOARD AND WORKING GROUPS.

(a) IN GENERAL.—

(1) ESTABLISHMENT AND FUNCTION.—The Secretary shall establish the National Biodefense Science Board (referred to in this section as the "Board") to provide expert advice and guidance to the Secretary on scientific, technical and other matters of special interest to the Department of Health and Human Services regarding current and future chemical, biological, nuclear, and radiological agents, whether naturally occurring, accidental, or deliberate.

(2) MEMBERSHIP.—The membership of the Board shall be comprised of individuals who represent the Nation's preeminent scientific, public health, and medical experts, as follows—

(A) such Federal officials as the Secretary may determine are necessary to support the functions of the Board;

(B) four individuals representing the pharmaceutical, biotechnology, and device industries;

(C) four individuals representing academia; and

(D) five other members as determined appropriate by the Secretary, of whom—

(i) one such member shall be a practicing healthcare professional;

(ii) one such member shall be an individual from an organization representing healthcare consumers;

(iii) one such member shall be an individual with pediatric subject matter expertise; and

(iv) one such member shall be a State, tribal, territorial, or local public health official.

Nothing in this paragraph shall preclude a member of the Board from satisfying two or more of the requirements described in subparagraph (D).

(3) TERM OF APPOINTMENT.—A member of the Board described in subparagraph (B), (C), or (D) of paragraph (2) shall serve for a term of 3 years, except that the Secretary may ad-

just the terms of the initial Board appointees in order to provide for a staggered term of appointment for all members.

(4) CONSECUTIVE APPOINTMENTS; MAXIMUM TERMS.—A member may be appointed to serve not more than 3 terms on the Board and may serve not more than 2 consecutive terms.

(5) DUTIES.—The Board shall—

(A) advise the Secretary on current and future trends, challenges, and opportunities presented by advances in biological and life sciences, biotechnology, and genetic engineering with respect to threats posed by naturally occurring infectious diseases and chemical, biological, radiological, and nuclear agents;

(B) at the request of the Secretary, review and consider any information and findings received from the working groups established under subsection (b);

(C) at the request of the Secretary, provide recommendations and findings for expanded, intensified, and coordinated biodefense research and development activities; and

(D) provide any recommendation, finding, or report provided to the Secretary under this paragraph to the appropriate committees of Congress.

(6) MEETINGS.—

(A) INITIAL MEETING.—Not later than one year after the date of enactment of the Pandemic and All-Hazards Preparedness Act, the Secretary shall hold the first meeting of the Board.

(B) SUBSEQUENT MEETINGS.—The Board shall meet at the call of the Secretary, but in no case less than twice annually.

(7) VACANCIES.—Any vacancy in the Board shall not affect its powers, but shall be filled in the same manner as the original appointment.

(8) CHAIRPERSON.—The Secretary shall appoint a chairperson from among the members of the Board.

(9) POWERS.—

(A) HEARINGS.—The Board may hold such hearings, sit and act at such times and places, take such testimony, and receive such evidence as the Board considers advisable to carry out this subsection.

(B) POSTAL SERVICES.—The Board may use the United States mails in the same manner and under the same conditions as other departments and agencies of the Federal Government.

(10) PERSONNEL.—

(A) EMPLOYEES OF THE FEDERAL GOVERNMENT.—A member of the Board that is an employee of the Federal Government may not receive additional pay, allowances, or benefits by reason of the member's service on the Board.

(B) OTHER MEMBERS.—A member of the Board that is not an employee of the Federal Government may be compensated at a rate not to exceed the daily equivalent of the annual rate of basic pay prescribed for level IV of the Executive Schedule under section 5315 of title 5, United

States Code, for each day (including travel time) during which the member is engaged in the actual performance of duties as a member of the Board.

(C) TRAVEL EXPENSES.—Each member of the Board shall receive travel expenses, including per diem in lieu of subsistence, in accordance with applicable provisions under subchapter I of chapter 57 of title 5, United States Code.

(D) DETAIL OF GOVERNMENT EMPLOYEES.—Any Federal Government employee may be detailed to the Board with the approval for the contributing agency without reimbursement, and such detail shall be without interruption or loss of civil service status or privilege.

(b) OTHER WORKING GROUPS.—The Secretary may establish a working group of experts, or may use an existing working group or advisory committee, to—

(1) identify innovative research with the potential to be developed as a qualified countermeasure or a qualified pandemic or epidemic product;

(2) identify accepted animal models for particular diseases and conditions associated with any biological, chemical, radiological, or nuclear agent, any toxin, or any potential pandemic infectious disease, and identify strategies to accelerate animal model and research tool development and validation; and

(3) obtain advice regarding supporting and facilitating advanced research and development related to qualified countermeasures and qualified pandemic or epidemic products that are likely to be safe and effective with respect to children, pregnant women, and other vulnerable populations, and other issues regarding activities under this section that affect such populations.

(c) DEFINITIONS.—Any term that is defined in section 319L and that is used in this section shall have the same meaning in this section as such term is given in section 319L.

(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated $1,000,000 to carry out this section for fiscal year 2007 and each fiscal year thereafter.

HANSEN'S DISEASE PROGRAM

SEC. 320. [247e] (a)(1) At or through the National Hansen's Disease Programs Center (located in the State of Louisiana), the Secretary shall without charge provide short-term care and treatment, including outpatient care, for Hansen's disease and related complications to any person determined by the Secretary to be in need of such care and treatment. The Secretary may not at or through such Center provide long-term care for any such disease or complication.

(2) The Center referred to in paragraph (1) shall conduct training in the diagnosis and management of Hansen's disease and related complications, and shall conduct and promote the coordination of research (including clinical research), investigations, demonstrations, and studies relating to the causes, diagnosis, treat-

ment, 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.[25]

(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.[26] **[**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.

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

[26] 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.

(c) DISTRIBUTION.—In awarding grants under this section, the Secretary shall, to the extent practicable, ensure an equitable national geographic distribution of the grants, including areas of the United States where the incidence of early childhood caries is highest.

(d) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $10,000,000 for each the fiscal years 2001 through 2005.

SEC. 320B. [247d–11] STATE ALL PAYER CLAIMS DATABASES.

(a) IN GENERAL.—The Secretary shall make one-time grants to eligible States for the purposes described in subsection (b).

(b) USES.—A State may use a grant received under subsection (a) for one of the following purposes:

(1) To establish a State All Payer Claims Database.

(2) To improve an existing State All Payer Claims Databases.

(c) ELIGIBILITY.—To be eligible to receive a grant under subsection (a), a State shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary specifies, including, with respect to a State All Payer Claims Database, at least specifics on how the State will ensure uniform data collection and the privacy and security of such data.

(d) GRANT PERIOD AND AMOUNT.—Grants awarded under this section shall be for a period of 3-years, and in an amount of $2,500,000, of which $1,000,000 shall be made available to the State for each of the first 2 years of the grant period, and $500,000 shall be made available to the State for the third year of the grant period.

(e) AUTHORIZED USERS.—

(1) APPLICATION.—An entity desiring authorization for access to a State All Payer Claims Database that has received a grant under this section shall submit to the State All Payer Claims Database an application for such access, which shall include—

(A) in the case of an entity requesting access for research purposes—

(i) a description of the uses and methodologies for evaluating health system performance using such data; and

(ii) documentation of approval of the research by an institutional review board, if applicable for a particular plan of research; or

(B) in the case of an entity such as an employer, health insurance issuer, third-party administrator, or health care provider, requesting access for the purpose of quality improvement or cost-containment, a description of the intended uses for such data.

(2) REQUIREMENTS.—

(A) ACCESS FOR RESEARCH PURPOSES.—Upon approval of an application for research purposes under paragraph (1)(A), the authorized user shall enter into a data use and confidentiality agreement with the State All Payer Claims Database that has received a grant under this subsection,

which shall include a prohibition on attempts to reidentify and disclose individually identifiable health information and proprietary financial information.

(B) CUSTOMIZED REPORTS.—Employers and employer organizations may request customized reports from a State All Payer Claims Database that has received a grant under this section, at cost, subject to the requirements of this section with respect to privacy, security, and proprietary financial information.

(C) NON-CUSTOMIZED REPORTS.—A State All Payer Claims Database that has received a grant under this section shall make available to all authorized users aggregate data sets available through the State All Payer Claims Database, free of charge.

(3) WAIVERS.—The Secretary may waive the requirements of this subsection of a State All Payer Claims Database to provide access of entities to such database if such State All Payer Claims Database is substantially in compliance with this subsection.

(f) EXPANDED ACCESS.—

(1) MULTI-STATE APPLICATIONS.—The Secretary may prioritize applications submitted by a State whose application demonstrates that the State will work with other State All Payer Claims Databases to establish a single application for access to data by authorized users across multiple States.

(2) EXPANSION OF DATA SETS.—The Secretary may prioritize applications submitted by a State whose application demonstrates that the State will implement the reporting format for self-insured group health plans described in section 735 of the Employee Retirement Income Security Act of 1974.

(g) DEFINITIONS.—In this section—

(1) the term "individually identifiable health information" has the meaning given such term in section 1171(6) of the Social Security Act;

(2) the term "proprietary financial information" means data that would disclose the terms of a specific contract between an individual health care provider or facility and a specific group health plan, managed care entity (as defined in section 1932(a)(1)(B) of the Social Security Act) or other managed care organization, or health insurance issuer offering group or individual health insurance coverage; and

(3) the term "State All Payer Claims Database" means, with respect to a State, a database that may include medical claims, pharmacy claims, dental claims, and eligibility and provider files, which are collected from private and public payers.

(h) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $50,000,000 for each of fiscal years 2022 and 2023, and $25,000,000 for fiscal year 2024, to remain available until expended.

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 [27]

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), [28] 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 [29] 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), [30] as requested by any deputy commissioner thereunder.

(b) The Secretary is authorized to provide medical, surgical, and dental treatment and hospitalization and optometric care for Federal employees (as defined in section 8901(1) of title 5 of the United States Code) and their dependents at remote medical facilities of the Public Health Service where such care and treatment are not otherwise available. Such employees and their dependents who are not entitled to this care and treatment under any other provision of law shall be charged for it at rates established by the Secretary to reflect the reasonable cost of providing the care and treatment. Any payments pursuant to the preceding sentence shall be credited to the applicable appropriation to the Public Health Service for the year in which such payments are received.

EXAMINATION OF ALIENS

SEC. 325. [252] The Surgeon General shall provide for making, at places within the United States or in other countries, such physical and mental examinations of aliens as are required by the immigration laws, subject to administrative regulations prescribed

[27] 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.

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

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

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

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 executive department to furnish any materials, supplies, or equipment, or perform any work or services, requested by the Department of Health, Education, and Welfare for the Service in accordance with that section.

SHARING OF MEDICAL CARE FACILITIES AND RESOURCES

SEC. 327A. [254a] (a) For purposes of this section—

(1) the term "specialized health resources" means health care resources (whether equipment, space, or personnel) which, because of cost, limited availability, or unusual nature, are either unique in the health care community or are subject to maximum utilization only through mutual use;

(2) the term "hospital", unless otherwise specified, includes (in addition to other hospitals) any Federal hospital.

(b) For the purpose of maintaining or improving the quality of care in Public Health Service facilities and to provide a professional environment therein which will help to attract and retain highly qualified and talented health personnel, to encourage mutually beneficial relationships between Public Health Service facilities and hospitals and other health facilities in the health care community, and to promote the full utilization of hospitals and other health facilities and resources, the Secretary may—

(1) enter into agreements or arrangements with schools of medicine, schools of osteopathic medicine, and with other health professions schools, agencies, or institutions, for such interchange or cooperative use of facilities and services on a reciprocal or reimbursable basis, as will be of benefit to the training or research programs of the participating agencies; and

(2) enter into agreement or arrangements with hospitals and other health care facilities for the mutual use or the exchange of use of specialized health resources, and providing for reciprocal reimbursement.

Any reimbursement pursuant to any such agreement or arrangement shall be based on charges covering the reasonable cost of such utilization, including normal depreciation and amortization costs of equipment. Any proceeds to the Government under this subsection shall be credited to the applicable appropriation of the Public Health Service for the year in which such proceeds are received.

PART D—PRIMARY HEALTH CARE

Subpart I—Health Centers

SEC. 330. [254b] HEALTH CENTERS.

(a) DEFINITION OF HEALTH CENTER.—

(1) IN GENERAL.—For purposes of this section, the term "health center" means an entity that serves a population that is medically underserved, or a special medically underserved population comprised of migratory and seasonal agricultural workers, the homeless, and residents of public housing, by providing, either through the staff and supporting resources of the center or through contracts or cooperative arrangements—

(A) required primary health services (as defined in subsection (b)(1)); and

(B) as may be appropriate for particular centers, additional health services (as defined in subsection (b)(2)) necessary for the adequate support of the primary health services required under subparagraph (A);

for all residents of the area served by the center (hereafter referred to in this section as the "catchment area").

(2) LIMITATION.—The requirement in paragraph (1) to provide services for all residents within a catchment area shall not apply in the case of a health center receiving a grant only under subsection (g), (h), or (i).

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

(1) REQUIRED PRIMARY HEALTH SERVICES.—

(A) IN GENERAL.—The term "required primary health services" means—

(i) basic health services which, for purposes of this section, shall consist of—

(I) health services related to family medicine, internal medicine, pediatrics, obstetrics, or gynecology that are furnished by physicians and where appropriate, physician assistants, nurse practitioners, and nurse midwives;

(II) diagnostic laboratory and radiologic services;

(III) preventive health services, including—

(aa) prenatal and perinatal services;

(bb) appropriate cancer screening;

(cc) well-child services;

(dd) immunizations against vaccine-preventable diseases;

(ee) screenings for elevated blood lead levels, communicable diseases, and cholesterol;

(ff) pediatric eye, ear, and dental screenings to determine the need for vision and hearing correction and dental care;

(gg) voluntary family planning services; and

(hh) preventive dental services;

(IV) emergency medical services; and

(V) pharmaceutical services as may be appropriate for particular centers;

(ii) referrals to providers of medical services (including specialty referral when medically indicated) and other health-related services (including substance use disorder 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 use disorder services;

(B) recuperative care services;

(C) environmental health services, including—

(i) the detection and alleviation of unhealthful conditions associated with—

(I) water supply;

(II) chemical and pesticide exposures;

(III) air quality; or

(IV) exposure to lead;

(ii) sewage treatment;

(iii) solid waste disposal;

(iv) rodent and parasitic infestation;

(v) field sanitation;

(vi) housing; and

(vii) other environmental factors related to health; and

(D) in the case of health centers receiving grants under subsection (g), special occupation-related health services for migratory and seasonal agricultural workers, including—

(i) screening for and control of infectious diseases, including parasitic diseases; and

(ii) injury prevention programs, including prevention of exposure to unsafe levels of agricultural chemicals including pesticides.

(3) MEDICALLY UNDERSERVED POPULATIONS.—

(A) IN GENERAL.—The term "medically underserved population" means the population of an urban or rural area designated by the Secretary as an area with a shortage of personal health services or a population group designated by the Secretary as having a shortage of such services.

(B) CRITERIA.—In carrying out subparagraph (A), the Secretary shall prescribe criteria for determining the specific shortages of personal health services of an area or population group. Such criteria shall—

(i) take into account comments received by the Secretary from the chief executive officer of a State and local officials in a State; and

(ii) include factors indicative of the health status of a population group or residents of an area, the ability of the residents of an area or of a population group to pay for health services and their accessibility to them, and the availability of health professionals to residents of an area or to a population group.

(C) LIMITATION.—The Secretary may not designate a medically underserved population in a State or terminate the designation of such a population unless, prior to such designation or termination, the Secretary provides reasonable notice and opportunity for comment and consults with—

(i) the chief executive officer of such State;

(ii) local officials in such State; and

(iii) the organization, if any, which represents a majority of health centers in such State.

(D) PERMISSIBLE DESIGNATION.—The Secretary may designate a medically underserved population that does not meet the criteria established under subparagraph (B) if the chief executive officer of the State in which such population is located and local officials of such State recommend the designation of such population based on unusual local conditions which are a barrier to access to or the availability of personal health services.

(c) PLANNING GRANTS.—

(1) 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—

(A) 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;

(B) the design of a health center program for such population based on such assessment;

(C) efforts to secure, within the proposed catchment area of such center, financial and professional assistance and support for the project;

(D) initiation and encouragement of continuing community involvement in the development and operation of the project; and

(E) 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.

(2) LIMITATION.—Not more than two grants may be made under this subsection for the same project, except that upon a showing of good cause, the Secretary may make additional grant awards.

(3) RECOGNITION OF HIGH POVERTY.—

(A) IN GENERAL.—In making grants under this subsection, the Secretary may recognize the unique needs of high poverty areas.

(B) HIGH POVERTY AREA DEFINED.—For purposes of subparagraph (A), the term "high poverty area" means a catchment area which is established in a manner that is consistent with the factors in subsection (k)(3)(J), and the poverty rate of which is greater than the national average poverty rate as determined by the Bureau of the Census.

(d) IMPROVING QUALITY OF CARE.—

(1) SUPPLEMENTAL AWARDS.—The Secretary may award supplemental grant funds to health centers funded under this section to implement evidence-based models for increasing access to high-quality primary care services, which may include models related to—

(A) improving the delivery of care for individuals with multiple chronic conditions;

(B) workforce configuration;

(C) reducing the cost of care;

(D) enhancing care coordination;

(E) expanding the use of telehealth and technology-enabled collaborative learning and capacity building models;

(F) care integration, including integration of behavioral health, mental health, or substance use disorder services;

(G) addressing emerging public health or substance use disorder issues to meet the health needs of the population served by the health center; and

(H) improving access to recommended immunizations.

(2) SUSTAINABILITY.—In making supplemental awards under this subsection, the Secretary may consider whether the health center involved has submitted a plan for continuing the activities funded under this subsection after supplemental funding is expended.

(3) SPECIAL CONSIDERATION.—The Secretary may give special consideration to applications for supplemental funding under this subsection that seek to address significant barriers to access to care in areas with a greater shortage of health care providers and health services relative to the national average.

(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 1 year, for the costs of the operation of public and nonprofit private entities which provide health serv-

ices to medically underserved populations but with respect to which the Secretary is unable to make each of the determinations required by subsection (k)(3). The Secretary shall not make a grant under this paragraph unless the applicant provides assurances to the Secretary that within 120 days of receiving grant funding for the operation of the health center, the applicant will submit, for approval by the Secretary, an implementation plan to meet the requirements of subsection (k)(3). The Secretary may extend such 120-day period for achieving compliance upon a demonstration of good cause by the health center.

(C) OPERATION OF NETWORKS.—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 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 including—

(i) the purchase or lease of equipment, which may include data and information systems (including the costs of amortizing the principal of, and paying the interest on, loans for equipment);

(ii) the provision of training and technical assistance; and

(iii) other activities that—

(I) reduce costs associated with the provision of health services;

(II) improve access to, and availability of, health services provided to individuals served by the centers;

(III) enhance the quality and coordination of health services; or

(IV) improve the health status of communities.

(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 para-

graph (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.—The total amount of grant funds made available for any fiscal year under paragraph (1)(C) to a health center or to a network 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.

(6) NEW ACCESS POINTS AND EXPANDED SERVICES.—

(A) APPROVAL OF NEW ACCESS POINTS.—

(i) IN GENERAL.—The Secretary may approve applications for grants under subparagraph (A) or (B) of paragraph (1) to establish new delivery sites.

(ii) SPECIAL CONSIDERATION.—In carrying out clause (i), the Secretary may give special consideration to applicants that have demonstrated the new delivery site will be located within a sparsely populated area, or an area which has a level of unmet need that is higher relative to other applicants.

(iii) CONSIDERATION OF APPLICATIONS.—In carrying out clause (i), the Secretary shall approve applications for grants 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 the applicants involved to the medically underserved populations in urban areas which may be expected to use the services provided by the applicants is not less than two to three or greater than three to two.

(iv) SERVICE AREA OVERLAP.—If in carrying out clause (i) the applicant proposes to serve an area that is currently served by another health center funded under this section, the Secretary may consider whether the award of funding to an additional health center in the area can be justified based on the unmet need for additional services within the catchment area.

(v) MOBILE UNITS.—An existing health center may be awarded funds under clause (i) to establish a new delivery site that is a mobile unit, regardless of whether the applicant additionally proposes to establish a permanent, full-time site. In the case of a health center that is not currently receiving funds under this section, such health center may be awarded funds under clause (i) to establish a new delivery site that is a mobile unit only if such health center uses a portion of such funds to also establish a permanent, full-time site.

(B) APPROVAL OF EXPANDED SERVICE APPLICATIONS.—

(i) IN GENERAL.—The Secretary may approve applications for grants under subparagraph (A) or (B) of paragraph (1) to expand the capacity of the applicant to provide required primary health services described in subsection (b)(1) or additional health services described in subsection (b)(2).

(ii) PRIORITY EXPANSION PROJECTS.—In carrying out clause (i), the Secretary may give special consideration to expanded service applications that seek to address emerging public health or behavioral health, mental health, or substance abuse issues through increasing the availability of additional health services described in subsection (b)(2) in an area in which there are significant barriers to accessing care.

(iii) CONSIDERATION OF APPLICATIONS.—In carrying out clause (i), the Secretary shall approve applications for grants 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 the applicants involved to the medically underserved populations in urban areas which may be expected to use the services provided by such applicants is not less than two to three or greater than three to two.

(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 es-

tablishes for the purposes of such employment a temporary abode.

(B) SEASONAL AGRICULTURAL WORKER.—The term "seasonal agricultural worker" means an individual whose principal employment is in agriculture on a seasonal basis and who is not a migratory agricultural worker.

(C) AGRICULTURE.—The term "agriculture" means farming in all its branches, including—

(i) cultivation and tillage of the soil;

(ii) the production, cultivation, growing, and harvesting of any commodity grown on, in, or as an adjunct to or part of a commodity grown in or on, the land; and

(iii) any practice (including preparation and processing for market and delivery to storage or to market or to carriers for transportation to market) performed by a farmer or on a farm incident to or in conjunction with an activity described in clause (ii).

(h) HOMELESS POPULATION.—

(1) IN GENERAL.—The Secretary may award grants for the purposes described in subsections (c), (e), and (f) for the planning and delivery of services to a special medically underserved population comprised of homeless individuals, including grants for innovative programs that provide outreach and comprehensive primary health services to homeless children and youth, children and youth at risk of homelessness, homeless veterans, and veterans 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 USE DISORDER SERVICES.—The term "substance abuse[31]services" includes detoxification, risk reduction, outpatient treatment, residential treatment, and rehabilitation for substance abuse[31] 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.

[31] Section 50901(b)(8)(B)(iii)(II) of division E of Public Law 115–123 provides for an amendment to strike "abuse" and insert "use disorder". The term "abuse" appears twice and, as such, the amendment has not been carried out above.

(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 UNMET NEED.—An application for a grant under subparagraph (A) or (B) of subsection (e)(1) or subsection (e)(6) for a health center shall include—

(A) a description of the unmet 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;

(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; and

(D) in the case of an application for a grant pursuant to subsection (e)(6), a demonstration that the applicant has consulted with appropriate State and local government

agencies, and health care providers regarding the need for the health services to be provided at the proposed delivery site.

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) or subsection (e)(6), 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, including other health care providers that provide care within the catchment area, local hospitals, and specialty providers in the catchment area of the center, to provide access to services not available through the health center and to reduce the non-urgent use of hospital emergency departments;

(C) the center will have an ongoing quality improvement system that includes clinical services and management, and that maintains the confidentiality of patient records;

(D) the center will demonstrate its financial responsibility by the use of such accounting procedures and other requirements as may be prescribed by the Secretary;

(E) the center—

(i)(I) has or will have a contractual or other arrangement with the agency of the State, in which it provides services, which administers or supervises the administration of a State plan approved under title XIX of the Social Security Act for the payment of all or a part of the center's costs in providing health services to persons who are eligible for medical assistance under such a State plan; and

(II)[32] has or will have a contractual or other arrangement with the State agency administering the program under title XXI of such Act (42 U.S.C. 1397aa et seq.) with respect to individuals who are State children's health insurance program beneficiaries; or

(ii) has made or will make every reasonable effort to enter into arrangements described in subclauses (I) and (II) of clause (i);

(F) the center has made or will make and will continue to make every reasonable effort to collect appropriate reimbursement for its costs in providing health services to persons who are entitled to insurance benefits under title XVIII of the Social Security Act, to medical assistance under a State plan approved under title XIX of such Act, or to assistance for medical expenses under any other public assistance program or private health insurance program;

(G) the center—

(i) has prepared a schedule of fees or payments for the provision of its services consistent with locally prevailing rates or charges and designed to cover its reasonable costs of operation and has prepared a corresponding schedule of discounts to be applied to the payment of such fees or payments, which discounts are adjusted on the basis of the patient's ability to pay;

(ii) has made and will continue to make every reasonable effort—

(I) to secure from patients payment for services in accordance with such schedules; and

(II) to collect reimbursement for health services to persons described in subparagraph (F) on the basis of the full amount of fees and payments for such services without application of any discount;

(iii)(I) will assure that no patient will be denied health care services due to an individual's inability to pay for such services; and

(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.)—

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

(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 who shall be directly employed by 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;

(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); and

(N) the center has written policies and procedures in place to ensure the appropriate use of Federal funds in compliance with applicable Federal statutes, regulations, and the terms and conditions of the Federal award.

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.

(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. Funds expended to carry out activities under this subsection and operational support activities under subsection (m) shall not exceed 3 percent of the amount appropriated for this section for the fiscal year involved.

(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 tech-

nical assistance plan which is responsive to the requests of health centers; and

(5) share information and data relevant to the operation of new and existing health centers.

(n) RECORDS.—

(1) IN GENERAL.—Each entity which receives a grant under subsection (e) shall establish and maintain such records as the Secretary shall require.

(2) AVAILABILITY.—Each entity which is required to establish and maintain records under this subsection shall make such books, documents, papers, and records available to the Secretary or the Comptroller General of the United States, or any of their duly authorized representatives, for examination, copying or mechanical reproduction on or off the premises of such entity upon a reasonable request therefore. The Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have the authority to conduct such examination, copying, and reproduction.

(o) DELEGATION OF AUTHORITY.—The Secretary may delegate the authority to administer the programs authorized by this section to any office, except that the authority to enter into, modify, or issue approvals with respect to grants or contracts may be delegated only within the central office of the Health Resources and Services Administration.

(p) SPECIAL CONSIDERATION.—In making grants under this section, the Secretary shall give special consideration to the unique needs of sparsely populated rural areas, including giving priority in the awarding of grants for new health centers under subsections (c) and (e), and the granting of waivers as appropriate and permitted under subsections (b)(1)(B)(i) and (k)(3)(G).

(q) AUDITS.—

(1) IN GENERAL.—Each entity which receives a grant under this section shall provide for an independent annual financial audit of any books, accounts, financial records, files, and other papers and property which relate to the disposition or use of the funds received under such grant and such other funds 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. A waiver provided by the Secretary under this paragraph may not remain in effect for more than 1 year and may not be extended after such period. An entity may not receive more than one waiver under this paragraph in consecutive years.

(r) AUTHORIZATION OF APPROPRIATIONS.—

(1) GENERAL AMOUNTS FOR GRANTS.—For the purpose of carrying out this section, in addition to the amounts authorized to be appropriated under subsection (d), there is authorized to be appropriated the following:

(A) For fiscal year 2010, $2,988,821,592.

(B) For fiscal year 2011, $3,862,107,440.

(C) For fiscal year 2012, $4,990,553,440.

(D) For fiscal year 2013, $6,448,713,307.

(E) For fiscal year 2014, $7,332,924,155.

(F) For fiscal year 2015, $8,332,924,155.

(G) For fiscal year 2016, and each subsequent fiscal year, the amount appropriated for the preceding fiscal year adjusted by the product of—

(i) one plus the average percentage increase in costs incurred per patient served; and

(ii) one plus the average percentage increase in the total number of patients served.

(2) SPECIAL PROVISIONS.—

(A) PUBLIC CENTERS.—The Secretary may not expend in any fiscal year, for grants under this section to public centers (as defined in the second sentence of subsection (k)(3)) the governing boards of which (as described in subsection (k)(3)(H)) do not establish general policies for such centers, an amount which exceeds 5 percent of the amounts appropriated under this section for that fiscal year. For purposes of applying the preceding sentence, the term "public centers" shall not include health centers that receive grants pursuant to subsection (h) or (i).

(B) DISTRIBUTION OF GRANTS.—For fiscal year 2002 and each of the following fiscal years, the Secretary, in awarding grants under this section, shall ensure that the proportion of the amount made available under each of subsections (g), (h), and (i), relative to the total amount appropriated to carry out this section for that fiscal year, is equal to the proportion of the amount made available under that subsection for fiscal year 2001, relative to the total amount appropriated to carry out this section for fiscal year 2001.

(3) FUNDING REPORT.—The Secretary shall annually prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives, a report including, at a minimum—

(A) the distribution of funds for carrying out 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;

(B) an assessment of the relative health care access needs of the targeted populations;

(C) the distribution of awards and funding for new or expanded services in each of rural areas and urban areas;

(D) the distribution of awards and funding for establishing new access points, and the number of new access points created;

(E) the amount of unexpended funding for loan guarantees and loan guarantee authority under title XVI;

(F) the rationale for any substantial changes in the distribution of funds;

(G) the rate of closures for health centers and access points;

(H) the number and reason for any grants awarded pursuant to subsection (e)(1)(B); and

(I) the number and reason for any waivers provided pursuant to subsection (q)(4).

(4) RULE OF CONSTRUCTION WITH RESPECT TO RURAL HEALTH CLINICS.—

(A) IN GENERAL.—Nothing in this section shall be construed to prevent a community health center from contracting with a Federally certified rural health clinic (as defined in section 1861(aa)(2) of the Social Security Act), a low-volume hospital (as defined for purposes of section 1886 of such Act), a critical access hospital, a sole community hospital (as defined for purposes of section 1886(d)(5)(D)(iii) of such Act), or a medicare-dependent share hospital (as defined for purposes of section 1886(d)(5)(G)(iv) of such Act) for the delivery of primary health care services that are available at the clinic or hospital to individuals who would otherwise be eligible for free or reduced cost care if that individual were able to ob-

tain that care at the community health center. Such services may be limited in scope to those primary health care services available in that clinic or hospitals.

(B) ASSURANCES.—In order for a clinic or hospital to receive funds under this section through a contract with a community health center under subparagraph (A), such clinic or hospital shall establish policies to ensure—

(i) nondiscrimination based on the ability of a patient to pay; and

(ii) the establishment of a sliding fee scale for low-income patients.

(5) FUNDING FOR PARTICIPATION OF HEALTH CENTERS IN ALL OF US RESEARCH PROGRAM.—In addition to any amounts made available pursuant to paragraph (1) of this subsection, section 402A of this Act, or section 10503 of the Patient Protection and Affordable Care Act, there is authorized to be appropriated, and there is appropriated, out of any monies in the Treasury not otherwise appropriated, to the Secretary $25,000,000 for fiscal year 2018 to support the participation of health centers in the All of Us Research Program under the Precision Medicine Initiative under section 498E of this Act.

(6) ADDITIONAL AMOUNTS FOR SUPPLEMENTAL AWARDS.—In addition to any amounts made available pursuant to this subsection, section 402A of this Act, or section 10503 of the Patient Protection and Affordable Care Act, there is authorized to be appropriated, and there is appropriated, out of any monies in the Treasury not otherwise appropriated, $1,320,000,000 for fiscal year 2020 for supplemental awards under subsection (d) for the detection of SARS–CoV–2 or the prevention, diagnosis, and treatment of COVID–19.

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 basic health care services, and enhance the delivery of health care, in rural areas.

(B) TYPES OF GRANTS.—The Director may award the grants to—

(i) promote expanded delivery of health care services in rural areas under subsection (e);

(ii) provide for the planning and implementation of integrated health care networks in rural areas under subsection (f); and

(iii) 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 improving and expanding the delivery of health care services to include new and enhanced services in rural areas, through community engagement and evidence-based or innovative, evidence-informed models. The Director may award the grants for periods of not more than 5 years.

(2) ELIGIBILITY.—To be eligible to receive a grant under this subsection for a project, an entity shall—

(A) be an entity with demonstrated experience serving, or the capacity to serve, rural underserved populations;

(B) represent a consortium composed of members that—

(i) include 3 or more health care providers; and

(ii) may be nonprofit or for-profit entities; and

(C) 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 rural underserved populations in 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 plan, develop, and implement integrated health care networks that collaborate in order to—

(i) achieve efficiencies;

(ii) expand access to, coordinate, and improve the quality of basic health care services and associated health outcomes; and

(iii) strengthen the rural health care system as a whole.

(B) GRANT PERIODS.—The Director may award grants under this subsection for periods of not more than 5 years.

(2) ELIGIBILITY.—To be eligible to receive a grant under this subsection, an entity shall—

(A) be an entity with demonstrated experience serving, or the capacity to serve, rural underserved populations;

(B) represent a network composed of participants that—

(i) include 3 or more health care providers; and

(ii) may be nonprofit or for-profit entities; and

(C) 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 rural underserved populations in the local community or region to be served will benefit from and be involved in the development and ongoing operations of the network;

(D) a description of how the rural underserved populations in 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, including activities related to increasing care coordination, enhancing chronic disease management, and improving patient health outcomes. The Director may award the grants for periods of 1 to 5 years.

(2) ELIGIBILITY.—To be eligible for a grant under this subsection, an entity shall—

(A)(i) 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) be another rural provider or network of small rural providers identified by the Secretary as a key source of local or regional care; and

(B) not previously have received a grant under this subsection for the same or a similar project.

(3) APPLICATIONS.—To be eligible to receive a grant under this subsection, an eligible entity, in consultation with the appropriate State office of rural health or another appropriate State entity shall prepare and submit to the Secretary an application, at such time, in such manner, and containing such information as the Secretary may require, including—

(A) a description of the project that the eligible entity will carry out using the funds provided under the grant;

(B) an explanation of the reasons why Federal assistance is required to carry out the project;

(C) a description of the manner in which the project funded under the grant will assure continuous quality improvement in the provision of services by the entity;

(D) a description of how the rural underserved populations in 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, as appropriate, 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 4 years after the date of enactment of the Coronavirus Aid, Relief, and Economic Security Act, and every 5 years thereafter, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the activities and outcomes of the grant programs under subsections (e), (f), and (g), including the impact of projects funded under such programs on the health status of rural residents with chronic conditions.

(j) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $79,500,000 for each of fiscal years 2021 through 2025.

SEC. 330A–1. [254c–1a] GRANTS TO NURSE–MANAGED HEALTH CLINICS.

(a) DEFINITIONS.—

(1) COMPREHENSIVE PRIMARY HEALTH CARE SERVICES.—In this section, the term "comprehensive primary health care

services" means the primary health services described in section 330(b)(1).

(2) NURSE-MANAGED HEALTH CLINIC.—The term "nurse-managed health clinic" means a nurse-practice arrangement, managed by advanced practice nurses, that provides primary care or wellness services to underserved or vulnerable populations and that is associated with a school, college, university or department of nursing, federally qualified health center, or independent nonprofit health or social services agency.

(b) AUTHORITY TO AWARD GRANTS.—The Secretary shall award grants for the cost of the operation of nurse-managed health clinics that meet the requirements of this section.

(c) APPLICATIONS.—To be eligible to receive a grant under this section, an entity shall—

(1) be an NMHC; and

(2) submit to the Secretary an application at such time, in such manner, and containing—

(A) assurances that nurses are the major providers of services at the NMHC and that at least 1 advanced practice nurse holds an executive management position within the organizational structure of the NMHC;

(B) an assurance that the NMHC will continue providing comprehensive primary health care services or wellness services without regard to income or insurance status of the patient for the duration of the grant period; and

(C) an assurance that, not later than 90 days of receiving a grant under this section, the NMHC will establish a community advisory committee, for which a majority of the members shall be individuals who are served by the NMHC.

(d) GRANT AMOUNT.—The amount of any grant made under this section for any fiscal year shall be determined by the Secretary, taking into account—

(1) the financial need of the NMHC, considering State, local, and other operational funding provided to the NMHC; and

(2) other factors, as the Secretary determines appropriate.

(e) AUTHORIZATION OF APPROPRIATIONS.—For the purposes of carrying out this section, there are authorized to be appropriated $50,000,000 for the fiscal year 2010 and such sums as may be necessary for each of the fiscal years 2011 through 2014.

SEC. 330A–2. [254c-1b] RURAL OBSTETRIC NETWORK GRANTS.

(a) PROGRAM ESTABLISHED.—The Secretary shall award grants or cooperative agreements to eligible entities to establish collaborative improvement and innovation networks (referred to in this section as "rural obstetric networks") to improve maternal and infant health outcomes and reduce preventable maternal mortality and severe maternal morbidity by improving maternity care and access to care in rural areas, frontier areas, maternity care health professional target areas, or jurisdictions of Indian Tribes and Tribal organizations.

(b) USE OF FUNDS.—Grants or cooperative agreements awarded pursuant to this section shall be used for the establishment or continuation of collaborative improvement and innovation networks to improve maternal and infant health outcomes and reduce preventable maternal mortality and severe maternal morbidity by improving prenatal care, labor care, birthing, and postpartum care services in rural areas. Rural obstetric networks established in accordance with this section may—

(1) develop a network to improve coordination and increase access to maternal health care and assist pregnant women in the areas described in subsection (a) with accessing and utilizing prenatal care, labor care, birthing, and postpartum care services to improve outcomes in birth and maternal mortality and morbidity;

(2) identify and implement evidence-based and sustainable delivery models for providing prenatal care, labor care, birthing, and postpartum care services, including home visiting programs and culturally appropriate care models that reduce health disparities;

(3) develop a model for maternal health care collaboration between health care settings to improve access to care in areas described in subsection (a), which may include the use of telehealth;

(4) provide training for professionals in health care settings that do not have specialty maternity care;

(5) collaborate with academic institutions that can provide regional expertise and help identify barriers to providing maternal health care, including strategies for addressing such barriers; and

(6) assess and address disparities in infant and maternal health outcomes, including among racial and ethnic minority populations and underserved populations in such areas described in subsection (a).

(c) DEFINITIONS.—In this section:

(1) ELIGIBLE ENTITIES.—The term "eligible entities" means entities providing prenatal care, labor care, birthing, and postpartum care services in rural areas, frontier areas, or medically underserved areas, or to medically underserved populations or Indian Tribes or Tribal organizations.

(2) FRONTIER AREA.—The term "frontier area" means a frontier county, as defined in section 1886(d)(3)(E)(iii)(III) of the Social Security Act.

(3) INDIAN TRIBES; TRIBAL ORGANIZATION.—The terms "Indian Tribe" and "Tribal organization" have the meanings given the terms "Indian tribe" and "tribal organization" in section 4 of the Indian Self-Determination and Education Assistance Act.

(4) MATERNITY CARE HEALTH PROFESSIONAL TARGET AREA.—The term "maternity care health professional target area" has the meaning described in section 332(k)(2).

(d) REPORT TO CONGRESS.—Not later than September 30, 2026, the Secretary shall submit to Congress a report on activities supported by grants awarded under this section, including—

(1) a description of activities conducted pursuant to paragraphs (1) through (6) of subsection (b); and

(2) an analysis of the effects of rural obstetric networks on improving maternal and infant health outcomes.

(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $3,000,000 for each of fiscal years 2023 through 2027.

SEC. 330B. [254c–2] SPECIAL DIABETES PROGRAMS FOR TYPE I DIABETES.[33]

(a) IN GENERAL.—The Secretary, directly or through grants, shall provide for research into the prevention and cure of Type I diabetes.

(b) FUNDING.—

(1) TRANSFERRED FUNDS.—Notwithstanding section 2104(a) of the Social Security Act, from the amounts appropriated in such section for each of fiscal years 1998 through 2002, $30,000,000 is hereby transferred and made available in such fiscal year for grants under this section.

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

(A) $70,000,000 for each of fiscal years 2001 and 2002 (which shall be combined with amounts transferred under paragraph (1) for each such fiscal years);

(B) $100,000,000 for fiscal year 2003;

(C) $150,000,000 for each of fiscal years 2004 through 2017;

(D) $150,000,000 for each of fiscal years 2018 through 2023, to remain available until expended;

(E) $155,619,196 for fiscal year 2024, to remain available until expended;

(F) $159,228,188 for fiscal year 2025, to remain available until expended;

(G) $200,000,000 for fiscal year 2026, to remain available until expended; and

(H) $50,410,959 for the period beginning on October 1, 2026, and ending on December 31, 2026, to remain available until expended.

SEC. 330C. [254c–3] SPECIAL DIABETES PROGRAMS FOR INDIANS.[34]

(a) IN GENERAL.—The Secretary shall make grants for providing services for the prevention and treatment of diabetes in accordance with subsection (b).

(b) SERVICES THROUGH INDIAN HEALTH FACILITIES.—For purposes of subsection (a), services under such subsection are provided in accordance with this subsection if the services are provided through any of the following entities:

(1) The Indian Health Service.

---

[33] Section 4923 of Public Law 105–33 (111 Stat. 574, as amended by section 1(c) of Public Law 107–360 (116 Stat. 3019),) requires the Secretary of Health and Human Services to conduct evaluations regarding programs under sections 330B and 330C. An interim report is required to be submitted to the appropriate committees of Congress not later than January 1, 2000, and a final report is required to be submitted not later than January 1, 2007.

[34] See footnote to section 330B.

(2) 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—

(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;

(C) $150,000,000 for each of fiscal years 2004 through 2017;

(D) $150,000,000 for each of fiscal years 2018 through 2023, to remain available until expended;

(E) $155,619,196 for fiscal year 2024, to remain available until expended;

(F) $159,228,188 for fiscal year 2025, to remain available until expended;

(G) $200,000,000 for fiscal year 2026, to remain available until expended; and

(H) $50,410,959 for the period beginning on October 1, 2026, and ending on December 31, 2026, to remain available until expended.

SEC. 330E. [254c–5] EPILEPSY; SEIZURE DISORDER.

(a) NATIONAL PUBLIC HEALTH CAMPAIGN.—

(1) IN GENERAL.—The Secretary shall develop and implement public health surveillance, education, research, and intervention strategies to improve the lives of persons with epilepsy, with a particular emphasis on children. Such projects may be carried out by the Secretary directly and through awards of grants or contracts to public or nonprofit private entities. The Secretary may directly or through such awards provide technical assistance with respect to the planning, development, and operation of such projects.

(2) CERTAIN ACTIVITIES.—Activities under paragraph (1) shall include—

(A) expanding current surveillance activities through existing monitoring systems and improving registries that maintain data on individuals with epilepsy, including children;

(B) enhancing research activities on the diagnosis, treatment, and management of epilepsy;

(C) implementing public and professional information and education programs regarding epilepsy, including initiatives which promote effective management of the disease through children's programs which are targeted to parents, schools, daycare providers, patients;

(D) undertaking educational efforts with the media, providers of health care, schools and others regarding stigmas and secondary disabilities related to epilepsy and seizures, and its effects on youth;

(E) utilizing and expanding partnerships with organizations with experience addressing the health and related needs of people with disabilities; and

(F) other activities the Secretary deems appropriate.

(3) COORDINATION OF ACTIVITIES.—The Secretary shall ensure that activities under this subsection are coordinated as appropriate with other agencies of the Public Health Service that carry out activities regarding epilepsy and seizure.

(b) SEIZURE DISORDER; DEMONSTRATION PROJECTS IN MEDICALLY UNDERSERVED AREAS.—

(1) IN GENERAL.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, may make grants for the purpose of carrying out demonstration projects to improve access to health and other services regarding seizures to encourage early detection and treatment in children and others residing in medically underserved areas.

(2) APPLICATION FOR GRANT.—A grant may not be awarded under paragraph (1) unless an application therefore is submitted to the Secretary and the Secretary approves such application. Such application shall be submitted in such form and manner and shall contain such information as the Secretary may prescribe.

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

(1) The term "epilepsy" refers to a chronic and serious neurological condition characterized by excessive electrical discharges in the brain causing recurring seizures affecting all life activities. The Secretary may revise the definition of such term to the extent the Secretary determines necessary.

(2) The term "medically underserved" has the meaning applicable under section 799B(6).

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

SEC. 330F. [254c–6] CERTAIN SERVICES FOR PREGNANT WOMEN.

(a) INFANT ADOPTION AWARENESS.—

(1) IN GENERAL.—The Secretary shall make grants to national, regional, or local adoption organizations for the purpose of developing and implementing programs to train the designated staff of eligible health centers in providing adoption information and referrals to pregnant women on an equal basis

with all other courses of action included in nondirective counseling to pregnant women.

(2) BEST-PRACTICES GUIDELINES.—

(A) IN GENERAL.—A condition for the receipt of a grant under paragraph (1) is that the adoption organization involved agree that, in providing training under such paragraph, the organization will follow the guidelines developed under subparagraph (B).

(B) PROCESS FOR DEVELOPMENT OF GUIDELINES.—

(i) IN GENERAL.—The Secretary shall establish and supervise a process described in clause (ii) in which the participants are—

(I) an appropriate number and variety of adoption organizations that, as a group, have expertise in all models of adoption practice and that represent all members of the adoption triad (birth mother, infant, and adoptive parent); and

(II) affected public health entities.

(ii) DESCRIPTION OF PROCESS.—The process referred to in clause (i) is a process in which the participants described in such clause collaborate to develop best-practices guidelines on the provision of adoption information and referrals to pregnant women on an equal basis with all other courses of action included in nondirective counseling to pregnant women.

(iii) DATE CERTAIN FOR DEVELOPMENT.—The Secretary shall ensure that the guidelines described in clause (ii) are developed not later than 180 days after the date of the enactment of the Children's Health Act of 2000[35].

(C) RELATION TO AUTHORITY FOR GRANTS.—The Secretary may not make any grant under paragraph (1) before the date on which the guidelines under subparagraph (B) are developed.

(3) USE OF GRANT.—

(A) IN GENERAL.—With respect to a grant under paragraph (1)—

(i) an adoption organization may expend the grant to carry out the programs directly or through grants to or contracts with other adoption organizations;

(ii) the purposes for which the adoption organization expends the grant may include the development of a training curriculum, consistent with the guidelines developed under paragraph (2)(B); and

(iii) a condition for the receipt of the grant is that the adoption organization agree that, in providing training for the designated staff of eligible health centers, such organization will make reasonable efforts to ensure that the individuals who provide the training are individuals who are knowledgeable in all elements of the adoption process and are experienced in providing adoption information and referrals in the geo-

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

graphic 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 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 cen-

ters to arrange for designated staff to participate in such training. Such efforts shall affirm Federal requirements, if any, that the eligible health center provide nondirective counseling to pregnant women.

(B) All costs of such centers in obtaining the training shall be reimbursed by the organization that provides the training, using grants under paragraph (1).

(C) Not later than 1 year after the date of the enactment of the Children's Health Act of 2000 [36], the Secretary shall submit to the appropriate committees of the Congress a report evaluating the extent to which adoption information and referral, upon request, are provided by eligible health centers. Within a reasonable time after training under this section is initiated, the Secretary shall submit to the appropriate committees of the Congress a report evaluating the extent to which adoption information and referral, upon request, are provided by eligible health centers in order to determine the effectiveness of such training and the extent to which such training complies with subsection (a)(1). In preparing the reports required by this subparagraph, the Secretary shall in no respect interpret the provisions of this section to allow any interference in the provider-patient relationship, any breach of patient confidentiality, or any monitoring or auditing of the counseling process or patient records which breaches patient confidentiality or reveals patient identity. The reports required by this subparagraph shall be conducted by the Secretary acting through the Administrator of the Health Resources and Services Administration and in collaboration with the Director of the Agency for Healthcare Research and Quality.

(b) APPLICATION FOR GRANT.—The Secretary may make a grant under subsection (a) only if an application for the grant is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

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

SEC. 330G. [254c–7] SPECIAL NEEDS ADOPTION PROGRAMS; PUBLIC AWARENESS CAMPAIGN AND OTHER ACTIVITIES.

(a) SPECIAL NEEDS ADOPTION AWARENESS CAMPAIGN.—

(1) IN GENERAL.—The Secretary shall, through making grants to nonprofit private entities, provide for the planning, development, and carrying out of a national campaign to provide information to the public regarding the adoption of children with special needs.

(2) INPUT ON PLANNING AND DEVELOPMENT.—In providing for the planning and development of the national campaign under paragraph (1), the Secretary shall provide for input from

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

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.

(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 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 or increasing above the national average annual rates of infant mortality and that, prior to the effective date of this section, was a demonstration program carried out under section 301.

(b) CONSIDERATIONS IN MAKING GRANTS.—

(1) REQUIREMENTS.—In making grants under subsection (a), the Secretary shall require that applicants (in addition to meeting all eligibility criteria established by the Secretary) establish, for project areas under such subsection, community-based consortia of individuals and organizations (including agencies responsible for administering block grant programs under title V of the Social Security Act, participants and former participants of project services, public health departments, hospitals, health centers under section 330, State substance abuse agencies, and other significant sources of health care services) that are appropriate for participation in projects under subsection (a).

(2) OTHER CONSIDERATIONS.—In making grants under subsection (a), the Secretary shall take into consideration the following:

(A) Factors that contribute to infant mortality, including poor birth outcomes (such as low birthweight and preterm birth) and social determinants of health.

(B) Communities with—

(i) high rates of infant mortality or poor perinatal outcomes; or

(ii) high rates of infant mortality or poor perinatal outcomes in specific subpopulations within the community.

(C) The extent to which applicants for such grants facilitate—

(i) collaboration with the local community in the development of the project;

(ii) a community-based approach to the delivery of services;

(iii) a comprehensive approach to women's health care to improve perinatal outcomes; and

(iv) the use and collection of data demonstrating the effectiveness of such program in decreasing infant mortality rates and improving perinatal outcomes, as applicable, or the process by which new applicants plan to collect this data.

(3) SPECIAL PROJECTS.—Nothing in paragraph (2) shall be construed to prevent the Secretary from awarding grants under subsection (a) for special projects that are intended to address significant disparities in perinatal health indicators in communities along the United States-Mexico border or in Alaska or Hawaii.

(c) COORDINATION.—

(1) IN GENERAL.—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.

(2) OTHER PROGRAMS.—The Secretary shall ensure coordination of the program carried out pursuant to this section with other programs and activities related to the reduction of the rate of infant mortality and improved perinatal and infant health outcomes supported by the Department.

(d) RULE OF CONSTRUCTION.—Except to the extent inconsistent with this section, this section may not be construed as affecting the authority of the Secretary to make modifications in the program carried out under subsection (a).

(e) FUNDING.—

(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $125,500,000 for each of fiscal years 2021 through 2025.

(2) ALLOCATION.—

(A) PROGRAM ADMINISTRATION.—Of the amounts appropriated under paragraph (1) for a fiscal year, the Secretary may reserve up to 5 percent for coordination, dis-

semination, technical assistance, and data activities that are determined by the Secretary to be appropriate for carrying out the program under this section.

(B) EVALUATION.—Of the amounts appropriated under paragraph (1) for a fiscal year, the Secretary may reserve up to 1 percent for evaluations of projects carried out under subsection (a). Each such evaluation shall include a determination of whether such projects have been effective in reducing the disparity in health status between the general population and individuals who are members of racial or ethnic minority groups. Evaluations may also include, to the extent practicable, information related to—

(i) progress toward achieving any grant metrics or outcomes related to reducing infant mortality rates, improving perinatal outcomes, or reducing the disparity in health status;

(ii) recommendations on potential improvements that may assist with addressing gaps, as applicable and appropriate; and

(iii) the extent to which the grantee coordinated with the community in which the grantee is located in the development of the project and delivery of services, including with respect to technical assistance and mentorship programs.

(f) GAO REPORT.—

(1) IN GENERAL.—Not later than 4 years after the date of the enactment of this subsection, the Comptroller General of the United States shall conduct an independent evaluation, and submit to the appropriate Committees of Congress a report, concerning the Healthy Start program under this section.

(2) EVALUATION.—In conducting the evaluation under paragraph (1), the Comptroller General shall consider, as applicable and appropriate, information from the evaluations under subsection (e)(2)(B).

(3) REPORT.—The report described in paragraph (1) shall review, assess, and provide recommendations, as appropriate, on the following:

(A) The allocation of Healthy Start program grants by the Health Resources and Services Administration, including considerations made by such Administration regarding disparities in infant mortality or perinatal outcomes among urban and rural areas in making such awards.

(B) Trends in the progress made toward meeting the evaluation criteria pursuant to subsection (e)(2)(B), including programs which decrease infant mortality rates and improve perinatal outcomes, programs that have not decreased infant mortality rates or improved perinatal outcomes, and programs that have made an impact on disparities in infant mortality or perinatal outcomes.

(C) The ability of grantees to improve health outcomes for project participants, promote the awareness of the Healthy Start program services, incorporate and promote family participation, facilitate coordination with the community in which the grantee is located, and increase

grantee accountability through quality improvement, performance monitoring, evaluation, and the effect such metrics may have toward decreasing the rate of infant mortality and improving perinatal outcomes.

(D) The extent to which such Federal programs are coordinated across agencies and the identification of opportunities for improved coordination in such Federal programs and activities.

SEC. 330I. [254c–14] TELEHEALTH NETWORK AND TELEHEALTH RESOURCE CENTERS GRANT PROGRAMS.

(a) DEFINITIONS.—In this section:

(1) DIRECTOR; OFFICE.—The terms "Director" and "Office" mean the Director and Office specified in subsection (c).

(2) FEDERALLY QUALIFIED HEALTH CENTER AND RURAL HEALTH CLINIC.—The term "Federally qualified health center" and "rural health clinic" have the meanings given the terms in section 1861(aa) of the Social Security Act (42 U.S.C. 1395x(aa)).

(3) FRONTIER COMMUNITY.—The term "frontier community" shall have the meaning given the term in regulations issued under subsection (r).

(4) MEDICALLY UNDERSERVED AREA.—The term "medically underserved area" has the meaning given the term "medically underserved community" in section 799B(6).

(5) MEDICALLY UNDERSERVED POPULATION.—The term "medically underserved population" has the meaning given the term in section 330(b)(3).

(6) TELEHEALTH SERVICES.—The term "telehealth services" means services provided through telehealth technologies.

(7) TELEHEALTH TECHNOLOGIES.—The term "telehealth technologies" means technologies relating to the use of electronic information, and telecommunications technologies, to support and promote, at a distance, health care, patient and professional health-related education, health administration, and public health.

(b) PROGRAMS.—The Secretary shall establish, under section 301, telehealth network and telehealth resource centers grant programs.

(c) ADMINISTRATION.—

(1) ESTABLISHMENT.—There is established in the Health Resources and Services Administration an Office for the Advancement of Telehealth. The Office shall be headed by a Director.

(2) DUTIES.—The telehealth network and telehealth resource centers grant programs established under section 301 shall be administered by the Director, in consultation with the State offices of rural health, State offices concerning primary care, or other appropriate State government entities.

(d) GRANTS.—

(1) TELEHEALTH NETWORK GRANTS.—The Director may, in carrying out the telehealth network grant program referred to in subsection (b), award grants to eligible entities for evidence-based projects that utilize telehealth technologies 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 access to, and the quality of, health care services; and

(B) expand and improve the quality of health information available to health care providers,, patients, and their families.

(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 support initiatives that utilize telehealth technologies in the areas and communities, and for the populations, described in paragraph (1).

(e) GRANT PERIODS.—The Director may award grants under this section for periods of not more than 5 years.

(f) ELIGIBLE ENTITIES.—

(1) 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.

(2) NATURE OF ENTITIES.—Each entity participating in the telehealth network may be a nonprofit or for-profit entity

(3) 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):

(A) Community or migrant health centers or other Federally qualified health centers.

(B) Health care providers, including pharmacists, in private practice.

(C) Entities operating clinics, including rural health clinics.

(D) Local health departments.

(E) Nonprofit hospitals, including community access hospitals.

(F) Other publicly funded health or social service agencies.

(G) Long-term care providers.

(H) Providers of health care services in the home.

(I) Providers of outpatient mental health and substance disorder services and entities operating outpatient mental health and substance disorder facilities.

(J) Local or regional emergency health care providers.

(K) Institutions of higher education.

(L) Entities operating dental clinics.

(M) Providers of prenatal, labor care, birthing, and postpartum care services, including hospitals that operate obstetric care units.

(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, and 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) 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 care, public health services, long-term care, home care, preventive care, case management services, prenatal care, labor care, birthing care, or postpartum care.

(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 and regional connectivity within areas, communities, or populations to be served through 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 rural areas, 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.

(i) 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 not less than 50 percent of the funds awarded shall be awarded for projects in rural areas.

(j) 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, 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 consumers in a more effective manner; and

(G) implementing special projects or studies under the direction of the Office.

(k) 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 20 percent of the total grant funds;

(3) in the case of a project involving a telehealth network, to purchase or install transmission 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.

(l) 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.

(m) 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.

(n) 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).

(o) 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.

(p) REPORT.—Not later than 4 years after the date of enactment of the Coronavirus Aid, Relief, and Economic Security Act, and every 5 years thereafter, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the activities and outcomes of the grant programs under subsection (b).

(q) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $29,000,000 for each of fiscal years 2021 through 2025.

[Section 330J was amended, redesignated as section 553, and transferred to the end of part D of title V of the Public Health Service Act by Public Law 118–84.]

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.

SEC. 330M. [254c–19] PEDIATRIC MENTAL HEALTH CARE ACCESS GRANTS.

(a) IN GENERAL.—The Secretary, acting through the Administrator of the Health Resources and Services Administration and in coordination with other relevant Federal agencies, shall award grants or cooperative agreements to States, political subdivisions of States, and Indian Tribes and Tribal organizations (for purposes of this section, as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450b)) to promote behavioral health integration in pediatric primary care by—

(1) supporting the development of statewide or regional pediatric mental health care telehealth access programs; and

(2) supporting the improvement of existing statewide or regional pediatric mental health care telehealth access programs.

(b) PROGRAM REQUIREMENTS.—

(1) IN GENERAL.—A pediatric mental health care telehealth access program referred to in subsection (a), with respect to which an award under such subsection may be used, shall—

(A) be a statewide or regional network of pediatric mental health teams that provide support to pediatric primary care sites as an integrated team;

(B) support and further develop organized State or regional networks of pediatric mental health teams to provide consultative support to pediatric primary care sites;

(C) conduct an assessment of critical behavioral consultation needs among pediatric providers and such providers' preferred mechanisms for receiving consultation, training, and technical assistance;

(D) develop an online database and communication mechanisms, including telehealth, to facilitate consultation support to pediatric practices;

(E) provide rapid statewide or regional clinical telephone or telehealth consultations when requested between the pediatric mental health teams and pediatric primary care providers;

(F) conduct training and provide technical assistance to pediatric primary care providers to support the early identification, diagnosis, treatment, and referral of children with behavioral health conditions;

(G) provide information to pediatric providers about, and assist pediatric providers in accessing, pediatric mental health care providers, including child and adolescent psychiatrists, developmental-behavioral pediatricians, and licensed mental health professionals, such as psychologists, social workers, or mental health counselors and in scheduling and conducting technical assistance;

(H) provide information to pediatric health care providers about available mental health services for children in the community and assist with referrals to specialty care and community or behavioral health resources; and

(I) establish mechanisms for measuring and monitoring increased access to pediatric mental health care services by pediatric primary care providers and expanded capacity of pediatric primary care providers to identify, treat, and refer children with mental health conditions.

(2) SUPPORT TO SCHOOLS AND EMERGENCY DEPARTMENTS.—

(A) IN GENERAL.—In addition to the activities required under paragraph (1), a pediatric mental health care access program referred to in subsection (a), with respect to which an award under such subsection may be used, may provide information, consultative support, training, and technical assistance to—

(i) emergency departments; and

(ii) State educational agencies, local educational agencies, Tribal educational agencies, and elementary and secondary schools.

(B) REQUIREMENTS FOR CERTAIN RECIPIENTS.—An entity receiving information, consultative support, training, and technical assistance under subparagraph (A)(ii) shall operate in a manner consistent with, and shall ensure consistency with, the requirements of subsections (a) and (c) of section 4001 of the Elementary and Secondary Education Act with respect to such information, consultative support, training, and technical assistance.

(3) PEDIATRIC MENTAL HEALTH TEAMS.—In this subsection, the term "pediatric mental health team" means a team consisting of at least one case coordinator, at least one child and adolescent psychiatrist, and at least one licensed clinical mental health professional, such as a psychologist, social worker, or mental health counselor, and which may include a developmental-behavioral pediatrician, and which may include a developmental-behavioral pediatrician. Such a team may be regionally based.

(c) APPLICATION.—A State, political subdivision of a State, Indian Tribe, or Tribal organization seeking an award under this section shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require, including a plan for the comprehensive evaluation of activities that are carried out with funds received under such award.

(d) EVALUATION.—A State, political subdivision of a State, Indian Tribe, or Tribal organization that receives an award under this section shall prepare and submit an evaluation of activities that are carried out with funds received under such award to the Secretary at such time, in such manner, and containing such information as the Secretary may reasonably require, including a process and outcome evaluation.

(e) ACCESS TO BROADBAND.—In administering awards under this section, the Secretary may coordinate with other agencies to ensure that funding opportunities are available to support access to reliable, high-speed Internet for providers.

(f) MATCHING REQUIREMENT.—The Secretary may not make an award under this section unless the State, political subdivision of a State, Indian Tribe, or Tribal organization involved agrees, with respect to the costs to be incurred by the State, political subdivision of a State, Indian Tribe, or Tribal organization in carrying out the purpose described in this section, to make available non-Federal contributions (in cash or in kind) toward such costs in an amount that is not less than 20 percent of Federal funds provided in the award.

(g) TECHNICAL ASSISTANCE.—The Secretary may—

(1) provide, or continue to provide, technical assistance to recipients of awards under subsection (a); and

(2) award a grant or contract to an eligible public or nonprofit private entity (as determined by the Secretary) for the purpose of providing such technical assistance pursuant to this subsection.

(h) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated, $31,000,000 for each of fiscal years 2023 through 2027.

SEC. 330N. [254c–20] EXPANDING CAPACITY FOR HEALTH OUTCOMES.

(a) DEFINITIONS.—In this section:

(1) ELIGIBLE ENTITY.—The term "eligible entity" means an entity that provides, or supports the provision of, health care services in rural areas, frontier areas, health professional shortage areas, or medically underserved areas, or to medically underserved populations or Native Americans, including Indian Tribes, Tribal organizations, and urban Indian organizations, and which may include entities leading, or capable of leading, a technology-enabled collaborative learning and capacity building model or engaging in technology-enabled collaborative training of participants in such model.

(2) HEALTH PROFESSIONAL SHORTAGE AREA.—The term "health professional shortage area" means a health professional shortage area designated under section 332.

(3) INDIAN TRIBE.—The terms "Indian Tribe" and "Tribal organization" have the meanings given the terms "Indian tribe" and "tribal organization" in section 4 of the Indian Self-Determination and Education Assistance Act.

(4) MEDICALLY UNDERSERVED POPULATION.—The term "medically underserved population" has the meaning given the term in section 330(b)(3).

(5) NATIVE AMERICANS.—The term "Native Americans" has the meaning given the term in section 736 and includes Indian Tribes and Tribal organizations.

(6) TECHNOLOGY-ENABLED COLLABORATIVE LEARNING AND CAPACITY BUILDING MODEL.—The term "technology-enabled collaborative learning and capacity building model" means a distance health education model that connects health care professionals, and particularly specialists, with multiple other health care professionals through simultaneous interactive videoconferencing for the purpose of facilitating case-based learning, disseminating best practices, and evaluating outcomes.

(7) URBAN INDIAN ORGANIZATION.—The term "urban Indian organization" has the meaning given the term in section 4 of the Indian Health Care Improvement Act.

(b) PROGRAM ESTABLISHED.—The Secretary shall, as appropriate, award grants to evaluate, develop, and, as appropriate, expand the use of technology-enabled collaborative learning and capacity building models, to improve retention of health care providers and increase access to health care services, such as those to address chronic diseases and conditions, infectious diseases, mental health, substance use disorders, prenatal and maternal health, pediatric care, pain management, palliative care, and other specialty care in rural areas, frontier areas, health professional shortage areas, or medically underserved areas and for medically underserved populations or Native Americans.

(c) USE OF FUNDS.—

(1) IN GENERAL.—Grants awarded under subsection (b) shall be used for—

(A) the development and acquisition of instructional programming, and the training of health care providers and other professionals that provide or assist in the provision of services through models described in subsection (b), such as training on best practices for data collection and leading or participating in such technology-enabled activities consistent with technology-enabled collaborative learning and capacity-building models;

(B) information collection and evaluation activities to study the impact of such models on patient outcomes and health care providers, and to identify best practices for the expansion and use of such models; or

(C) other activities consistent with achieving the objectives of the grants awarded under this section, as determined by the Secretary.

(2) OTHER USES.—In addition to any of the uses under paragraph (1), grants awarded under subsection (b) may be used for—

(A) equipment to support the use and expansion of technology-enabled collaborative learning and capacity building models, including for hardware and software that enables distance learning, health care provider support, and the secure exchange of electronic health information; or

(B) support for health care providers and other professionals that provide or assist in the provision of services through such models.

(d) LENGTH OF GRANTS.—Grants awarded under subsection (b) shall be for a period of up to 5 years.

(e) GRANT REQUIREMENTS.—The Secretary may require entities awarded a grant under this section to collect information on the effect of the use of technology-enabled collaborative learning and capacity building models, such as on health outcomes, access to health care services, quality of care, and provider retention in areas and populations described in subsection (b). The Secretary may award a grant or contract to assist in the coordination of such models, including to assess outcomes associated with the use of such models in grants awarded under subsection (b), including for the purpose described in subsection (c)(1)(B).

(f) APPLICATION.—An eligible entity that seeks to receive a grant under subsection (b) shall submit to the Secretary an application, at such time, in such manner, and containing such information as the Secretary may require. Such application shall include plans to assess the effect of technology-enabled collaborative learning and capacity building models on patient outcomes and health care providers.

(g) ACCESS TO BROADBAND.—In administering grants under this section, the Secretary may coordinate with other agencies to ensure that funding opportunities are available to support access to reliable, high-speed internet for grantees.

(h) TECHNICAL ASSISTANCE.—The Secretary shall provide (either directly through the Department of Health and Human Serv-

ices or by contract) technical assistance to eligible entities, including recipients of grants under subsection (b), on the development, use, and evaluation of technology-enabled collaborative learning and capacity building models in order to expand access to health care services provided by such entities, including for medically underserved areas and to medically underserved populations or Native Americans.

(i) RESEARCH AND EVALUATION.—The Secretary, in consultation with stakeholders with appropriate expertise in such models, shall develop a strategic plan to research and evaluate the evidence for such models. The Secretary shall use such plan to inform the activities carried out under this section.

(j) REPORT BY SECRETARY.—Not later than 4 years after the date of enactment of this section, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, and post on the internet website of the Department of Health and Human Services, a report including, at minimum—

(1) a description of any new and continuing grants awarded to entities under subsection (b) and the specific purpose and amounts of such grants;

(2) an overview of—

(A) the evaluations conducted under subsections (b);

(B) technical assistance provided under subsection (h); and

(C) activities conducted by entities awarded grants under subsection (b); and

(3) a description of any significant findings or developments related to patient outcomes or health care providers and best practices for eligible entities expanding, using, or evaluating technology-enabled collaborative learning and capacity building models, including through the activities described in subsection (h).

(k) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $10,000,000 for each of fiscal years 2022 through 2026.

SEC. 330O. [254c-21] INNOVATION FOR MATERNAL HEALTH.

(a) IN GENERAL.—The Secretary, in consultation with experts representing a variety of clinical specialties, State, Tribal, or local public health officials, researchers, epidemiologists, statisticians, and community organizations, shall establish or continue a program to award competitive grants to eligible entities for the purpose of—

(1) identifying, developing, or disseminating best practices to improve maternal health care quality and outcomes, improve maternal and infant health, and eliminate preventable maternal mortality and severe maternal morbidity, which may include—

(A) information on evidence-based practices to improve the quality and safety of maternal health care in hospitals and other health care settings of a State or health care system by addressing topics commonly associated with

health complications or risks related to prenatal care, labor care, birthing, and postpartum care;

(B) best practices for improving maternal health care based on data findings and reviews conducted by a State maternal mortality review committee that address topics of relevance to common complications or health risks related to prenatal care, labor care, birthing, and postpartum care; and

(C) information on addressing determinants of health that impact maternal health outcomes for women before, during, and after pregnancy;

(2) collaborating with State maternal mortality review committees to identify issues for the development and implementation of evidence-based practices to improve maternal health outcomes and reduce preventable maternal mortality and severe maternal morbidity, consistent with section 317K;

(3) providing technical assistance and supporting the implementation of best practices identified in paragraph (1) to entities providing health care services to pregnant and postpartum women; and

(4) identifying, developing, and evaluating new models of care that improve maternal and infant health outcomes, which may include the integration of community-based services and clinical care.

(b) ELIGIBLE ENTITIES.—To be eligible for a grant under subsection (a), an entity shall—

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

(2) demonstrate in such application that the entity is capable of carrying out data-driven maternal safety and quality improvement initiatives in the areas of obstetrics and gynecology or maternal health.

(c) REPORT.—Not later than September 30, 2025, and every 2 years thereafter, the Secretary shall submit a report to Congress on the practices described in paragraphs (1) and (2) of subsection (a). Such report shall include a description of the extent to which such practices reduced preventable maternal mortality and severe maternal morbidity, and whether such practices improved maternal and infant health. The Secretary shall disseminate information on such practices, as appropriate.

(d) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $9,000,000 for each of fiscal years 2023 through 2027.

SEC. 330P. [254c-22] INTEGRATED SERVICES FOR PREGNANT AND POSTPARTUM WOMEN.

(a) IN GENERAL.—The Secretary may award grants for the purpose of establishing or operating evidence-based or innovative, evidence-informed programs to deliver integrated health care services to pregnant and postpartum women to optimize the health of women and their infants, including to reduce adverse maternal health outcomes, pregnancy-related deaths, and related health disparities (including such disparities associated with racial and eth-

nic minority populations), and, as appropriate, by addressing issues researched under subsection (b)(2) of section 317K.

(b) INTEGRATED SERVICES FOR PREGNANT AND POSTPARTUM WOMEN.—

(1) ELIGIBILITY.—To be eligible to receive a grant under subsection (a), a State, Indian Tribe, or Tribal organization (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act) shall work with relevant stakeholders that coordinate care to develop and carry out the program, including—

(A) State, Tribal, and local agencies responsible for Medicaid, public health, social services, mental health, and substance use disorder treatment and services;

(B) health care providers who serve pregnant and postpartum women; and

(C) community-based health organizations and health workers, including providers of home visiting services and individuals representing communities with disproportionately high rates of maternal mortality and severe maternal morbidity, and including those representing racial and ethnic minority populations.

(2) TERMS.—

(A) PERIOD.—A grant awarded under subsection (a) shall be made for a period of 5 years. Any supplemental award made to a grantee under subsection (a) may be made for a period of less than 5 years.

(B) PRIORITIES.—In awarding grants under subsection (a), the Secretary shall—

(i) give priority to States, Indian Tribes, and Tribal organizations that have the highest rates of maternal mortality and severe maternal morbidity relative to other such States, Indian Tribes, or Tribal organizations, respectively; and

(ii) shall consider health disparities related to maternal mortality and severe maternal morbidity, including such disparities associated with racial and ethnic minority populations.

(C) EVALUATION.—The Secretary shall require grantees to evaluate the outcomes of the programs supported under the grant.

(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $10,000,000 for each of fiscal years 2023 through 2027.

Subpart II—National Health Service Corps Program

NATIONAL HEALTH SERVICE CORPS

SEC. 331. [254d] (a)(1) For the purpose of eliminating health manpower[37] shortages in health professional shortage areas, there is established, within the Service, the National Health Service Corps, which shall consist of—

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

(A) such officers of the Regular and Reserve Corps of the Service as the Secretary may designate,

(B) such civilian employees of the United States as the Secretary may appoint, and

(C) such other individuals who are not employees of the United States.

(2) The Corps shall be utilized by the Secretary to provide primary health services in health professional shortage areas.

(3) For purposes of this subpart and subpart III:

(A) The term "Corps" means the National Health Service Corps.

(B) The term "Corps member" means each of the officers, employees, and individuals of which the Corps consists pursuant to paragraph (1).

(C) The term "health professional shortage area" has the meaning given such term in section 332(a).

(D) The term "primary health services" means health services regarding family medicine, internal medicine, pediatrics, obstetrics and gynecology, dentistry, or mental health, that are provided by physicians or other health professionals.

(E)(i) The term "behavioral and mental health professionals" means health service psychologists, licensed clinical social workers, licensed professional counselors, marriage and family therapists, psychiatric nurse specialists, and psychiatrists.

(ii) The term "graduate program of behavioral and mental health" means a program that trains behavioral and mental health professionals.

(b)(1) The Secretary may conduct at schools of medicine, osteopathic medicine, dentistry, and, as appropriate, nursing and other schools of the health professions, including schools at which graduate programs of behavioral and mental health are offered, and at entities which train allied health personnel, recruiting programs for the Corps, the Scholarship Program, and the Loan Repayment Program. Such recruiting programs shall include efforts to recruit individuals who will serve in the Corps other than pursuant to obligated service under the Scholarship or Loan Repayment Program.

(2) In the case of physicians, dentists, behavioral and mental health professionals, certified nurse midwives, certified nurse practitioners, and physician assistants who have an interest and a commitment to providing primary health care, the Secretary may establish fellowship programs to enable such health professionals to gain exposure to and expertise in the delivery of primary health services in health professional shortage areas. To the maximum 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, except when such members are Commissioned Corps officers who entered into a contract with Secretary under section 338A or 338B after December 31, 2006 and when the Secretary determines that exercising the authority provided under section 214 or 216 with respect to any such officer to would not cause unreasonable disruption to health care services provided in the community in which such officer is providing health care services.

(g)(1) The Secretary shall, by rule, prescribe conversion provisions applicable to any individual who, within a year after completion of service as a member of the Corps described in subsection (a)(1)(C), becomes a commissioned officer in the Regular or Reserve Corps of the Service.

(2) The rules prescribed under paragraph (1) shall provide that in applying the appropriate provisions of this Act which relate to retirement, any individual who becomes such an officer shall be entitled to have credit for any period of service as a member of the Corps described in subsection (a)(1)(C).

(h) The Secretary shall ensure that adequate staff is provided to the Service with respect to effectively administering the program for the Corps.

(i)(1) In carrying out subpart III, the Secretary may, in accordance with this subsection, issue waivers to individuals who have entered into a contract for obligated service under the Scholarship Program or the Loan Repayment Program under which the individuals are authorized to satisfy the requirement of obligated service through providing clinical practice that is half time.

(2) A waiver described in paragraph (1) may be provided by the Secretary only if—

(A) the entity for which the service is to be performed—

(i) has been approved under section 333A for assignment of a Corps member; and

(ii) has requested in writing assignment of a health professional who would serve half time;

(B) the Secretary has determined that assignment of a health professional who would serve half time would be appropriate for the area where the entity is located;

(C) a Corps member who is required to perform obligated service has agreed in writing to be assigned for half-time service to an entity described in subparagraph (A);

(D) the entity and the Corps member agree in writing that the Corps member will perform half-time clinical practice;

(E) the Corps member agrees in writing to fulfill all of the service obligations under section 338C through half-time clinical practice and either—

(i) double the period of obligated service that would otherwise be required; or

(ii) in the case of contracts entered into under section 338B, accept a minimum service obligation of 2 years with an award amount equal to 50 percent of the amount that would otherwise be payable for full-time service; and

(F) the Corps member agrees in writing that if the Corps member begins providing half-time service but fails to begin or complete the period of obligated service, the method stated in 338E(c) for determining the damages for breach of the individual's written contract will be used after converting periods of obligated service or of service performed into their full-time equivalents.

(3) In evaluating waivers issued under paragraph (1), the Secretary shall examine the effect of multidisciplinary teams.

(j) For the purposes of this subpart and subpart III:

(1) The term "Department" means the Department of Health and Human Services.

(2) The term "Loan Repayment Program" means the National Health Service Corps Loan Repayment Program established under section 338B.

(3) The term "Scholarship Program" means the National Health Service Corps Scholarship Program established under section 338A.

(4) The term "State" includes, in addition to the several States, only the District of Columbia, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, the Virgin Islands, Guam, American Samoa, and the Trust Territory of the Pacific Islands.

(5) The terms "full time" and "full-time" mean a minimum of 40 hours per week in a clinical practice, for a minimum of 45 weeks per year.

(6) The terms "half time" and "half-time" mean a minimum of 20 hours per week (not to exceed 39 hours per week) in a clinical practice, for a minimum of 45 weeks per year.

DESIGNATION OF HEALTH PROFESSIONAL SHORTAGE AREAS

SEC. 332. **[**254e**]** (a)(1) For purposes of this subpart the term "health professional shortage area" means (A) an area in an urban or rural area (which need not conform to the geographic boundaries of a political subdivision and which is a rational area for the delivery of health services) which the Secretary determines has a health

manpower shortage, (B) a population group which the Secretary determines has such a shortage, or (C) a public or nonprofit private medical facility or other public facility which the Secretary determines has such a shortage. All Federally qualified health centers and rural health clinics, as defined in section 1861(aa) of the Social Security Act (42 U.S.C. 1395x(aa)), that meet the requirements of section 334 shall be automatically designated as having such a shortage. The Secretary shall not remove an area from the areas determined to be health professional shortage areas under subparagraph (A) of the preceding sentence until the Secretary has afforded interested persons and groups in such area an opportunity to provide data and information in support of the designation as a health professional shortage area or a population group described in subparagraph (B) of such sentence or a facility described in subparagraph (C) of such sentence, and has made a determination on the basis of the data and information submitted by such persons and groups and other data and information available to the Secretary.

(2) For purposes of this subsection, the term "medical facility" means a facility for the delivery of health services and includes—

(A) a hospital, State mental hospital, public health center, outpatient medical facility, rehabilitation facility, facility for long-term care, community mental health center, migrant health center, facility operated by a city or county health department, and community health center and which is not reasonably accessible to an adequately served area;

(B) such a facility of a State correctional institution or of the Indian Health Service, and a health program or facility operated by a tribe or tribal organization under the Indian Self-Determination Act;

(C) such a facility used in connection with the delivery of health services under section 321 (relating to hospitals), 322 (relating to care and treatment of persons under quarantine and others), 323 (relating to care and treatment of Federal prisoners), 324 (relating to examination and treatment of certain Federal employees), 325 (relating to examination of aliens), 326 (relating to services to certain Federal employees), 320 (relating to services for persons with Hansen's disease), or 330(h) (relating to the provision of health services to homeless individuals); and

(D) a Federal medical facility.

(3) Homeless individuals (as defined in section 330(h)(5)), seasonal agricultural workers (as defined in section 330(g)(3)) and 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.

(k)(1) The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall identify, based on the data collected under paragraph (3), maternity care health professional target areas that satisfy the criteria described in paragraph (2) for purposes of, in connection with receipt of assistance under this title, assigning to such identified areas maternity care health professionals who, without application of this subsection, would otherwise be eligible for such assistance. The Secretary shall distribute maternity care health professionals within health professional shortage areas using the maternity care health professional target areas so identified.

(2) For purposes of paragraph (1), the Secretary shall establish criteria for maternity care health professional target areas that identify geographic areas within health professional shortage areas that have a shortage of maternity care health professionals.

(3) For purposes of this subsection, the Secretary shall collect and publish in the Federal Register data comparing the availability

and need of maternity care health services in health professional shortage areas and in areas within such health professional shortage areas.

(4) In carrying out paragraph (1), the Secretary shall seek input from relevant provider organizations, including medical societies, organizations representing medical facilities, and other organizations with expertise in maternity care.

(5) For purposes of this subsection, the term "full scope maternity care health services" includes during labor care, birthing, prenatal care, and postpartum care.

(6) Nothing in this subsection shall be construed as—

(A) requiring the identification of a maternity care health professional target area in an area not otherwise already designated as a health professional shortage area; or

(B) affecting the types of health professionals, without application of this subsection, otherwise eligible for assistance, including a loan repayment or scholarship, pursuant to the application of this section.

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;

(V) there is a reasonable prospect of sound fiscal management, including efficient collection of fee-for-service, third-party, and other appropriate funds, by the entity with respect to Corps members assigned to such entity; and

(VI)[38] the entity demonstrates willingness to support or facilitate mentorship, professional development, and training opportunities for Corps members.

An application for assignment of a Corps member to a health professional shortage area shall include a demonstration by the applicant that the area or population group to be served by the applicant has a shortage of personal health services and that the Corps member will be located so that the member will provide services to the greatest number of persons residing in such area or included in such population group. Such a demonstration shall be made on the basis of the criteria prescribed by the Secretary under section 332(b) and on additional criteria which the Secretary shall prescribe to determine if the area or population group to be served by the applicant has a shortage of personal health services.

(2) Corps members may be assigned to a Federal health care facility, but only upon the request of the head of the department or agency of which such facility is a part.

(3) In approving applications for assignment of members of the Corps the Secretary shall not discriminate against applications from entities which are not receiving Federal financial assistance under this Act. In approving such applications, the Secretary shall 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

[38] Margin so in law.

such form, submitted in such manner, and contain such information, as the Secretary shall by regulation prescribe.

(c) The Secretary shall assign Corps members to entities in health professional shortage areas without regard to the ability of the individuals in such areas, population groups, medical facilities, or other public facilities to pay for such services.

(d)(1) The Secretary may provide technical assistance to a public or private entity which is located in a health professional shortage area and which desires to make an application under this section for assignment of a Corps member to such area. Assistance provided under this paragraph may include assistance to an entity in (A) analyzing the potential use of health professions personnel in defined health services delivery areas by the residents of such areas, (B) determining the need for such personnel in such areas, (C) determining the extent to which such areas will have a financial base to support the practice of such personnel and the extent to which additional financial resources are needed to adequately support the practice, (D) determining the types of inpatient and other health services that should be provided by such personnel in such areas, and (E) developing long-term plans for addressing health professional shortages and improving access to health care. The Secretary shall encourage entities that receive technical assistance under this paragraph to communicate with other communities, State Offices of Rural Health, State Primary Care 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 ob-

ligations under the Scholarship or Loan Repayment Programs.

The Secretary may set forth such specifications by medical specialty.

(3) NOTIFICATION OF AFFECTED PARTIES.—

(A) ENTITIES.—Not later than 30 days after the Secretary has added to a list under paragraph (2) an entity specified as described in subparagraph (A) of such paragraph, the Secretary shall notify such entity that the entity has been provided an authorization to receive assignments of Corps members in the event that Corps members are available for the assignments.

(B) INDIVIDUALS.—In the case of an individual obligated to provide service under the Scholarship Program, not later than 3 months before the date described in section 338C(b)(5), the Secretary shall provide to such individual the names of each of the entities specified as described in paragraph (2)(B)(i) that is appropriate for the individual's medical specialty and discipline.

(4) REVISIONS.—If the Secretary proposes to make a revision in the list under paragraph (2), and the revision would adversely alter the status of an entity with respect to the list, the Secretary shall notify the entity of the revision. Any entity adversely affected by such a revision shall be notified in writing by the Secretary of the reasons for the revision and shall have 30 days from such notification to file a written appeal of the determination involved which shall be reasonably considered by the Secretary before the revision to the list becomes final. The revision to the list shall be effective with respect to assignment of Corps members beginning on the date that the revision becomes final.

(d) LIMITATION ON NUMBER OF ENTITIES OFFERED AS ASSIGNMENT CHOICES IN SCHOLARSHIP PROGRAM.—

(1) DETERMINATION OF AVAILABLE CORPS MEMBERS.—By April 1 of each calendar year, the Secretary shall determine the number of participants in the Scholarship Program who will be available for assignments under section 333 during the program year beginning on July 1 of that calendar year.

(2) DETERMINATION OF NUMBER OF ENTITIES.—At all times during a program year, the number of entities specified under subsection (c)(2)(B)(i) shall be—

(A) not less than the number of participants determined with respect to that program year under paragraph (1); and

(B) not greater than twice the number of participants determined with respect to that program year under paragraph (1).

SEC. 334. [254g] CHARGES FOR SERVICES BY ENTITIES USING CORPS MEMBERS.

(a) AVAILABILITY OF SERVICES REGARDLESS OF ABILITY TO PAY OR PAYMENT SOURCE.—An entity to which a Corps member is assigned shall not deny requested health care services, and shall not discriminate in the provision of services to an individual—

(1) because the individual is unable to pay for the services; or

(2) because payment for the services would be made under—

(A) the medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.);

(B) the medicaid program under title XIX of such Act (42 U.S.C. 1396 et seq.); or

(C) the State children's health insurance program under title XXI of such Act (42 U.S.C. 1397aa et seq.).

(b) CHARGES FOR SERVICES.—The following rules shall apply to charges for health care services provided by an entity to which a Corps member is assigned:

(1) IN GENERAL.—

(A) SCHEDULE OF FEES OR PAYMENTS.—Except as provided in paragraph (2), the entity shall prepare a schedule of fees or payments for the entity's services, consistent with locally prevailing rates or charges and designed to cover the entity's reasonable cost of operation.

(B) SCHEDULE OF DISCOUNTS.—Except as provided in paragraph (2), the entity shall prepare a corresponding schedule of discounts (including, in appropriate cases, waivers) to be applied to the payment of such fees or payments. In preparing the schedule, the entity shall adjust the discounts on the basis of a patient's ability to pay.

(C) USE OF SCHEDULES.—The entity shall make every reasonable effort to secure from patients fees and payments for services in accordance with such schedules, and fees or payments shall be sufficiently discounted in accordance with the schedule described in subparagraph (B).

(2) SERVICES TO BENEFICIARIES OF FEDERAL AND FEDERALLY ASSISTED PROGRAMS.—In the case of health care services furnished to an individual who is a beneficiary of a program listed in subsection (a)(2), the entity—

(A) shall accept an assignment pursuant to section 1842(b)(3)(B)(ii) of the Social Security Act (42 U.S.C. 1395u(b)(3)(B)(ii)) with respect to an individual who is a beneficiary under the medicare program; and

(B) shall enter into an appropriate agreement with—

(i) the State agency administering the program under title XIX of such Act with respect to an individual who is a beneficiary under the medicaid program; and

(ii) the State agency administering the program under title XXI of such Act with respect to an individual who is a beneficiary under the State children's health insurance program.

(3) COLLECTION OF PAYMENTS.—The entity shall take reasonable and appropriate steps to collect all payments due for health care services provided by the entity, including payments from any third party (including a Federal, State, or local government agency and any other third party) that is responsible for part or all of the charge for such services.

PROVISION OF HEALTH SERVICES BY CORPS MEMBERS

SEC. 335. [254h] (a) In providing health services in a health professional shortage area, Corps members shall utilize the techniques, facilities, and organizational forms most appropriate for the area, population group, medical facility, or other public facility, and shall, to the maximum extent feasible, provide such services (1) to all individuals in, or served by, such health professional shortage area regardless of their ability to pay for the services, and (2) in a manner which is cooperative with other health care providers serving such health professional shortage area.

(b)(1) Notwithstanding any other provision of law, the Secretary may (A) to the maximum extent feasible make such arrangements as he determines necessary to enable Corps members to utilize the health facilities in or serving the health professional shortage area in providing health services; (B) make such arrangements as he determines are necessary for the use of equipment and supplies of the Service and for the lease or acquisition of other equipment and supplies; and (C) secure the permanent or temporary services of physicians, dentists, nurses, administrators, and other health personnel. If there are no health facilities in or serving such area, the Secretary may arrange to have Corps members provide health services in the nearest health facilities of the Service or may lease or otherwise provide facilities in or serving such area for the provision of health services.

(2) If the individuals in or served by a health professional shortage area are being served (as determined under regulations of the Secretary) by a hospital or other health care delivery facility of the Service, the Secretary may, in addition to such other arrangements as he may make under paragraph (1), arrange for the utilization of such hospital or facility by Corps members in providing health services, but only to the extent that such utilization will not impair the delivery of health services and treatment through such hospital or facility to individuals who are entitled to health services and treatment through such hospital or facility.

(c) The Secretary may make one loan to any entity with an approved application under section 333 to assist such entity in meeting the costs of (1) establishing medical, dental, or other health profession practices, including the development of medical practice management systems; (2) acquiring equipment for use in providing health services; and (3) renovating buildings to establish health facilities. No loan may be made under this subsection unless an application therefor is submitted to, and approved by, the Secretary. The amount of any such loan shall be determined by the Secretary, except that no such loan may exceed $50,000.

(d) Upon the expiration of the assignment of all Corps members to a health professional shortage area, the Secretary may (notwithstanding any other provision of law) sell, to any appropriate local entity, equipment and other property of the United States utilized by such members in providing health services. Sales made under this subsection shall be made at the fair market value (as determined by the Secretary) of the equipment or such other property; except that the Secretary may make such sales for a lesser

value to an appropriate local entity, if he determines that the entity is financially unable to pay the full market value.

(e)(1)(A) It shall be unlawful for any hospital to deny an authorized Corps member admitting privileges when such Corps member otherwise meets the professional qualifications established by the hospital for granting such privileges and agrees to abide by the published bylaws of the hospital and the published bylaws, rules, and regulations of its medical staff.

(B) Any hospital which is found by the Secretary, after notice and an opportunity for a hearing on the record, to have violated this subsection shall upon such finding cease, for a period to be determined by the Secretary, to receive and to be eligible to receive any Federal funds under this Act or under titles XVIII, XIX, or XXI of the Social Security Act.

(2) For purposes of this subsection, the term "hospital" includes a State or local public hospital, a private profit hospital, a private nonprofit hospital, a general or special hospital, and any other type of hospital (excluding a hospital owned or operated by an agency of the Federal Government), and any related facilities.

SEC. 336. [254h–1] FACILITATION OF EFFECTIVE PROVISION OF CORPS SERVICES.

(a) CONSIDERATION OF INDIVIDUAL CHARACTERISTICS OF MEMBERS IN MAKING ASSIGNMENTS.—In making an assignment of a Corps member to an entity that has had an application approved under section 333, the Secretary shall, subject to making the assignment in accordance with section 333A, seek to assign to the 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) PROFESSIONAL DEVELOPMENT AND TRAINING.—

(1) IN GENERAL.—The Secretary shall assist Corps members in establishing and maintaining professional relationships and development opportunities, including by—

(A) establishing appropriate professional relationships between the Corps member involved and the health professions community of the geographic area with respect to which the member is assigned;

(B) establishing professional development, training, and mentorship linkages between the Corps member involved and the larger health professions community, including through distance learning, direct mentorship, and development and implementation of training modules designed to meet the educational needs of offsite Corps members;

(C) establishing professional networks among Corps members; or

(D) engaging in other professional development, mentorship, and training activities for Corps members, at the discretion of the Secretary.

(2) ASSISTANCE IN ESTABLISHING PROFESSIONAL RELATIONSHIPS.—In providing such assistance under paragraph (1), the Secretary shall focus on establishing relationships with hospitals, with academic medical centers and health professions schools, with area health education centers under section 751, with health education and training centers under section 752, and with border health education and training centers under such section 752. Such assistance shall include assistance in obtaining faculty appointments at health professions schools.

(3) SUPPLEMENT NOT SUPPLANT.—Such efforts under this subsection shall supplement, not supplant, non-government efforts by professional health provider societies to establish and maintain professional relationships and development opportunities.

(e) TEMPORARY RELIEF FROM CORPS DUTIES.—

(1) IN GENERAL.—The Secretary shall, subject to paragraph (4), provide assistance to Corps members in establishing arrangements through which Corps members may, as appropriate, be provided temporary relief from duties in the Corps in order to pursue continuing education in the health profes-

sions, to participate in exchange programs with teaching centers, to attend professional conferences, or to pursue other interests, including vacations.

(2) ASSUMPTION OF DUTIES OF MEMBER.—

(A) Temporary relief under paragraph (1) may be provided only if the duties of the Corps member involved are assumed by another health professional. With respect to such temporary relief, the duties may be assumed by Corps members or by health professionals who are not Corps members, if the Secretary approves the professionals for such purpose. Any health professional so approved by the Secretary shall, during the period of providing such temporary relief, be deemed to be a Corps member for purposes of section 224 (including for purposes of the remedy described in such section), section 333(f)[39], and section 335(e).

(B) In carrying out paragraph (1), the Secretary shall provide for the formation and continued existence of a group of health professionals to provide temporary relief under such paragraph.

(3) RECRUITMENT FROM GENERAL HEALTH PROFESSIONS COMMUNITY.—In carrying out paragraph (1), the Secretary shall—

(A) encourage health professionals who are not Corps members to enter into arrangements under which the health professionals temporarily assume the duties of Corps members for purposes of paragraph (1); and

(B) with respect to the entities to which Corps members have been assigned under section 333, encourage the entities to facilitate the development of arrangements described in subparagraph (A).

(4) LIMITATION.—In carrying out paragraph (1), the Secretary may not, except as provided in paragraph (5), obligate any amounts (other than for incidental expenses) for the purpose of—

(A) compensating a health professional who is not a Corps member for assuming the duties of a Corps member; or

(B) paying the costs of a vacation, or other interests that a Corps member may pursue during the period of temporary relief under such paragraph.

(5) SOLE PROVIDERS OF HEALTH SERVICES.—In the case of any Corps member who is the sole provider of health services in the geographic area involved, the Secretary may, from amounts appropriated under section 338, obligate on behalf of the member such sums as the Secretary determines to be necessary for purposes of providing temporary relief under paragraph (1).

(f) DETERMINATIONS REGARDING EFFECTIVE SERVICE.—In carrying out subsection (a) and sections 338A(d) and 338B(d), the Secretary shall carry out activities to determine—

[39] So in law. As a result of the amendments made by section 103(b) of Public Law 101–597 (104 Stat. 3015), there is no subsection (f) in section 333. (Subsection (e) of section 333, like sections 224 and 335(e), establishes a right for Corps members.)

(1) the characteristics of physicians, dentists, and other health professionals who are more likely to remain in practice in health professional shortage areas after the completion of the period of service in the Corps;

(2) the characteristics of health manpower shortage areas[40], and of entities seeking assignments of Corps members, that are more likely to retain Corps members after the members have completed the period of service in the Corps; and

(3) the appropriate conditions for the assignment and utilization in health manpower shortage areas[40] 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;

(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,

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

and the amount which was paid to the Secretary in such year under such agreements [41].

NATIONAL ADVISORY COUNCIL

SEC. 337. [254j] (a) There is established a council to be known as the National Advisory Council on the National Health Service Corps (hereinafter in this section referred to as the "Council"). The Council shall be composed of fifteen members appointed by the Secretary. The Council shall consult with, advise, and make recommendations to, the Secretary with respect to his responsibilities in carrying out this subpart (other than section 338G), and shall review and comment upon regulations promulgated by the Secretary under this subpart.

(b)(1) Members of the Council shall be appointed for a term of three years, except that any member appointed to fill a vacancy occurring prior to the expiration of the term for which the member's predecessor was appointed shall be appointed for the remainder of such term. No member shall be removed, except for cause.

(2) Members of the Council (other than members who are officers or employees of the United States), while attending meetings or conferences thereof or otherwise serving on the business of the Council, shall be entitled to receive for each day (including 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.

(c) Section 1013 of title 5, United States Code, shall not apply with respect to the Council.

AUTHORIZATION OF APPROPRIATION

SEC. 338. [254k] (a) For the purpose of carrying out this subpart, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2008 through 2012.

(b) An appropriation under an authorization under subsection (a) for any fiscal year may be made at any time before that fiscal year and may be included in an Act making an appropriation under an authorization under subsection (a) for another fiscal year; but no funds may be made available from any appropriation under such authorization for obligation under sections 331 through 335, section 336A, and section 337 before the fiscal year for which such appropriation is authorized.

[41] There is no antecedent reference to "agreements". Formerly, paragraph (8) contained the clause ", the amount which was collected in such year by entities in accordance with agreements under section 334,". Section 307(b) of Public Law 107–251 (116 Stat. 1649) struck "agreements under" in that clause.

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 contract is accepted) by the Secretary, including in the summary a clear explanation of the damages to which the United States is entitled under section 338E in the case of the individual's breach of the contract; and

(B) information respecting meeting a service obligation through private practice under an agreement under section 338D and such other information as may be necessary for the individual to understand the individual's prospective participation in the Loan Repayment Program and service in the Corps.

(2) UNDERSTANDABILITY.—The application form, contract form, and all other information furnished by the Secretary under this subpart shall be written in a manner calculated to be understood by the average individual applying to participate in the Loan Repayment Program.

(3) AVAILABILITY.—The Secretary shall make such application forms, contract forms, and other information available to

individuals desiring to participate in the Loan Repayment Program on a date sufficiently early to ensure that such individuals have adequate time to carefully review and evaluate such forms and information.

(4) RECRUITMENT AND RETENTION.—

(A) The Secretary shall distribute to health professions schools materials providing information on the Loan Repayment Program and shall encourage the schools to disseminate the materials to the students of the schools.

(B)(i) In the case of any health professional whose period of obligated service under the Loan Repayment Program is nearing completion, the Secretary shall encourage the individual to remain in a health professional shortage area and to continue providing primary health services.

(ii) During the period in which a health professional is planning and making the transition to private practice from obligated service under the Loan Repayment Program, the Secretary may provide assistance to the professional regarding such transition if the professional is remaining in a health professional shortage area and is continuing to provide primary health services.

(C) In the case of entities to which participants in the Loan Repayment Program are assigned under section 333, the Secretary shall encourage the entities to provide options with respect to assisting the participants in remaining in the health professional shortage areas involved, and in continuing to provide primary health services, after the period of obligated service under the Loan Repayment Program is completed. The options with respect to which the Secretary provides such encouragement may include options regarding the sharing of a single employment position in the health professions by 2 or more health professionals, and options regarding the recruitment of couples where both of the individuals are health professionals.

(d)(1) Subject to section 333A, in providing contracts under the Loan Repayment Program—

(A) the Secretary shall consider the extent of the demonstrated interest of the applicants for the contracts in providing primary health services; and

(B) may consider such other factors regarding the applicants as the Secretary determines to be relevant to selecting qualified individuals to participate in such Program.

(2) In providing contracts under the Loan Repayment Program, the Secretary shall give priority—

(A) to any application for such a contract submitted by an individual whose training is in a health profession or specialty determined by the Secretary to be needed by the Corps;

(B) to any application for such a contract submitted by an individual who has (and whose spouse, if any, has) characteristics that increase the probability that the individual will continue to serve in a health professional shortage area after the period of obligated service pursuant to subsection (f) is completed; and

(C) subject to subparagraph (B), to any application for such a contract submitted by an individual who is from a disadvantaged background.

(e) APPROVAL REQUIRED FOR PARTICIPATION.—An individual becomes a participant in the Loan Repayment Program only upon the Secretary and the individual entering into a written contract described in subsection (f).

(f) CONTENTS OF CONTRACTS.—The written contract (referred to in this subpart) between the Secretary and an individual shall contain—

(1) an agreement that—

(A) subject to paragraph (3), the Secretary agrees—

(i) to pay on behalf of the individual loans in accordance with subsection (g); and

(ii) to accept (subject to the availability of appropriated funds for carrying out sections 331 through 335 and section 337) the individual into the Corps (or for equivalent service as otherwise provided in this subpart); and

(B) subject to paragraph (3), the individual agrees—

(i) to accept loan payments on behalf of the individual;

(ii) in the case of an individual described in subsection (b)(1)(C), to maintain enrollment in a course of study or training described in such subsection until the individual completes the course of study or training;

(iii) in the case of an individual described in subsection (b)(1)(C), while enrolled in such course of study or training, to maintain an acceptable level of 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 $50,000, plus, beginning with fiscal year 2012, an amount determined by the Secretary on an annual basis to reflect inflation, on behalf of the individual for loans described in paragraph (1). In making a determination of the amount to pay for a year of such service by an individual, the Secretary shall consider the extent to which each such determination—

(i) affects the ability of the Secretary to maximize the number of contracts that can be provided under the Loan Repayment Program from the amounts appropriated for such contracts;

(ii) provides an incentive to serve in health professional shortage areas with the greatest such shortages; and

(iii) provides an incentive with respect to the health professional involved remaining in a health professional shortage area, and continuing to provide primary health services, after the completion of the period of obligated service under the Loan Repayment Program.

(B) REPAYMENT SCHEDULE.—Any arrangement made by the Secretary for the making of loan repayments in accordance with this subsection shall provide that any repayments for a year of obligated service shall be made no later than the end of the fiscal year in which the individual completes such year of service.

(3) TAX LIABILITY.—For the purpose of providing reimbursements for tax liability resulting from payments under paragraph (2) on behalf of an individual—

(A) the Secretary shall, in addition to such payments, make payments to the individual in an amount equal to 39 percent of the total amount of loan repayments made for the taxable year involved; and

(B) may make such additional payments as the Secretary determines to be appropriate with respect to such purpose.

(4) PAYMENT SCHEDULE.—The Secretary may enter into an agreement with the holder of any loan for which payments are made under the Loan Repayment Program to establish a schedule for the making of such payments.

(h) EMPLOYMENT CEILING.—Notwithstanding any other provision of law, individuals who have entered into written contracts with the Secretary under this section, while undergoing academic or other training, shall not be counted against any employment ceiling affecting the Department.

OBLIGATED SERVICE

SEC. 338C. [254m] (a) SERVICE IN FULL-TIME CLINICAL PRACTICE.—Except as provided in section 338D, each individual who has entered into a written contract with the Secretary under section 338A or 338B shall provide service in the full-time clinical practice of such individual's profession as a member of the Corps for the period of obligated service provided in such contract. The Secretary may treat teaching as clinical practice for up to 20 percent of such period of obligated service. Notwithstanding the preceding sentence, with respect to a member of the Corps participating in the teaching health centers graduate medical education program under section 340H, for the purpose of calculating time spent in full-time clinical practice under this section, up to 50 percent of time spent teaching by such member may be counted toward his or her service obligation.

(b)(1) If an individual is required under subsection (a) to provide service as specified in section 338A(f)(1)(B)(v) or 338B(f)(1)(B)(iv) (hereinafter in this subsection referred to as "obligated service"), the Secretary shall, not later than ninety days before the date described in paragraph (5), determine if the individual shall provide such service—

(A) as a member of the Corps who is a commissioned officer in the Regular or Reserve Corps of the Service or who is a civilian employee of the United States, or

(B) as a member of the Corps who is not such an officer or employee,

and shall notify such individual of such determination.

(2) If the Secretary determines that an individual shall provide obligated service as a member of the Corps who is a commissioned officer in the Service or a civilian employee of the United States, the Secretary shall, not later than sixty days before the date described in paragraph (5), provide such individual with sufficient information regarding the advantages and disadvantages of service as such a commissioned officer or civilian employee to enable the individual to make a decision on an informed basis. To be eligible to provide obligated service as a commissioned officer in the Serv-

ice, 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 purpose of carrying out this section[42], there is authorized to be appropriated, out of any funds in the Treasury not otherwise appropriated, the following:

(1) For fiscal year 2010, $320,461,632.
(2) For fiscal year 2011, $414,095,394.
(3) For fiscal year 2012, $535,087,442.
(4) For fiscal year 2013, $691,431,432.
(5) For fiscal year 2014, $893,456,433.
(6) For fiscal year 2015, $1,154,510,336.
(7) For fiscal year 2016, and each subsequent fiscal year, the amount appropriated for the preceding fiscal year adjusted by the product of—

(A) one plus the average percentage increase in the costs of health professions education during the prior fiscal year; and

(B) one plus the average percentage change in the number of individuals residing in health professions shortage areas designated under section 333 during the prior fiscal year, relative to the number of individuals residing in such areas during the previous fiscal year.

(b) SCHOLARSHIPS FOR NEW PARTICIPANTS.—Of the amounts appropriated under subsection (a) for a fiscal year, the Secretary shall obligate not less than 10 percent for the purpose of providing contracts for—

(1) scholarships under this subpart to individuals who have not previously received such scholarships; or

(2) scholarships or loan repayments under the Loan Repayment Program under section 338B to individuals from disadvantaged backgrounds.

(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

[42] The reference to "this section" in section 338H(a) probably should be a reference to "this subpart".

areas. The National Advisory Council established under section 337 shall advise the Administrator regarding the program under this section.

(2) LOAN REPAYMENT PROGRAMS.—The programs referred to in paragraph (1) are, subject to subsection (c), programs of entering into contracts under which the State involved agrees to pay all or part of the principal, interest, and related expenses of the educational loans of health professionals in consideration of the professionals agreeing to provide primary health services in health professional shortage areas.

(3) DIRECT ADMINISTRATION BY STATE AGENCY.—The Secretary may not make a grant under paragraph (1) unless the State involved agrees that the program operated with the grant will be administered directly by a State agency.

(b) REQUIREMENT OF MATCHING FUNDS.—

(1) IN GENERAL.—The Secretary may not make a grant under subsection (a) unless the State agrees that, with respect to the costs of making payments on behalf of individuals under contracts made pursuant to paragraph (2) of such subsection, the State will make available (directly or through donations from public or private entities) non-Federal contributions in cash toward such costs in an amount equal to not less than $1 for each $1 of Federal funds provided in the grant.

(2) DETERMINATION OF AMOUNT OF NON-FEDERAL CONTRIBUTION.—In determining the amount of non-Federal contributions in cash that a State has provided pursuant to paragraph (1), the Secretary may not include any amounts provided to the State by the Federal Government.

(c) COORDINATION WITH FEDERAL PROGRAM.—

(1) ASSIGNMENTS FOR HEALTH PROFESSIONAL SHORTAGE AREAS UNDER FEDERAL PROGRAM.—The Secretary may not make a grant under subsection (a) unless the State involved agrees that, in carrying out the program operated with the grant, the State will assign health professionals participating in the program only to public and nonprofit private entities located in and providing health services in health professional shortage areas.

(2) REMEDIES FOR BREACH OF CONTRACTS.—The Secretary may not make a grant under subsection (a) unless the State involved agrees that the contracts provided by the State pursuant to paragraph (2) of such subsection will provide remedies for any breach of the contracts by the health professionals involved.

(3) LIMITATION REGARDING CONTRACT INDUCEMENTS.—

(A) Except as provided in subparagraph (B), the Secretary may not make a grant under subsection (a) unless the State involved agrees that the contracts provided by the State pursuant to paragraph (2) of such subsection will not be provided on terms that are more favorable to health professionals than the most favorable terms that the Secretary is authorized to provide for contracts under the Loan Repayment Program under section 338B, including terms regarding—

(i) the annual amount of payments provided on behalf of the professionals regarding educational loans; and

(ii) the availability of remedies for any breach of the contracts by the health professionals involved.

(B) With respect to the limitation established in subparagraph (A) regarding the annual amount of payments that may be provided to a health professional under a contract provided by a State pursuant to subsection (a)(2), such limitation shall not apply with respect to a contract if—

(i) the excess of such annual payments above the maximum amount authorized in section 338B(g)(2)(A) for annual payments regarding contracts is paid solely from non-Federal contributions under subsection (b); and

(ii) the contract provides that the health professional involved will satisfy the requirement of obligated service under the contract solely through the provision of primary health services in a health professional shortage area that is receiving priority for purposes of section 333A(a)(1) and that is authorized to receive assignments under section 333 of individuals who are participating in the Scholarship Program under section 338A.

(d) RESTRICTIONS ON USE OF FUNDS.—The Secretary may not make a grant under subsection (a) unless the State involved agrees that the grant will not be expended—

(1) to conduct activities for which Federal funds are expended—

(A) within the State to provide technical or other nonfinancial assistance under subsection (f) of section 330;

(B) under a memorandum of agreement entered into with the State under subsection (h) of such section; or

(C) under a grant under section 338J; or

(2) for any purpose other than making payments on behalf of health professionals under contracts entered into pursuant to subsection (a)(2).

(e) REPORTS.—The Secretary may not make a grant under subsection (a) unless the State involved agrees—

(1) to submit to the Secretary such reports regarding the States loan repayment program, as are determined to be appropriate by the Secretary; and

(2) to submit such a report not later than January 10 of each fiscal year immediately following any fiscal year for which the State has received such a grant.

(f) REQUIREMENT OF APPLICATION.—The Secretary may not make a grant under subsection (a) unless an application for the grant is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out such subsection.

(g) NONCOMPLIANCE.—

(1) IN GENERAL.—The Secretary may not make payments under subsection (a) to a State for any fiscal year subsequent to the first fiscal year of such payments unless the Secretary determines that, for the immediately preceding fiscal year, the State has complied with each of the agreements made by the State under this section.

(2) REDUCTION IN GRANT RELATIVE TO NUMBER OF BREACHED CONTRACTS.—

(A) Before making a grant under subsection (a) to a State for a fiscal year, the Secretary shall determine the number of contracts provided by the State under paragraph (2) of such subsection with respect to which there has been an initial breach by the health professionals involved during the fiscal year preceding the fiscal year for which the State is applying to receive the grant.

(B) Subject to paragraph (3), in the case of a State with 1 or more initial breaches for purposes of subparagraph (A), the Secretary shall reduce the amount of a grant under subsection (a) to the State for the fiscal year involved by an amount equal to the sum of the expenditures of Federal funds made regarding the contracts involved and an amount representing interest on the amount of such expenditures, determined with respect to each contract on the basis of the maximum legal rate prevailing for loans made during the time amounts were paid under the contract, as determined by the Treasurer of the United States.

(3) WAIVER REGARDING REDUCTION IN GRANT.—The Secretary may waive the requirement established in paragraph (2)(B) with respect to the initial breach of a contract if the Secretary determines that such breach by the health professional involved was attributable solely to the professional having a serious illness.

(h) DEFINITIONS.—For purposes of this section, the term "State" means each of the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the United States Virgin Islands, Guam, American Samoa, Palau, the Marshall Islands, and the Commonwealth of the Northern Mariana Islands.

(i) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—For the purpose of making grants under subsection (a), there are authorized to be appropriated $12,000,000 for fiscal year 2008, and such sums as may be necessary for each of fiscal years 2009 through 2012.

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

(j) PUBLIC HEALTH LOAN REPAYMENT.—

(1) IN GENERAL.—The Secretary may award grants to States for the purpose of assisting such States in operating loan repayment programs under which such States enter into contracts to repay all or part of the eligible loans borrowed by, or on behalf of, individuals who agree to serve in State, local, or tribal health departments that serve health professional shortage areas or other areas at risk of a public health emergency, as designated by the Secretary.

(2) LOANS ELIGIBLE FOR REPAYMENT.—To be eligible for repayment under this subsection, a loan shall be a loan made, insured, or guaranteed by the Federal Government that is borrowed by, or on behalf of, an individual to pay the cost of attendance for a program of education leading to a degree appropriate for serving in a State, local, or tribal health department as determined by the Secretary and the chief executive officer of the State in which the grant is administered, at an institution of higher education (as defined in section 102 of the Higher Education Act of 1965), including principal, interest, and related expenses on such loan.

(3) APPLICABILITY OF EXISTING REQUIREMENTS.—With respect to awards made under paragraph (1)—

(A) the requirements of subsections (b), (f), and (g) shall apply to such awards; and

(B) the requirements of subsection (c) shall apply to such awards except that with respect to paragraph (1) of such subsection, the State involved may assign an individual only to public and nonprofit private entities that serve health professional shortage areas or areas at risk of a public health emergency, as determined by the Secretary.

(4) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this subsection, such sums as may be necessary for each of fiscal years 2007 through 2010.

SEC. 338J. [254r] GRANTS TO STATE OFFICES OF RURAL HEALTH.

(a) IN GENERAL.—The Secretary, acting through the Director of the Federal Office of Rural Health Policy (established under section 711 of the Social Security Act), shall make grants to each State Office of Rural Health for the purpose of improving health care in rural areas.

(b) REQUIREMENT OF MATCHING FUNDS.—

(1) IN GENERAL.—Subject to paragraph (2), the Secretary may not make a grant under subsection (a) unless the State office of rural health involved agrees, with respect to the costs to be incurred in carrying out the purpose described in such subsection, to provide non-Federal contributions toward such costs in an amount equal to $3 for each $1 of Federal funds provided in the grant.

(2) WAIVER OR REDUCTION.—The Secretary may waive or reduce the non-Federal contribution if the Secretary determines that requiring matching funds would limit the State office of rural health's ability to carry out the purpose described in subsection (a).

(3) DETERMINATION OF AMOUNT OF NON-FEDERAL CONTRIBUTION.—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.

(c) CERTAIN REQUIRED ACTIVITIES.—Recipients of a grant under subsection (a) shall use the grant funds for purposes of—

(1) maintaining within the State office of rural health 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 office of rural health receives such a grant, the office operated pursuant to subsection (a) of this section will be provided with an annual budget of not less than $150,000.

(e) CERTAIN USES OF FUNDS.—

(1) RESTRICTIONS.—The Secretary may not make a grant under subsection (a) unless the State office of rural health involved agrees that the grant will not be expended—

(A) to provide health care (including providing cash payments regarding such care);

(B) to conduct activities for which Federal funds are expended—

(i) within the State to provide technical and other nonfinancial assistance under section 330A(f);

(ii) under a memorandum of agreement entered into with the State office of rural health under section 330A(h); or

(iii) under a grant under section 338I;

(C) to purchase medical equipment, to purchase ambulances, aircraft, or other vehicles, or to purchase major communications equipment;

(D) to purchase or improve real property; or

(E) to carry out any activity regarding a certificate of need.

(2) AUTHORITIES.—Activities for which a State office of rural health may expend a grant under subsection (a) include—

(A) paying the costs of maintaining an office of rural health for purposes of subsection (a);

(B) subject to paragraph (1)(B)(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.

(3) LIMIT ON INDIRECT COSTS.—The Secretary may impose a limit of no more than 15 percent on indirect costs claimed by the recipient of the grant.

(f) REPORTS.—The Secretary may not make a grant under subsection (a) unless the State office of rural health involved agrees—

(1) to submit to the Secretary reports or performance data containing such information as the Secretary may require regarding activities carried out under this section; and

(2) to submit such a report or performance data not later than September 30 of each fiscal year immediately following any fiscal year for which the State office of rural health 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 office of rural health 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 office of rural health has complied with each of the agreements made by the State office of rural health under this section.

(i) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—For the purpose of making grants under subsection (a), there are authorized to be appropriated $12,500,000 for each of fiscal years 2023 through 2027.

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

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[43].—If the Secretary determines and certifies to Congress by not later than September 30, 2004, that the number of individuals participating in the demonstration project established under this section is insufficient for purposes of performing the evaluation described in subsection (f)(1), the authorization of appropriations under paragraph (1) shall be extended to include fiscal year 2005.

SEC. 338M. [254u] PUBLIC HEALTH DEPARTMENTS.

(a) IN GENERAL.—To the extent that funds are appropriated under subsection (e), the Secretary shall establish a demonstration project to provide for the participation of individuals who are eligible for the Loan Repayment Program described in section 338B and who agree to complete their service obligation in a State health department that provides a significant amount of service to health professional shortage areas or areas at risk of a public health emergency, as determined by the Secretary, or in a local or tribal health department that serves a health professional shortage area or an area at risk of a public health emergency.

[43] So in law. The figure in the heading for paragraph (2) was erroneously enacted so that "2005" appears in full figures. However, the version represented here in the pdf reflects this figure so that it conforms to the proper size for figures that appear in a paragraph or below header.

(b) PROCEDURE.—To be eligible to receive assistance under subsection (a), with respect to the program described in section 338B, an individual shall—

(1) comply with all rules and requirements described in such section (other than section 338B(f)(1)(B)(iv)); and

(2) agree to serve for a time period equal to 2 years, or such longer period as the individual may agree to, in a State, local, or tribal health department, described in subsection (a).

(c) DESIGNATIONS.—The demonstration project described in subsection (a), and any healthcare providers who are selected to participate in such project, shall not be considered by the Secretary in the designation of health professional shortage areas under section 332 during fiscal years 2007 through 2010.

(d) REPORT.—Not later than 3 years after the date of enactment of this section, the Secretary shall submit a report to the relevant committees of Congress that evaluates the participation of individuals in the demonstration project under subsection (a), the impact of such participation on State, local, and tribal health departments, and the benefit and feasibility of permanently allowing such placements in the Loan Repayment Program.

(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, such sums as may be necessary for each of fiscal years 2007 through 2010.

SEC. 338N. [254v] CLARIFICATION REGARDING SERVICE IN SCHOOLS AND OTHER COMMUNITY-BASED SETTINGS.

(a) SCHOOLS AND COMMUNITY-BASED SETTINGS.—An entity to which a participant in the Scholarship Program or the Loan Repayment Program (referred to in this section as a "participant") is assigned under section 333 may direct such participant to provide service as a behavioral or mental health professional at a school or other community-based setting located in a health professional shortage area.

(b) OBLIGATED SERVICE.—

(1) IN GENERAL.—Any service described in subsection (a) that a participant provides may count towards such participant's completion of any obligated service requirements under the Scholarship Program or the Loan Repayment Program, subject to any limitation imposed under paragraph (2).

(2) LIMITATION.—The Secretary may impose a limitation on the number of hours of service described in subsection (a) that a participant may credit towards completing obligated service requirements, provided that the limitation allows a member to credit service described in subsection (a) for not less than 50 percent of the total hours required to complete such obligated service requirements.

(c) RULE OF CONSTRUCTION.—The authorization under subsection (a) shall be notwithstanding any other provision of this subpart or subpart II.

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 su-

pervised clinical instruction directed toward preparing students to deliver home health services;

(B) be carried out under appropriate professional supervision and be designed to train students to maintain or enhance the personal care of an individual in his home in a manner which promotes the functional independence of the individual; and

(C) include training in—

(i) personal care services designed to assist an individual in the activities of daily living such as bathing, exercising, personal grooming, and getting in and out of bed; and

(ii) household care services such as maintaining a safe living environment, light housekeeping, and assisting in providing good nutrition (by the purchasing and preparation of food).

(3) In making grants and entering into contracts under this subsection, special consideration shall be given to entities which establish or will establish programs to provide training for persons fifty years of age and older who wish to become paraprofessionals (including homemaker home health aides) to provide home health services.

(4) Applications for grants and contracts under this subsection shall be in such form and contain such information as the Secretary shall prescribe.

(5) There are authorized to be appropriated for grants and contracts under this subsection $2,000,000 for each of the fiscal years ending September 30, 1983, September 30, 1984, September 30, 1985, September 30, 1986, and September 30, 1987.

(c) The Secretary shall report to the Committee on Labor and Human Resources of the Senate and the Committee on Energy and Commerce of the House of Representatives on or before January 1, 1984, with respect to—

(1) the impact of grants made and contracts entered into under subsections (a) and (b) (as such subsections were in effect prior to October 1, 1981);

(2) the need to continue grants and loans under subsections (a) and (b) (as such subsections are in effect on the day after the date of enactment of the Orphan Drug Act); and

(3) the extent to which standards have been applied to the training of personnel who provide home health services.

(d) For purposes of this section, the term "home health services" has the meaning prescribed for the term by section 1861(m) of the Social Security Act.

Subpart V—Healthy Communities Access Program

SEC. 340. [256] GRANTS TO STRENGTHEN THE EFFECTIVENESS, EFFICIENCY, AND COORDINATION OF SERVICES FOR THE UNINSURED AND UNDERINSURED.

(a) IN GENERAL.—The Secretary may award grants to eligible entities to assist in the development of integrated health care delivery systems to serve communities of individuals who are uninsured and individuals who are underinsured—

(1) to improve the efficiency of, and coordination among, the providers providing services through such systems;

(2) to assist communities in developing programs targeted toward preventing and managing chronic diseases; and

(3) to expand and enhance the services provided through such systems.

(b) ELIGIBLE ENTITIES.—To be eligible to receive a grant under this section, an entity shall be an entity that—

(1) represents a consortium—

(A) whose principal purpose is to provide a broad range of coordinated health care services for a community defined in the entity's grant application as described in paragraph (2); and

(B) that includes at least one of each of the following providers that serve the community (unless such provider does not exist within the community, declines or refuses to participate, or places unreasonable conditions on their participation)—

(i) a Federally qualified health center (as defined in section 1861(aa) of the Social Security Act (42 U.S.C. 1395x(aa)));

(ii) a hospital with a low-income utilization rate (as defined in section 1923(b)(3) of the Social Security Act (42 U.S.C. 1396r–4(b)(3)), that is greater than 25 percent;

(iii) a public health department; and

(iv) an interested public or private sector health care provider or an organization that has traditionally served the medically uninsured and underserved; and

(2) submits to the Secretary an application, in such form and manner as the Secretary shall prescribe, that—

(A) defines a community or geographic area of uninsured and underinsured individuals;

(B) identifies the providers who will participate in the consortium's program under the grant, and specifies each provider's contribution to the care of uninsured and underinsured individuals in the community, including the volume of care the provider provides to beneficiaries under the medicare, medicaid, and State child health insurance programs and to patients who pay privately for services;

(C) describes the activities that the applicant and the consortium propose to perform under the grant to further the objectives of this section;

(D) demonstrates the consortium's ability to build on the current system (as of the date of submission of the 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.

SEC. 340A. [256a] PATIENT NAVIGATOR GRANTS.

(a) GRANTS.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, may make grants to eligible entities for the development and operation of demonstration programs to provide patient navigator services to improve health care outcomes. The Secretary shall coordinate with, and ensure the participation of, the Indian Health Service, the National Cancer Institute, the Office of Rural Health Policy, and such other offices and agencies as deemed appropriate by the Secretary, regarding the design and evaluation of the demonstration programs.

(b) USE OF FUNDS.—The Secretary shall require each recipient of a grant under this section to use the grant to recruit, assign, train, and employ patient navigators who have direct knowledge of the communities they serve to facilitate the care of individuals, including by performing each of the following duties:

(1) Acting as contacts, including by assisting in the coordination of health care services and provider referrals, for individuals who are seeking prevention or early detection services for, or who following a screening or early detection service are found to have a symptom, abnormal finding, or diagnosis of, cancer or other chronic disease.

(2) Facilitating the involvement of community organizations in assisting individuals who are at risk for or who have cancer or other chronic diseases to receive better access to high-quality health care services (such as by creating partnerships with patient advocacy groups, charities, health care centers, community hospice centers, other health care providers, or other organizations in the targeted community).

(3) Notifying individuals of clinical trials and, on request, facilitating enrollment of eligible individuals in these trials.

(4) Anticipating, identifying, and helping patients to overcome barriers within the health care system to ensure prompt diagnostic and treatment resolution of an abnormal finding of cancer or other chronic disease.

(5) Coordinating with the relevant health insurance ombudsman programs to provide information to individuals who are at risk for or who have cancer or other chronic diseases about health coverage, including private insurance, health care

savings accounts, and other publicly funded programs (such as Medicare, Medicaid, health programs operated by the Department of Veterans Affairs or the Department of Defense, the State children's health insurance program, and any private or governmental prescription assistance programs).

(6) Conducting ongoing outreach to health disparity populations, including the uninsured, rural populations, and other medically underserved populations, in addition to assisting other individuals who are at risk for or who have cancer or other chronic diseases to seek preventative care.

(c) PROHIBITIONS.—

(1) REFERRAL FEES.—The Secretary shall require each recipient of a grant under this section to prohibit any patient navigator providing services under the grant from accepting any referral fee, kickback, or other thing of value in return for referring an individual to a particular health care provider.

(2) LEGAL FEES AND COSTS.—The Secretary shall prohibit the use of any grant funds received under this section to pay any fees or costs resulting from any litigation, arbitration, mediation, or other proceeding to resolve a legal dispute.

(d) GRANT PERIOD.—

(1) IN GENERAL.—Subject to paragraphs (2) and (3), the Secretary may award grants under this section for periods of not more than 3 years.

(2) EXTENSIONS.—Subject to paragraph (3), the Secretary may extend the period of a grant under this section. Each such extension shall be for a period of not more than 1 year.

(3) LIMITATIONS ON GRANT PERIOD.—In carrying out this section, the Secretary shall ensure that the total period of a grant does not exceed 4 years.

(e) APPLICATION.—

(1) IN GENERAL.—To seek a grant under this section, an eligible entity shall submit an application to the Secretary in such form, in such manner, and containing such information as the Secretary may require.

(2) CONTENTS.—At a minimum, the Secretary shall require each such application to outline how the eligible entity will establish baseline measures and benchmarks that meet the Secretary's requirements to evaluate program outcomes.

(3) MINIMUM CORE PROFICIENCIES.—The Secretary shall not award a grant to an entity under this section unless such entity provides assurances that patient navigators recruited, assigned, trained, or employed using grant funds meet minimum core proficiencies, as defined by the entity that submits the application, that are tailored for the main focus or intervention of the navigator involved.

(f) UNIFORM BASELINE MEASURES.—The Secretary shall establish uniform baseline measures in order to properly evaluate the impact of the demonstration projects under this section.

(g) PREFERENCE.—In making grants under this section, the Secretary shall give preference to eligible entities that demonstrate in their applications plans to utilize patient navigator services to overcome significant barriers in order to improve health care outcomes in their respective communities.

(h) DUPLICATION OF SERVICES.—An eligible entity that is receiving Federal funds for activities described in subsection (b) on the date on which the entity submits an application under subsection (e) may not receive a grant under this section unless the entity can demonstrate that amounts received under the grant will be utilized to expand services or provide new services to individuals who would not otherwise be served.

(i) COORDINATION WITH OTHER PROGRAMS.—The Secretary shall ensure coordination of the demonstration grant program under this section with existing authorized programs in order to facilitate access to high-quality health care services.

(j) STUDY; REPORTS.—

(1) FINAL REPORT BY SECRETARY.—Not later than 6 months after the completion of the demonstration grant program under this section, the Secretary shall conduct a study of the results of the program and submit to the Congress a report on such results that includes the following:

(A) An evaluation of the program outcomes, including—

(i) quantitative analysis of baseline and benchmark measures; and

(ii) aggregate information about the patients served and program activities.

(B) Recommendations on whether patient navigator programs could be used to improve patient outcomes in other public health areas.

(2) INTERIM REPORTS BY SECRETARY.—The Secretary may provide interim reports to the Congress on the demonstration grant program under this section at such intervals as the Secretary determines to be appropriate.

(3) REPORTS BY GRANTEES.—The Secretary may require grant recipients under this section to submit interim and final reports on grant program outcomes.

(k) RULE OF CONSTRUCTION.—This section shall not be construed to authorize funding for the delivery of health care services (other than the patient navigator duties listed in subsection (b)).

(l) DEFINITIONS.—In this section:

(1) The term "eligible entity" means a public or nonprofit private health center (including a Federally qualified health center (as that term is defined in section 1861(aa)(4) of the Social Security Act)), a health facility operated by or pursuant to a contract with the Indian Health Service, a hospital, a cancer center, a rural health clinic, an academic health center, or a nonprofit entity that enters into a partnership or coordinates referrals with such a center, clinic, facility, or hospital to provide patient navigator services.

(2) The term "health disparity population" means a population that, as determined by the Secretary, has a significant disparity in the overall rate of disease incidence, prevalence, morbidity, mortality, or survival rates as compared to the health status of the general population.

(3) The term "patient navigator" means an individual who has completed a training program approved by the Secretary to perform the duties listed in subsection (b).

(m) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—To carry out this section, there are authorized to be appropriated $2,000,000 for fiscal year 2006, $5,000,000 for fiscal year 2007, $8,000,000 for fiscal year 2008, $6,500,000 for fiscal year 2009, $3,500,000 for fiscal year 2010, and such sums as may be necessary for each of fiscal years 2011 through 2015.

(2) AVAILABILITY.—The amounts appropriated pursuant to paragraph (1) shall remain available for obligation through the end of fiscal year 2015.

Subpart VII—Drug Pricing Agreements [44]

LIMITATION ON PRICES OF DRUGS PURCHASED BY COVERED ENTITIES

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

(1) IN GENERAL.—The Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid (taking into account any rebate or discount, as provided by the Secretary) to the manufacturer for covered outpatient drugs (other than drugs described in paragraph (3)) purchased by a covered entity on or after the first day of the first month that begins after the date of the enactment of this section, does not exceed an amount equal to the average manufacturer price for the drug under title XIX of the Social Security Act in the preceding calendar quarter, reduced by the rebate percentage described in paragraph (2). Each such agreement shall require that the manufacturer furnish the Secretary with reports, on a quarterly basis, of the price for each covered outpatient drug subject to the agreement that, according to the manufacturer, represents the maximum price that covered entities may permissibly be required to pay for the drug (referred to in this section as the "ceiling price"), and shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price.

(2) REBATE PERCENTAGE DEFINED.—

(A) IN GENERAL.—For a covered outpatient drug purchased in a calendar quarter, the "rebate percentage" is the amount (expressed as a percentage) equal to—

(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

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

percentage" shall be determined as if the rebate required under section 1927(c) of the Social Security Act is based on the applicable percentage provided under section 1927(c)(3) of such Act.

(ii) DEFINITION.—The term "over the counter drug" means a drug that may be sold without a prescription and which is prescribed by a physician (or other persons authorized to prescribe such drug under State law).

(3) DRUGS PROVIDED UNDER STATE MEDICAID PLANS.—Drugs described in this paragraph are drugs purchased by the entity for which payment is made by the State under the State plan for medical assistance under title XIX of the Social Security Act.

(4) COVERED ENTITY DEFINED.—In this section, the term "covered entity" means an entity that meets the requirements described in paragraph (5) and is one of the following:

(A) A Federally-qualified health center (as defined in section 1905(l)(2)(B) of the Social Security Act).

(B) An entity receiving a grant under section 340A[45].

(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

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

non-profit hospital which has a contract with a State or local government to provide health care services to low income individuals who are not entitled to benefits under title XVIII of the Social Security Act or eligible for assistance under the State plan under this title;

(ii) for the most recent cost reporting period that ended before the calendar quarter involved, had a disproportionate share adjustment percentage (as determined under section 1886(d)(5)(F) of the Social Security Act) greater than 11.75 percent or was described in section 1886(d)(5)(F)(i)(II) of such Act; and

(iii) does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement.

(M) A children's hospital excluded from the Medicare prospective payment system pursuant to section 1886(d)(1)(B)(iii) of the Social Security Act, or a free-standing cancer hospital excluded from the Medicare prospective payment system pursuant to section 1886(d)(1)(B)(v) of the Social Security Act, that would meet the requirements of subparagraph (L), including the disproportionate share adjustment percentage requirement under clause (ii) of such subparagraph, if the hospital were a subsection (d) hospital as defined by section 1886(d)(1)(B) of the Social Security Act.

(N) An entity that is a critical access hospital (as determined under section 1820(c)(2) of the Social Security Act), and that meets the requirements of subparagraph (L)(i).

(O) An entity that is a rural referral center, as defined by section 1886(d)(5)(C)(i) of the Social Security Act, or a sole community hospital, as defined by section 1886(d)(5)(C)(iii) of such Act, and that both meets the requirements of subparagraph (L)(i) and has a disproportionate share adjustment percentage equal to or greater than 8 percent.

(5) REQUIREMENTS FOR COVERED ENTITIES.—

(A) PROHIBITING DUPLICATE DISCOUNTS OR REBATES.—

(i) IN GENERAL.—A covered entity shall not request payment under title XIX of the Social Security Act for medical assistance described in section 1905(a)(12) of such Act with respect to a drug that is subject to an agreement under this section if the drug is subject to the payment of a rebate to the State under section 1927 of such Act.

(ii) ESTABLISHMENT OF MECHANISM.—The Secretary shall establish a mechanism to ensure that covered entities comply with clause (i). If the Secretary does not establish a mechanism within 12 months under the previous sentence, the requirements of section 1927(a)(5)(C) of the Social Security Act shall apply.

(B) PROHIBITING RESALE OF DRUGS.—With respect to any covered outpatient drug that is subject to an agree-

ment under this subsection, a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity.

(C) AUDITING.—A covered entity shall permit the Secretary and the manufacturer of a covered outpatient drug that is subject to an agreement under this subsection with the entity (acting in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits) to audit at the Secretary's or the manufacturer's expense the records of the entity that directly pertain to the entity's compliance with the requirements described in subparagraphs (A) or (B) with respect to drugs of the manufacturer.

(D) ADDITIONAL SANCTION FOR NONCOMPLIANCE.—If the Secretary finds, after audit as described in subparagraph (C) and after notice and hearing, that a covered entity is in violation of a requirement described in subparagraphs [46] (A) or (B), the covered entity shall be liable to the manufacturer of the covered outpatient drug that is the subject of the violation in an amount equal to the reduction in the price of the drug (as described in subparagraph (A)) provided under the agreement between the entity and the manufacturer under this paragraph.

(6) TREATMENT OF DISTINCT UNITS OF HOSPITALS.—In the case of a covered entity that is a distinct part of a hospital, the hospital shall not be considered a covered entity under this paragraph unless the hospital is otherwise a covered entity under this subsection.

(7) CERTIFICATION OF CERTAIN COVERED ENTITIES.—

(A) DEVELOPMENT OF PROCESS.—Not later than 60 days after the date of enactment of this subsection, the Secretary shall develop and implement a process for the certification of entities described in subparagraphs (J) and (K) of paragraph (4).

(B) INCLUSION OF PURCHASE INFORMATION.—The process developed under subparagraph (A) shall include a requirement that an entity applying for certification under this paragraph submit information to the Secretary concerning the amount such entity expended for covered outpatient drugs in the preceding year so as to assist the 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 de-

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

scribed 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[47].—

(1) IN GENERAL.—In this section, the terms "average manufacturer price", "covered outpatient drug", and "manufacturer" have the meaning given such terms in section 1927(k) of the Social Security Act.

(2)[48] COVERED DRUG.—In this section, the term "covered drug"—

(A) means a covered outpatient drug (as defined in section 1927(k)(2) of the Social Security Act); and

(B) includes, notwithstanding paragraph (3)(A) of section 1927(k) of such Act, a drug used in connection with an inpatient or outpatient service provided by a hospital described in subparagraph (L), (M), (N), or (O) of subsection (a)(4) that is enrolled to participate in the drug discount program under this section.

(d)[49] IMPROVEMENTS IN PROGRAM INTEGRITY.—

[47] The amendment made by section 7101(b)(2)(A) of Public Law 111–148 strikes "OTHER DEFINITION" and all that follows through "In this section" and inserts "OTHER DEFINITIONS.—
(1) IN GENERAL.—In this section".

The heading of such amendment should have been to strike "OTHER DEFINITIONS". The amendment made by such section has been carried out to reflect the probable intent of Congress.

[48] There are no references to the term "covered drug" in this section.

[49] In law, there is no subsection (c) in section 340B of the Public Health Service Act. Subsection (d) of section 340B of the Public Health Service, as in effect before the enactment of Public Law 111–148, was redesignated as subsection (c) by section 2501(f)(1)(C) of Public Law 111–148, amended to read by section 7101(d) of Public Law 111–148, and stricken by section 2302(2) of Public Law 111–152. Subsection (d) of section 340B of the Public Health Service, as currently in effect, is shown according to the probable intent of the Congress. Section 7102(a) of Public Law 111–148 does not execute because it amends to read a nonexistent subsection (d). Notably,

Continued

(1) MANUFACTURER COMPLIANCE.—

(A) IN GENERAL.—From amounts appropriated under paragraph (4), the Secretary shall provide for improvements in compliance by manufacturers with the requirements of this section in order to prevent overcharges and other violations of the discounted pricing requirements specified in this section.

(B) IMPROVEMENTS.—The improvements described in subparagraph (A) shall include the following:

(i) The development of a system to enable the Secretary to verify the accuracy of ceiling prices calculated by manufacturers under subsection (a)(1) and charged to covered entities, which shall include the following:

(I) Developing and publishing through an appropriate policy or regulatory issuance, precisely defined standards and methodology for the calculation of ceiling prices under such subsection.

(II) Comparing regularly the ceiling prices calculated by the Secretary with the quarterly pricing data that is reported by manufacturers to the Secretary.

(III) Performing spot checks of sales transactions by covered entities.

(IV) Inquiring into the cause of any pricing discrepancies that may be identified and either taking, or requiring manufacturers to take, such corrective action as is appropriate in response to such price discrepancies.

(ii) The establishment of procedures for manufacturers to issue refunds to covered entities in the event that there is an overcharge by the manufacturers, including the following:

(I) Providing the Secretary with an explanation of why and how the overcharge occurred, how the refunds will be calculated, and to whom the refunds will be issued.

(II) Oversight by the Secretary to ensure that the refunds are issued accurately and within a reasonable period of time, both in routine instances of retroactive adjustment to relevant pricing data and exceptional circumstances such as erroneous or intentional overcharging for covered outpatient drugs.

(iii) The provision of access through the Internet website of the Department of Health and Human Services to the applicable ceiling prices for covered outpatient drugs as calculated and verified by the Secretary in accordance with this section, in a manner (such as through the use of password protection) that limits such access to covered entities and adequately

section 2302(3) of Public Law 111–152 assumes that section 7102(a) of Public Law 111–148 executed properly and makes amendments to subsection (d).

assures security and protection of privileged pricing data from unauthorized re-disclosure.

(iv) The development of a mechanism by which—

(I) rebates and other discounts provided by manufacturers to other purchasers subsequent to the sale of covered outpatient drugs to covered entities are reported to the Secretary; and

(II) appropriate credits and refunds are issued to covered entities if such discounts or rebates have the effect of lowering the applicable ceiling price for the relevant quarter for the drugs involved.

(v) Selective auditing of manufacturers and wholesalers to ensure the integrity of the drug discount program under this section.

(vi) The imposition of sanctions in the form of civil monetary penalties, which—

(I) shall be assessed according to standards established in regulations to be promulgated by the Secretary not later than 180 days after the date of enactment of the Patient Protection and Affordable Care Act;

(II) shall not exceed $5,000 for each instance of overcharging a covered entity that may have occurred; and

(III) shall apply to any manufacturer with an agreement under this section that knowingly and intentionally charges a covered entity a price for purchase of a drug that exceeds the maximum applicable price under subsection (a)(1).

(2) COVERED ENTITY COMPLIANCE.—

(A) IN GENERAL.—From amounts appropriated under paragraph (4), the Secretary shall provide for improvements in compliance by covered entities with the requirements of this section in order to prevent diversion and violations of the duplicate discount provision and other requirements specified under subsection (a)(5).

(B) IMPROVEMENTS.—The improvements described in subparagraph (A) shall include the following:

(i) The development of procedures to enable and require covered entities to regularly update (at least annually) the information on the Internet website of the Department of Health and Human Services relating to this section.

(ii) The development of a system for the Secretary to verify the accuracy of information regarding covered entities that is listed on the website described in clause (i).

(iii) The development of more detailed guidance describing methodologies and options available to covered entities for billing covered outpatient drugs to State Medicaid agencies in a manner that avoids duplicate discounts pursuant to subsection (a)(5)(A).

(iv) The establishment of a single, universal, and standardized identification system by which each covered entity site can be identified by manufacturers, distributors, covered entities, and the Secretary for purposes of facilitating the ordering, purchasing, and delivery of covered outpatient drugs under this section, including the processing of chargebacks for such drugs.

(v) The imposition of sanctions, in appropriate cases as determined by the Secretary, additional to those to which covered entities are subject under subsection (a)(5)(D), through one or more of the following actions:

(I) Where a covered entity knowingly and intentionally violates subsection (a)(5)(B), the covered entity shall be required to pay a monetary penalty to a manufacturer or manufacturers in the form of interest on sums for which the covered entity is found liable under subsection (a)(5)(D), such interest to be compounded monthly and equal to the current short term interest rate as determined by the Federal Reserve for the time period for which the covered entity is liable.

(II) Where the Secretary determines a violation of subsection (a)(5)(B) was systematic and egregious as well as knowing and intentional, removing the covered entity from the drug discount program under this section and disqualifying the entity from re-entry into such program for a reasonable period of time to be determined by the Secretary.

(III) Referring matters to appropriate Federal authorities within the Food and Drug Administration, the Office of Inspector General of Department of Health and Human Services, or other Federal agencies for consideration of appropriate action under other Federal statutes, such as the Prescription Drug Marketing Act (21 U.S.C. 353).

(3) ADMINISTRATIVE DISPUTE RESOLUTION PROCESS.—

(A) IN GENERAL.—Not later than 180 days after the date of enactment of the Patient Protection and Affordable Care Act, the Secretary shall promulgate regulations to establish and implement an administrative process for the resolution of claims by covered entities that they have been overcharged for drugs purchased under this section, and claims by manufacturers, after the conduct of audits as authorized by subsection (a)(5)(C), of violations of subsections (a)(5)(A) or (a)(5)(B), including appropriate procedures for the provision of remedies and enforcement of determinations made pursuant to such process through mechanisms and sanctions described in paragraphs (1)(B) and (2)(B).

(B) DEADLINES AND PROCEDURES.—Regulations promulgated by the Secretary under subparagraph (A) shall—

(i) designate or establish a decision-making official or decision-making body within the Department of Health and Human Services to be responsible for reviewing and finally resolving claims by covered entities that they have been charged prices for covered outpatient drugs in excess of the ceiling price described in subsection (a)(1), and claims by manufacturers that violations of subsection (a)(5)(A) or (a)(5)(B) have occurred;

(ii) establish such deadlines and procedures as may be necessary to ensure that claims shall be resolved fairly, efficiently, and expeditiously;

(iii) establish procedures by which a covered entity may discover and obtain such information and documents from manufacturers and third parties as may be relevant to demonstrate the merits of a claim that charges for a manufacturer's product have exceeded the applicable ceiling price under this section, and may submit such documents and information to the administrative official or body responsible for adjudicating such claim;

(iv) require that a manufacturer conduct an audit of a covered entity pursuant to subsection (a)(5)(C) as a prerequisite to initiating administrative dispute resolution proceedings against a covered entity;

(v) permit the official or body designated under clause (i), at the request of a manufacturer or manufacturers, to consolidate claims brought by more than one manufacturer against the same covered entity where, in the judgment of such official or body, consolidation is appropriate and consistent with the goals of fairness and economy of resources; and

(vi) include provisions and procedures to permit multiple covered entities to jointly assert claims of overcharges by the same manufacturer for the same drug or drugs in one administrative proceeding, and permit such claims to be asserted on behalf of covered entities by associations or organizations representing the interests of such covered entities and of which the covered entities are members.

(C) FINALITY OF ADMINISTRATIVE RESOLUTION.—The administrative resolution of a claim or claims under the regulations promulgated under subparagraph (A) shall be a final agency decision and shall be binding upon the parties involved, unless invalidated by an order of a court of competent jurisdiction.

(4) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this subsection, such sums as may be necessary for fiscal year 2010 and each succeeding fiscal year.

(e)[50] EXCLUSION OF ORPHAN DRUGS FOR CERTAIN COVERED ENTITIES.—For covered entities described in subparagraph (M) (other than a children's hospital described in subparagraph (M)), (N), or (O) of subsection (a)(4), the term "covered outpatient drug" shall not include a drug designated by the Secretary under section 526 of the Federal Food, Drug, and Cosmetic Act for a rare disease or condition.

Subpart VIII—Bulk Purchases of Vaccines for Certain Programs

BULK PURCHASES OF VACCINES FOR CERTAIN PROGRAMS

SEC. 340C. [256c] (a) AGREEMENTS FOR PURCHASES.—

(1) IN GENERAL.—Not later than 180 days after the date of the enactment of the Preventive Health Amendments of 1992[51], 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).

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.

---

[50] Subsection (e) is shown according to the probable intent of Congress. Section 2302(4) of Public Law 111–152 inserts subsection (e) "after subsection (d)". See note in section 340B(d) of the Public Health Service Act regarding the inclusion of subsection (d) to reflect the probable intent of Congress.

Section 204(a)(1) of Public Law 111–309 amends subsection (e) of section 340B (effective on the enactment of such Public Law).

[51] Enacted October 27, 1992.

(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)[52].

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

(3) Migrant health centers receiving assistance under section 329[53].

(4) Community health centers receiving assistance under section 330[53].

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

(6) Entities receiving assistance under section 340A[53] (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 through 2005, each of fiscal years 2007 through 2011, each of fiscal years 2014 through 2018, and each of fiscal years 2019 through 2023, 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

[52] 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.

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

States Code, which shall govern payments made under this subpart.

(b) AMOUNT OF PAYMENTS.—

(1) IN GENERAL.—Subject to paragraphs (2) and (3), the amounts payable under this section to a children's hospital for an approved graduate medical residency training program for a fiscal year are each of the following amounts:

(A) DIRECT EXPENSE AMOUNT.—The amount determined under subsection (c) for direct expenses associated with operating approved graduate medical residency training programs.

(B) INDIRECT EXPENSE AMOUNT.—The amount determined under subsection (d) for indirect expenses associated with the treatment of more severely ill patients and the additional costs relating to teaching residents in such programs.

(2) CAPPED AMOUNT.—

(A) IN GENERAL.—The total of the payments made to children's hospitals under paragraph (1)(A) or paragraph (1)(B) in a fiscal year shall not exceed the funds appropriated under paragraph (1) or (2), respectively, of subsection (f) for such payments for that fiscal year.

(B) PRO RATA REDUCTIONS OF PAYMENTS FOR DIRECT EXPENSES.—If the Secretary determines that the amount of funds appropriated under subsection (f)(1) for a fiscal year is insufficient to provide the total amount of payments otherwise due for such periods under paragraph (1)(A), the Secretary shall reduce the amounts so payable on a pro rata basis to reflect such shortfall.

(3) ANNUAL REPORTING REQUIRED.—

(A) REDUCTION IN PAYMENT FOR FAILURE TO REPORT.—

(i) IN GENERAL.—The amount payable under this section to a children's hospital for a fiscal year (beginning with fiscal year 2008 and after taking into account paragraph (2)) shall be reduced by 25 percent if the Secretary determines that—

(I) the hospital has failed to provide the Secretary, as an addendum to the hospital's application under this section for such fiscal year, the report required under subparagraph (B) for the previous fiscal year; or

(II) such report fails to provide the information required under any clause of such subparagraph.

(ii) NOTICE AND OPPORTUNITY TO PROVIDE MISSING INFORMATION.—Before imposing a reduction under clause (i) on the basis of a hospital's failure to provide information described in clause (i)(II), the Secretary shall provide notice to the hospital of such failure and the Secretary's intention to impose such reduction and shall provide the hospital with the opportunity to provide the required information within a period of 30 days beginning on the date of such notice. If the hospital provides such information within such period, no

reduction shall be made under clause (i) on the basis of the previous failure to provide such information.

(B) ANNUAL REPORT.—The report required under this subparagraph for a children's hospital for a fiscal year is a report that includes (in a form and manner specified by the Secretary) the following information for the residency academic year completed immediately prior to such fiscal year:

(i) The types of resident training programs that the hospital provided for residents described in subparagraph (C), such as general pediatrics, internal medicine/pediatrics, and pediatric subspecialties, including both medical subspecialties certified by the American Board of Pediatrics (such as pediatric gastroenterology) and non-medical subspecialties approved by other medical certification boards (such as pediatric surgery).

(ii) The number of training positions for residents described in subparagraph (C), the number of such positions recruited to fill, and the number of such positions filled.

(iii) The types of training that the hospital provided for residents described in subparagraph (C) related to the health care needs of different populations, such as children who are underserved for reasons of family income or geographic location, including rural and urban areas.

(iv) The changes in residency training for residents described in subparagraph (C) which the hospital has made during such residency academic year (except that the first report submitted by the hospital under this subparagraph shall be for such changes since the first year in which the hospital received payment under this section), including—

(I) changes in curricula, training experiences, and types of training programs, and benefits that have resulted from such changes; and

(II) changes for purposes of training the residents in the measurement and improvement of the quality and safety of patient care.

(v) The numbers of residents described in subparagraph (C) who completed their residency training at the end of such residency academic year and care for children within the borders of the service area of the hospital or within the borders of the State in which the hospital is located. Such numbers shall be disaggregated with respect to residents who completed residencies in general pediatrics or internal medicine/pediatrics, subspecialty residencies, and dental residencies.

(C) RESIDENTS.—The residents described in this subparagraph are those who—

(i) are in full-time equivalent resident training positions in any training program sponsored by the hospital; or

(ii) are in a training program sponsored by an entity other than the hospital, but who spend more than 75 percent of their training time at the hospital.

(D) REPORT TO CONGRESS.—Not later than the end of fiscal year 2018, and the end of fiscal year 2022, the Secretary, acting through the Administrator of the Health Resources and Services Administration, shall submit a report to the Congress—

(i) summarizing the information submitted in reports to the Secretary under subparagraph (B);

(ii) describing the results of the program carried out under this section; and

(iii) making recommendations for improvements to the program.

(c) AMOUNT OF PAYMENT FOR DIRECT GRADUATE MEDICAL EDUCATION.—

(1) IN GENERAL.—The amount determined under this subsection for payments to a children's hospital for direct graduate expenses relating to approved graduate medical residency training programs for a fiscal year is equal to the product of—

(A) the updated per resident amount for direct graduate medical education, as determined under paragraph (2); and

(B) the average number of full-time equivalent residents in the hospital's graduate approved medical residency training programs (as determined under section 1886(h)(4) of the Social Security Act during the fiscal year.

(2) UPDATED PER RESIDENT AMOUNT FOR DIRECT GRADUATE MEDICAL EDUCATION.—The updated per resident amount for direct graduate medical education for a hospital for a fiscal year is an amount determined as follows:

(A) DETERMINATION OF HOSPITAL SINGLE PER RESIDENT AMOUNT.—The Secretary shall compute for each hospital operating an approved graduate medical education program (regardless of whether or not it is a children's hospital) a single per resident amount equal to the average (weighted by number of full-time equivalent residents) of the primary care per resident amount and the non-primary care per resident amount computed under section 1886(h)(2) of the Social Security Act for cost reporting periods ending during fiscal year 1997.

(B) DETERMINATION OF WAGE AND NON-WAGE-RELATED PROPORTION OF THE SINGLE PER RESIDENT AMOUNT.—The Secretary shall estimate the average proportion of the single per resident amounts computed under subparagraph (A) that is attributable to wages and wage-related costs.

(C) STANDARDIZING PER RESIDENT AMOUNTS.—The Secretary shall establish a standardized per resident amount for each such hospital—

(i) by dividing the single per resident amount computed under subparagraph (A) into a wage-related por-

tion and a non-wage-related portion by applying the proportion determined under subparagraph (B);

(ii) by dividing the wage-related portion by the factor applied under section 1886(d)(3)(E) of the Social Security Act for discharges occurring during fiscal year 1999 for the hospital's area; and

(iii) by adding the non-wage-related portion to the amount computed under clause (ii).

(D) DETERMINATION OF NATIONAL AVERAGE.—The Secretary shall compute a national average per resident amount equal to the average of the standardized per resident amounts computed under subparagraph (C) for such hospitals, with the amount for each hospital weighted by the average number of full-time equivalent residents at such hospital.

(E) APPLICATION TO INDIVIDUAL HOSPITALS.—The Secretary shall compute for each such hospital that is a children's hospital a per resident amount—

(i) by dividing the national average per resident amount computed under subparagraph (D) into a wage-related portion and a non-wage-related portion by applying the proportion determined under subparagraph (B);

(ii) by multiplying the wage-related portion by the factor applied under section 1886(d)(3)(E) of the Social Security Act for discharges occurring during the preceding fiscal year for the hospital's area; and

(iii) by adding the non-wage-related portion to the amount computed under clause (ii).

(F) UPDATING RATE.—The Secretary shall update such per resident amount for each such children's hospital by the estimated percentage increase in the consumer price index for all urban consumers during the period beginning October 1997 and ending with the midpoint of the Federal fiscal year for which payments are made.

(d) AMOUNT OF PAYMENT FOR INDIRECT MEDICAL EDUCATION.—

(1) IN GENERAL.—The amount determined under this subsection for payments to a children's hospital for indirect expenses associated with the treatment of more severely ill patients and the additional costs associated with the teaching of residents for a fiscal year is equal to an amount determined appropriate by the Secretary.

(2) FACTORS.—In determining the amount under paragraph (1), the Secretary shall—

(A) take into account variations in case mix among children's hospitals and the ratio of the number of full-time equivalent residents in the hospitals' approved graduate medical residency training programs to beds (but excluding beds or bassinets assigned to healthy newborn infants); and

(B) assure that the aggregate of the payments for indirect expenses associated with the treatment of more 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 12 equal interim installments during such period. Such interim payments to each individual hospital shall be based on the number of residents reported in the hospital's most recently filed Medicare cost report prior to the application date for the Federal fiscal year for which the interim payment amounts are established. In the case of a hospital that does not report residents on a Medicare cost report, such interim payments shall be based on the number of residents trained during the hospital's most recently completed Medicare cost report filing period.

(2) WITHHOLDING.—The Secretary shall withhold up to 25 percent from each interim installment for direct and indirect graduate medical education paid under paragraph (1) as necessary to ensure a hospital will not be overpaid on an interim basis.

(3) RECONCILIATION.—Prior to the end of each fiscal year, the Secretary shall determine any changes to the number of residents reported by a hospital in the application of the hospital for the current fiscal year to determine the final amount payable to the hospital for the current fiscal year for both direct expense and indirect expense amounts. Based on such determination, the Secretary shall recoup any overpayments made and pay any balance due to the extent possible. The final amount so determined shall be considered a final intermediary determination for the purposes of section 1878 of the Social Security Act and shall be subject to administrative and judicial review under that section in the same manner as the amount of payment under section 1186(d) of such Act is subject to review under such section.

(f) AUTHORIZATION OF APPROPRIATIONS.—

(1) DIRECT GRADUATE MEDICAL EDUCATION.—

(A) IN GENERAL.—There are hereby authorized to be appropriated, out of any money in the Treasury not otherwise appropriated, for payments under subsection (b)(1)(A)—

(i) for fiscal year 2000, $90,000,000;

(ii) for fiscal year 2001, $95,000,000;

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

(iv) for each of fiscal years 2007 through 2011, $110,000,000;

(v) for each of fiscal years 2014 through 2018, $100,000,000; and

(vi) for each of fiscal years 2019 through 2023, $105,000,000.

(B) CARRYOVER OF EXCESS.—The amounts appropriated under subparagraph (A) for fiscal year 2000 shall remain available for obligation through the end of fiscal year 2001.

(2) INDIRECT MEDICAL EDUCATION.—There are hereby authorized to be appropriated, out of any money in the Treasury not otherwise appropriated, for payments under subsection (b)(1)(B)—

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

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

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

(D) for each of fiscal years 2007 through 2011, $220,000,000;

(E) for each of fiscal years 2014 through 2018, $200,000,000; and

(F) for each of fiscal years 2019 through 2023, $220,000,000.

(g) DEFINITIONS.—In this section:

(1) APPROVED GRADUATE MEDICAL RESIDENCY TRAINING PROGRAM.—The term "approved graduate medical residency training program" has the meaning given the term "approved medical residency training program" in section 1886(h)(5)(A) of the Social Security Act.

(2) CHILDREN'S HOSPITAL.—The term "children's hospital" means a hospital with a Medicare payment agreement and which is excluded from the Medicare inpatient prospective payment system pursuant to section 1886(d)(1)(B)(iii) of the Social Security Act and its accompanying regulations.

(3) DIRECT GRADUATE MEDICAL EDUCATION COSTS.—The term "direct graduate medical education costs" has the meaning given such term in section 1886(h)(5)(C) of the Social Security Act.

(h) ADDITIONAL PROVISIONS.—

(1) IN GENERAL.—The Secretary is authorized to make available up to 25 percent of the total amounts in excess of $245,000,000 appropriated under paragraphs (1) and (2) of subsection (f), but not to exceed $7,000,000, for payments to hospitals qualified as described in paragraph (2), for the direct and indirect expenses associated with operating approved graduate medical residency training programs, as described in subsection (a).

(2) QUALIFIED HOSPITALS.—

(A) IN GENERAL.—To qualify to receive payments under paragraph (1), a hospital shall be a free-standing hospital—

(i) with a Medicare payment agreement and that is excluded from the Medicare inpatient hospital prospective payment system pursuant to section 1886(d)(1)(B) of the Social Security Act and its accompanying regulations;

(ii) whose inpatients are predominantly individuals under 18 years of age;

(iii) that has an approved medical residency training program as defined in section 1886(h)(5)(A) of the Social Security Act; and

(iv) that is not otherwise qualified to receive payments under this section or section 1886(h) of the Social Security Act.

(B) ESTABLISHMENT OF RESIDENCY CAP.—In the case of a freestanding children's hospital that, on the date of enactment of this subsection, meets the requirements of subparagraph (A) but for which the Secretary has not determined an average number of full-time equivalent residents under section 1886(h)(4) of the Social Security Act, the Secretary may establish such number of full-time equivalent residents for the purposes of calculating payments under this subsection.

(3) PAYMENTS.—Payments to hospitals made under this subsection shall be made in the same manner as payments are made to children's hospitals, as described in subsections (b) through (e).

(4) PAYMENT AMOUNTS.—The direct and indirect payment amounts under this subsection shall be determined using per resident amounts that are no greater than the per resident amounts used for determining direct and indirect payment amounts under subsection (a).

(5) REPORTING.—A hospital receiving payments under this subsection shall be subject to the reporting requirements under subsection (b)(3).

(6) REMAINING FUNDS.—

(A) IN GENERAL.—If the payments to qualified hospitals under paragraph (1) for a fiscal year are less than the total amount made available under such paragraph for that fiscal year, any remaining amounts for such fiscal year may be made available to all hospitals participating in the program under this subsection or subsection (a).

(B) QUALITY BONUS SYSTEM.—For purposes of distributing the remaining amounts described in subparagraph (A), the Secretary may establish a quality bonus system, whereby the Secretary distributes bonus payments to hospitals participating in the program under this subsection or subsection (a) that meet standards specified by the Secretary, which may include a focus on quality measurement and improvement, interpersonal and communications skills, delivering patient-centered care, and practicing in integrated health systems, including training in community-based settings. In developing such standards, the Secretary shall collaborate with relevant stakeholders, including program accrediting bodies, certifying boards, training programs, health care organizations, health care purchasers, and patient and consumer groups.

Subpart X—Primary Dental Programs

SEC. 340F. [256f] DESIGNATED DENTAL HEALTH PROFESSIONAL SHORTAGE AREA.

In this subpart, the term "designated dental health professional shortage area" means an area, population group, or facility that is designated by the Secretary as a dental health professional shortage area under section 332 or designated by the applicable State as having a dental health professional shortage.

SEC. 340G. [256g] GRANTS FOR INNOVATIVE PROGRAMS.

(a) GRANT PROGRAM AUTHORIZED.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, is authorized to award grants to States for the purpose of helping States develop and implement innovative programs to address the dental workforce needs of designated dental health professional shortage areas in a manner that is appropriate to the States' individual needs.

(b) STATE ACTIVITIES.—A State receiving a grant under subsection (a) may use funds received under the grant for—

(1) loan forgiveness and repayment programs for dentists who—

(A) agree to practice in designated dental health professional shortage areas;

(B) are dental school graduates who agree to serve as public health dentists for the Federal, State, or local government; and

(C) agree to—

(i) provide services to patients regardless of such patients' ability to pay; and

(ii) use a sliding payment scale for patients who are unable to pay the total cost of services;

(2) dental recruitment and retention efforts;

(3) grants and low-interest or no-interest loans to help dentists who participate in the medicaid program under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) to establish or expand practices in designated dental health professional shortage areas by equipping dental offices or sharing in the overhead costs of such practices;

(4) the establishment or expansion of dental residency programs in coordination with accredited dental training institutions in States without dental schools;

(5) programs developed in consultation with State and local dental societies to expand or establish oral health services and facilities in designated dental health professional shortage areas, including services and facilities for children with special needs, such as—

(A) the expansion or establishment of a community-based dental facility, free-standing dental clinic, consolidated health center dental facility, school-linked dental facility, or United States dental school-based facility;

(B) the establishment of a mobile or portable dental clinic;

(C) the establishment or expansion of private dental services to enhance capacity through additional equipment or additional hours of operation;

(D) the establishment or development of models for the provision of dental services to children and adults, such as dental homes, including for the elderly, blind, individuals with disabilities, and individuals living in long-term care facilities; and

(E) the establishment of initiatives to reduce the use of emergency departments by individuals who seek dental services more appropriately delivered in a dental primary care setting;

(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, $13,903,000 for each of fiscal years 2019 through 2023.

SEC. 340G–1. [256g–1] DEMONSTRATION PROGRAM.

(a) IN GENERAL.—

(1) AUTHORIZATION.—The Secretary is authorized to award grants to 15 eligible entities to enable such entities to establish a demonstration program to establish training programs to train, or to employ, alternative dental health care providers in order to increase access to dental health care services in rural and other underserved communities.

(2) DEFINITION.—The term "alternative dental health care providers" includes community dental health coordinators, advance practice dental hygienists, independent dental hygienists, supervised dental hygienists, primary care physicians, dental therapists, dental health aides, and any other health professional that the Secretary determines appropriate.

(b) TIMEFRAME.—The demonstration projects funded under this section shall begin not later than 2 years after the date of enactment of this section, and shall conclude not later than 7 years after such date of enactment.

(c) ELIGIBLE ENTITIES.—To be eligible to receive a grant under subsection (a), an entity shall—

(1) be—

(A) an institution of higher education, including a community college;

(B) a public-private partnership;

(C) a federally qualified health center;

(D) an Indian Health Service facility or a tribe or tribal organization (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act);

(E) a State or county public health clinic, a health facility operated by an Indian tribe or tribal organization, or urban Indian organization providing dental services; or

(F) a public hospital or health system;

(2) be within a program accredited by the Commission on Dental Accreditation or within a dental education program in an accredited institution; and

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

(d) ADMINISTRATIVE PROVISIONS.—

(1) AMOUNT OF GRANT.—Each grant under this section shall be in an amount that is not less than $4,000,000 for the 5-year period during which the demonstration project being conducted.

(2) DISBURSEMENT OF FUNDS.—

(A) PRELIMINARY DISBURSEMENTS.—Beginning 1 year after the enactment of this section, the Secretary may dis-

perse to any entity receiving a grant under this section not more than 20 percent of the total funding awarded to such entity under such grant, for the purpose of enabling the entity to plan the demonstration project to be conducted under such grant.

(B) SUBSEQUENT DISBURSEMENTS.—The remaining amount of grant funds not dispersed under subparagraph (A) shall be dispersed such that not less than 15 percent of such remaining amount is dispersed each subsequent year.

(e) COMPLIANCE WITH STATE REQUIREMENTS.—Each entity receiving a grant under this section shall certify that it is in compliance with all applicable State licensing requirements.

(f) EVALUATION.—The Secretary shall contract with the Director of the Institute of Medicine to conduct a study of the demonstration programs conducted under this section that shall provide analysis, based upon quantitative and qualitative data, regarding access to dental health care in the United States.

(g) CLARIFICATION REGARDING DENTAL HEALTH AIDE PROGRAM.—Nothing in this section shall prohibit a dental health aide training program approved by the Indian Health Service from being eligible for a grant under this section.

(h) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated such sums as may be necessary to carry out this section.

Subpart XI—Support of Graduate Medical Education in Qualified Teaching Health Centers

SEC. 340H. [256h] PROGRAM OF PAYMENTS TO TEACHING HEALTH CENTERS THAT OPERATE GRADUATE MEDICAL EDUCATION PROGRAMS.

(a) PAYMENTS.—

(1) IN GENERAL.—Subject to subsection (h)(2), the Secretary shall make payments under this section for direct expenses and indirect expenses to qualified teaching health centers that are listed as sponsoring institutions by the relevant accrediting body for, as appropriate—

(A) maintenance of filled positions at existing approved graduate medical residency training programs;

(B) expansion of existing approved graduate medical residency training programs; and

(C) establishment of new approved graduate medical residency training programs.

(2) PER RESIDENT AMOUNT.—In making payments under paragraph (1), the Secretary shall consider the cost of training residents at teaching health centers and the implications of the per resident amount on approved graduate medical residency training programs at teaching health centers.

(3) PRIORITY.—In making payments under paragraph (1)(C), the Secretary shall give priority to qualified teaching health centers that—

(A) serve a health professional shortage area with a designation in effect under section 332 or a medically underserved community (as defined in section 799B); or

(B) are located in a rural area (as defined in section 1886(d)(2)(D) of the Social Security Act).

(b) AMOUNT OF PAYMENTS.—

(1) IN GENERAL.—Subject to paragraph (2), the amounts payable under this section to qualified teaching health centers for an approved graduate medical residency training program for a fiscal year are each of the following amounts:

(A) DIRECT EXPENSE AMOUNT.—The amount determined under subsection (c) for direct expenses associated with sponsoring approved graduate medical residency training programs.

(B) INDIRECT EXPENSE AMOUNT.—The amount determined under subsection (d) for indirect expenses associated with the additional costs relating to teaching residents in such programs.

(2) CAPPED AMOUNT.—

(A) IN GENERAL.—The total of the payments made to qualified teaching health centers under paragraph (1)(A) or paragraph (1)(B) in a fiscal year shall not exceed the amount of funds appropriated under subsection (g) for such payments for that fiscal year.

(B) LIMITATION.—The Secretary shall limit the funding of full-time equivalent residents in order to ensure the direct and indirect payments as determined under subsection (c) and (d) do not exceed the total amount of funds appropriated in a fiscal year under subsection (g).

(C) ADDITION.—Notwithstanding any provision of this section, for the period beginning on October 1, 2023, and ending on December 31, 2024, the Secretary may use any amounts made available in any fiscal year to carry out this section (including amounts recouped under subsection (f)) to make payments described in paragraphs (1)(A) and (1)(B), in addition to the total amount of funds appropriated under subsection (g).

(c) AMOUNT OF PAYMENT FOR DIRECT GRADUATE MEDICAL EDUCATION.—

(1) IN GENERAL.—The amount determined under this subsection for payments to qualified teaching health centers for direct graduate expenses relating to approved graduate medical residency training programs for a fiscal year is equal to the product of—

(A) the updated national per resident amount for direct graduate medical education, as determined under paragraph (2); and

(B) the average number of full-time equivalent residents in the teaching health center's graduate approved medical residency training programs as determined under section 1886(h)(4) of the Social Security Act (without regard to the limitation under subparagraph (F) of such section) during the fiscal year.

(2) UPDATED NATIONAL PER RESIDENT AMOUNT FOR DIRECT GRADUATE MEDICAL EDUCATION.—The updated per resident amount for direct graduate medical education for a qualified teaching health center for a fiscal year is an amount determined as follows:

(A) DETERMINATION OF QUALIFIED TEACHING HEALTH CENTER PER RESIDENT AMOUNT.—The Secretary shall compute for each individual qualified teaching health center a per resident amount—

(i) by dividing the national average per resident amount computed under section 340E(c)(2)(D) into a wage-related portion and a non-wage related portion by applying the proportion determined under subparagraph (B);

(ii) by multiplying the wage-related portion by the factor applied under section 1886(d)(3)(E) of the Social Security Act (but without application of section 4410 of the Balanced Budget Act of 1997 (42 U.S.C. 1395ww note)) during the preceding fiscal year for the teaching health center's area; and

(iii) by adding the non-wage-related portion to the amount computed under clause (ii).

(B) UPDATING RATE.—The Secretary shall update such per resident amount for each such qualified teaching health center as determined appropriate by the Secretary.

(d) AMOUNT OF PAYMENT FOR INDIRECT MEDICAL EDUCATION.—

(1) IN GENERAL.—The amount determined under this subsection for payments to qualified teaching health centers for indirect expenses associated with the additional costs of teaching residents for a fiscal year is equal to an amount determined appropriate by the Secretary.

(2) FACTORS.—In determining the amount under paragraph (1), the Secretary shall—

(A) evaluate indirect training costs relative to supporting a primary care residency program in qualified teaching health centers; and

(B) based on this evaluation, assure that the aggregate of the payments for indirect expenses under this section and the payments for direct graduate medical education as determined under subsection (c) in a fiscal year do not exceed the amount appropriated for such expenses as determined in subsection (g).

(3) INTERIM PAYMENT.—Before the Secretary makes a payment under this subsection pursuant to a determination of indirect expenses under paragraph (1), the Secretary may provide to qualified teaching health centers a payment, in addition to any payment made under subsection (c), for expected indirect expenses associated with the additional costs of teaching residents for a fiscal year, based on an estimate by the Secretary.

(e) CLARIFICATION REGARDING RELATIONSHIP TO OTHER PAYMENTS FOR GRADUATE MEDICAL EDUCATION.—Payments under this section—

(1) shall be in addition to any payments—

(A) for the indirect costs of medical education under section 1886(d)(5)(B) of the Social Security Act;

(B) for direct graduate medical education costs under section 1886(h) of such Act; and

(C) for direct costs of medical education under section 1886(k) of such Act;

(2) shall not be taken into account in applying the limitation on the number of total full-time equivalent residents under subparagraphs (F) and (G) of section 1886(h)(4) of such Act and clauses (v), (vi)(I), and (vi)(II) of section 1886(d)(5)(B) of such Act for the portion of time that a resident rotates to a hospital; and

(3) shall not include the time in which a resident is counted toward full-time equivalency by a hospital under paragraph (2) or under section 1886(d)(5)(B)(iv) of the Social Security Act, section 1886(h)(4)(E) of such Act, or section 340E of this Act.

(f) RECONCILIATION.—The Secretary shall determine any changes to the number of residents reported by a teaching health center in the application of the teaching health center for the current fiscal year to determine the final amount payable to the teaching health center for the current fiscal year for both direct expense and indirect expense amounts. Based on such determination, the Secretary shall recoup any overpayments made to pay any balance due to the extent possible. The final amount so determined shall be considered a final intermediary determination for the purposes of section 1878 of the Social Security Act and shall be subject to administrative and judicial review under that section in the same manner as the amount of payment under section 1186(d) of such Act is subject to review under such section.

(g) FUNDING.—

(1) IN GENERAL.—To carry out this section, there are appropriated such sums as may be necessary, to remain available until expended, not to exceed—

(A) $230,000,000, for the period of fiscal years 2011 through 2015;

(B) $60,000,000 for each of fiscal years 2016 and 2017;

(C) $126,500,000 for each of fiscal years 2018 through 2023;

(D) $168,915,878 for fiscal year 2024;

(E) $181,563,574 for fiscal year 2025;

(F) $225,000,000 for fiscal year 2026;

(G) $250,000,000 for fiscal year 2027;

(H) $275,000,000 for fiscal year 2028; and

(I) $300,000,000 for fiscal year 2029.

(2) ADMINISTRATIVE EXPENSES.—Of the amount made available to carry out this section for any fiscal year, the Secretary may not use more than 5 percent of such amount for the expenses of administering this section.

(h) ANNUAL REPORTING REQUIRED.—

(1) ANNUAL REPORT.—The report required under this paragraph for a qualified teaching health center for a fiscal year is a report that includes (in a form and manner specified by the Secretary) the following information for the residency academic year completed immediately prior to such fiscal year:

(A) The types of primary care resident approved training programs that the qualified teaching health center provided for residents.

(B) The number of approved training positions for residents described in paragraph (4).

(C) The number of residents described in paragraph (4) who completed their residency training at the end of such residency academic year and care for vulnerable populations living in underserved areas.

(D) The number of patients treated by residents described in paragraph (4).

(E) The number of visits by patients treated by residents described in paragraph (4).

(F) Of the number of residents described in paragraph (4) who completed their residency training at the end of such residency academic year, the number and percentage of such residents entering primary care practice (meaning any of the areas of practice listed in the definition of a primary care residency program in section 749A).

(G) Of the number of residents described in paragraph (4) who completed their residency training at the end of such residency academic year, the number and percentage of such residents who entered practice at a health care facility—

(i) primarily serving a health professional shortage area with a designation in effect under section 332 or a medically underserved community (as defined in section 799B); or

(ii) located in a rural area (as defined in section 1886(d)(2)(D) of the Social Security Act).

(H) Other information as deemed appropriate by the Secretary.

(2) AUDIT AUTHORITY; LIMITATION ON PAYMENT.—

(A) AUDIT AUTHORITY.—The Secretary may audit a qualified teaching health center to ensure the accuracy and completeness of the information submitted in a report under paragraph (1).

(B) LIMITATION ON PAYMENT.—A teaching health center may only receive payment in a cost reporting period for a number of such resident positions that is greater than the base level of primary care resident positions, as determined by the Secretary. For purposes of this subparagraph, the "base level of primary care residents" for a teaching health center is the level of such residents as of a base period.

(3) REDUCTION IN PAYMENT FOR FAILURE TO REPORT.—

(A) IN GENERAL.—The amount payable under this section to a qualified teaching health center for a fiscal year shall be reduced by at least 25 percent if the Secretary determines that—

(i) the qualified teaching health center has failed to provide the Secretary, as an addendum to the qualified teaching health center's application under this

section for such fiscal year, the report required under paragraph (1) for the previous fiscal year; or

(ii) such report fails to provide complete and accurate information required under any subparagraph of such paragraph.

(B) NOTICE AND OPPORTUNITY TO PROVIDE ACCURATE AND MISSING INFORMATION.—Before imposing a reduction under subparagraph (A) on the basis of a qualified teaching health center's failure to provide complete and accurate information described in subparagraph (A)(ii), the Secretary shall provide notice to the teaching health center of such failure and the Secretary's intention to impose such reduction and shall provide the teaching health center with the opportunity to provide the required information within the period of 30 days beginning on the date of such notice. If the teaching health center provides such information within such period, no reduction shall be made under subparagraph (A) on the basis of the previous failure to provide such information.

(4) RESIDENTS.—The residents described in this paragraph are those who are in part-time or full-time equivalent resident training positions at a qualified teaching health center in any approved graduate medical residency training program.

(i) REGULATIONS.—The Secretary shall promulgate regulations to carry out this section.

(j) DEFINITIONS.—In this section:

(1) APPROVED GRADUATE MEDICAL RESIDENCY TRAINING PROGRAM.—The term "approved graduate medical residency training program" means a residency or other postgraduate medical training program—

(A) participation in which may be counted toward certification in a specialty or subspecialty and includes formal postgraduate training programs in geriatric medicine approved by the Secretary; and

(B) that meets criteria for accreditation (as established by the Accreditation Council for Graduate Medical Education, the American Osteopathic Association, or the American Dental Association).

(2) NEW APPROVED GRADUATE MEDICAL RESIDENCY TRAINING PROGRAM.—The term "new approved graduate medical residency training program" means an approved graduate medical residency training program for which the sponsoring qualified teaching health center has not received a payment under this section for a previous fiscal year (other than pursuant to subsection (a)(1)(C)).

(3) PRIMARY CARE RESIDENCY PROGRAM.—The term "primary care residency program" has the meaning given that term in section 749A.

(4) QUALIFIED TEACHING HEALTH CENTER.—The term "qualified teaching health center" has the meaning given the term "teaching health center" in section 749A.

Subpart XII—Community-Based Collaborative Care Network Program

SEC. 340I. [256i] COMMUNITY-BASED COLLABORATIVE CARE NETWORK PROGRAM. [54]

(a) IN GENERAL.—The Secretary may award grants to eligible entities to support community-based collaborative care networks that meet the requirements of subsection (b).

(b) COMMUNITY-BASED COLLABORATIVE CARE NETWORKS.—

(1) DESCRIPTION.—A community-based collaborative care network (referred to in this section as a "network") shall be a consortium of health care providers with a joint governance structure (including providers within a single entity) that provides comprehensive coordinated and integrated health care services (as defined by the Secretary) for low-income populations.

(2) REQUIRED INCLUSION.—A network shall include the following providers (unless such provider does not exist within the community, declines or refuses to participate, or places unreasonable conditions on their participation):

(A) A hospital that meets the criteria in section 1923(b)(1) of the Social Security Act; and

(B) All Federally qualified health centers (as defined in section 1861(aa) of the Social Security Act located in the community.

(3) PRIORITY.—In awarding grants, the Secretary shall give priority to networks that include—

(A) the capability to provide the broadest range of services to low-income individuals;

(B) the broadest range of providers that currently serve a high volume of low-income individuals; and

(C) a county or municipal department of health.

(c) APPLICATION.—

(1) APPLICATION.—A network described in subsection (b) shall submit an application to the Secretary.

(2) RENEWAL.—In subsequent years, based on the performance of grantees, the Secretary may provide renewal grants to prior year grant recipients.

(d) USE OF FUNDS.—

(1) USE BY GRANTEES.—Grant funds may be used for the following activities:

(A) Assist low-income individuals to—

(i) access and appropriately use health services;

(ii) enroll in health coverage programs; and

(iii) obtain a regular primary care provider or a medical home.

(B) Provide case management and care management.

(C) Perform health outreach using neighborhood health workers or through other means.

[54] Section 301(c) of Public Law 115–63 provides for amendments to part D of the Public Health Service Act by redesignating the second subpart XI and the second section 340H as subpart XII and section 340I, respectively. Such amendment probably should have included a reference to title III in the amendment instruction; however, such amendments were carried out to reflect the probable intent of Congress.

(D) Provide transportation.

(E) Expand capacity, including through telehealth, after-hours services or urgent care.

(F) Provide direct patient care services.

(2) GRANT FUNDS TO HRSA GRANTEES.—The Secretary may limit the percent of grant funding that may be spent on direct care services provided by grantees of programs administered by the Health Resources and Services Administration or impose other requirements on such grantees deemed necessary.

(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section such sums as may be necessary for each of fiscal years 2011 through 2015.

[Part E (secs. 341–347) repealed by section 3405(a) of Public Law 106–310 (as amended by section 110(b) of Public Law 114–198).]

PART F—LICENSING—BIOLOGICAL PRODUCTS AND CLINICAL LABORATORIES [55]

Subpart 1—Biological Products

REGULATION OF BIOLOGICAL PRODUCTS [56]

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

(A) a biologics license under this subsection or subsection (k) is in effect for the biological product; and

(B) each package of the biological product is plainly marked with—

(i) the proper name of the biological product contained in the package;

(ii) the name, address, and applicable license number of the manufacturer of the biological product; and

(iii) the expiration date of the biological product.

(2)(A) The Secretary shall establish, by regulation, requirements for the approval, suspension, and revocation of biologics licenses.

(B) PEDIATRIC STUDIES.—A person that submits an application for a license under this paragraph shall submit to the Secretary as part of the application any assessments required under section 505B of the Federal Food, Drug, and Cosmetic Act.

(C) The Secretary shall approve a biologics license application—

(i) on the basis of a demonstration that—

[55] 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".

[56] Section 123(f) of Public Law 105–115 (111 Stat. 2324) provides as follows:

"(f) SPECIAL RULE.—The Secretary of Health and Human Services shall take measures to minimize differences in the review and approval of products required to have approved biologics license applications under section 351 of the Public Health Service Act (42 U.S.C. 262) and products required to have approved new drug applications under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(1)).".

(I) the biological product that is the subject of the application is safe, pure, and potent; and

(II) the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent; and

(ii) if the applicant (or other appropriate person) consents to the inspection of the facility that is the subject of the application, in accordance with subsection (c).

(D) POSTMARKET STUDIES AND CLINICAL TRIALS; LABELING; RISK EVALUATION AND MITIGATION STRATEGY.—A person that submits an application for a license under this paragraph is subject to sections 505(o), 505(p), and 505–1 of the Federal Food, Drug, and Cosmetic Act.

(E)(i) The Secretary may rely upon qualified data summaries to support the approval of a supplemental application, with respect to a qualified indication for a drug, submitted under this subsection, if such supplemental application complies with the requirements of subparagraph (B) of section 505(c)(5) of the Federal Food, Drug, and Cosmetic Act.

(ii) In this subparagraph, the terms "qualified indication" and "qualified data summary" have the meanings given such terms in section 505(c)(5) of the Federal Food, Drug, and Cosmetic Act.

(3) The Secretary shall prescribe requirements under which a biological product undergoing investigation shall be exempt from the requirements of paragraph (1).

(b) No person shall falsely label or mark any package or container of any biological product or alter any label or mark on the package or container of the biological product so as to falsify the label or mark.

(c) Any officer, agent, or employee of the Department of Health and Human Services, authorized by the Secretary for the purpose, may during all reasonable hours enter and inspect any establishment for the propagation or manufacture and preparation of any biological product.

(d)(1) Upon a determination that a batch, lot, or other quantity of a product licensed under this section presents an imminent or substantial hazard to the public health, the Secretary shall issue an order immediately ordering the recall of such batch, lot, or other quantity of such product. An order under this paragraph shall be issued in accordance with section 554 of title 5, United States Code.

(2) Any violation of paragraph (1) shall subject the violator to a civil penalty of up to $100,000 per day of violation. The amount of a civil penalty under this paragraph shall, effective December 1 of each year beginning 1 year after the effective date of this paragraph, be increased by the percent change in the Consumer Price Index for the base quarter of such year over the Consumer Price Index for the base quarter of the preceding year, adjusted to the nearest 1/10 of 1 percent. For purposes of this paragraph, the term "base quarter", as used with respect to a year, means the calendar quarter ending on September 30 of such year and the price index for a base quarter is the arithmetical mean of such index for the 3 months comprising such quarter.

(e) No person shall interfere with any officer, agent, or employee of the Service in the performance of any duty imposed upon him by this section or by regulations made by authority thereof.

(f) Any person who shall violate, or aid or abet in violating, any of the provisions of this section shall be punished upon conviction by a fine not exceeding $500 or by imprisonment not exceeding one year, or by both such fine and imprisonment, in the discretion of the court.

(g) Nothing contained in this Act shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of the Federal Food, Drug, and Cosmetic Act (U.S.C., 1940 edition, title 21, ch. 9).[57]

(h)[58] A partially processed biological product which—

(1) is not in a form applicable to the prevention, treatment, or cure of diseases or injuries of man;

(2) is not intended for sale in the United States; and

(3) is intended for further manufacture into final dosage form outside the United States,

shall be subject to no restriction on the export of the product under this Act or the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et. seq.) if the product is manufactured, processed, packaged, and held in conformity with current good manufacturing practice requirements or meets international manufacturing standards as certified by an international standards organization recognized by the Secretary and meets the requirements of section 801(e)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(e)).

(i) In this section:

(1) The term "biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.

(2) The term "biosimilar" or "biosimilarity", in reference to a biological product that is the subject of an application under subsection (k), means—

(A) that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components; and

(B) there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.

(3) The term "interchangeable" or "interchangeability", in reference to a biological product that is shown to meet the standards described in subsection (k)(4), means that the biological product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

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

[58] 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.

(4) The term "reference product" means the single biological product licensed under subsection (a) against which a biological product is evaluated in an application submitted under subsection (k).

(j) The Federal Food, Drug, and Cosmetic Act, including the requirements under sections 505(o), 505(p), and 505–1 of such Act, applies to a biological product subject to regulation under this section, except that a product for which a license has been approved under subsection (a) shall not be required to have an approved application under section 505 of such Act.

(k) LICENSURE OF BIOLOGICAL PRODUCTS AS BIOSIMILAR OR INTERCHANGEABLE.—

(1) IN GENERAL.—Any person may submit an application for licensure of a biological product under this subsection.

(2) CONTENT.—

(A) IN GENERAL.—

(i) REQUIRED INFORMATION.—An application submitted under this subsection shall include information demonstrating that—

(I) the biological product is biosimilar to a reference product based upon data derived from—

(aa) analytical studies that demonstrate that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components;

(bb) an assessment of toxicity (which may rely on, or consist of, a study or studies described in item (aa) or (cc)); and

(cc) a clinical study or studies (including the assessment of immunogenicity and pharmacokinetics or pharmacodynamics) that are sufficient to demonstrate safety, purity, and potency in 1 or more appropriate conditions of use for which the reference product is licensed and intended to be used and for which licensure is sought for the biological product;

(II) the biological product and reference product utilize the same mechanism or mechanisms of action for the condition or conditions of use prescribed, recommended, or suggested in the proposed labeling, but only to the extent the mechanism or mechanisms of action are known for the reference product;

(III) the condition or conditions of use prescribed, recommended, or suggested in the labeling proposed for the biological product have been previously approved for the reference product;

(IV) the route of administration, the dosage form, and the strength of the biological product are the same as those of the reference product; and

(V) the facility in which the biological product is manufactured, processed, packed, or held meets

standards designed to assure that the biological product continues to be safe, pure, and potent.

(ii) DETERMINATION BY SECRETARY.—The Secretary may determine, in the Secretary's discretion, that an element described in clause (i)(I) is unnecessary in an application submitted under this subsection.

(iii) ADDITIONAL INFORMATION.—An application submitted under this subsection—

(I) shall include publicly-available information regarding the Secretary's previous determination that the reference product is safe, pure, and potent;

(II) may include any additional information in support of the application, including publicly-available information with respect to the reference product or another biological product; and

(III) may include information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the biological product have been previously approved for the reference product.

(B) INTERCHANGEABILITY.—An application (or a supplement to an application) submitted under this subsection may include information demonstrating that the biological product meets the standards described in paragraph (4).

(3) EVALUATION BY SECRETARY.—Upon review of an application (or a supplement to an application) submitted under this subsection, the Secretary shall license the biological product under this subsection if—

(A) the Secretary determines that the information submitted in the application (or the supplement) is sufficient to show that the biological product—

(i) is biosimilar to the reference product; or

(ii) meets the standards described in paragraph (4), and therefore is interchangeable with the reference product; and

(B) the applicant (or other appropriate person) consents to the inspection of the facility that is the subject of the application, in accordance with subsection (c).

(4) SAFETY STANDARDS FOR DETERMINING INTERCHANGEABILITY.—Upon review of an application submitted under this subsection or any supplement to such application, the Secretary shall determine the biological product to be interchangeable with the reference product if the Secretary determines that the information submitted in the application (or a supplement to such application) is sufficient to show that—

(A) the biological product—

(i) is biosimilar to the reference product; and

(ii) can be expected to produce the same clinical result as the reference product in any given patient; and

(B) for a biological product that is administered more than once to an individual, the risk in terms of safety or

diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch.

(5) GENERAL RULES.—

(A) ONE REFERENCE PRODUCT PER APPLICATION.—A biological product, in an application submitted under this subsection, may not be evaluated against more than 1 reference product.

(B) REVIEW.—An application submitted under this subsection shall be reviewed by the division within the Food and Drug Administration that is responsible for the review and approval of the application under which the reference product is licensed.

(C) RISK EVALUATION AND MITIGATION STRATEGIES.—The authority of the Secretary with respect to risk evaluation and mitigation strategies under the Federal Food, Drug, and Cosmetic Act shall apply to biological products licensed under this subsection in the same manner as such authority applies to biological products licensed under subsection (a).

(6) EXCLUSIVITY FOR FIRST INTERCHANGEABLE BIOLOGICAL PRODUCT.—The Secretary shall not make approval as an interchangeable biological product effective with respect to an application submitted under this subsection that relies on the same reference product for which a prior biological product has received a determination of interchangeability for any condition of use, until the earlier of—

(A) 1 year after the first commercial marketing of the first interchangeable biosimilar biological product to be approved as interchangeable for that reference product;

(B) 18 months after—

(i) a final court decision on all patents in suit in an action instituted under subsection (l)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or

(ii) the dismissal with or without prejudice of an action instituted under subsection (l)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or

(C)(i) 42 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has been sued under subsection (l)(6) and such litigation is still ongoing within such 42-month period; or

(ii) 18 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has not been sued under subsection (l)(6).

For purposes of this paragraph, the term "final court decision" means a final decision of a court from which no appeal (other than a petition to the United States Supreme Court for a writ

of certiorari) has been or can be taken, and the term "first interchangeable biosimilar biological product" means any interchangeable biosimilar biological product that is approved on the first day on which such a product is approved as interchangeable with the reference product.

(7) EXCLUSIVITY FOR REFERENCE PRODUCT.—

(A) EFFECTIVE DATE OF BIOSIMILAR APPLICATION APPROVAL.—Approval of an application under this subsection may not be made effective by the Secretary until the date that is 12 years after the date on which the reference product was first licensed under subsection (a).

(B) FILING PERIOD.—An application under this subsection may not be submitted to the Secretary until the date that is 4 years after the date on which the reference product was first licensed under subsection (a).

(C) FIRST LICENSURE.—Subparagraphs (A) and (B) shall not apply to a license for or approval of—

(i) a supplement for the biological product that is the reference product; or

(ii) a subsequent application filed by the same sponsor or manufacturer of the biological product that is the reference product (or a licensor, predecessor in interest, or other related entity) for—

(I) a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength; or

(II) a modification to the structure of the biological product that does not result in a change in safety, purity, or potency.

(D) DEEMED LICENSES.—

(i) NO ADDITIONAL EXCLUSIVITY THROUGH DEEMING.—An approved application that is deemed to be a license for a biological product under this section pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009 shall not be treated as having been first licensed under subsection (a) for purposes of subparagraphs (A) and (B).

(ii) APPLICATION OF LIMITATIONS ON EXCLUSIVITY.—Subparagraph (C) shall apply with respect to a reference product referred to in such subparagraph that was the subject of an approved application that was deemed to be a license pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009.

(iii) APPLICABILITY.—The exclusivity periods described in section 527, section 505A(b)(1)(A)(ii), and section 505A(c)(1)(A)(ii) of the Federal Food, Drug, and Cosmetic Act shall continue to apply to a biological product after an approved application for the biological product is deemed to be a license for the biological product under subsection (a) pursuant to section

7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009.

(8) GUIDANCE DOCUMENTS.—

(A) IN GENERAL.—The Secretary may, after opportunity for public comment, issue guidance in accordance, except as provided in subparagraph (B)(i), with section 701(h) of the Federal Food, Drug, and Cosmetic Act with respect to the licensure of a biological product under this subsection. Any such guidance may be general or specific.

(B) PUBLIC COMMENT.—

(i) IN GENERAL.—The Secretary shall provide the public an opportunity to comment on any proposed guidance issued under subparagraph (A) before issuing final guidance.

(ii) INPUT REGARDING MOST VALUABLE GUIDANCE.—The Secretary shall establish a process through which the public may provide the Secretary with input regarding priorities for issuing guidance.

(C) NO REQUIREMENT FOR APPLICATION CONSIDERATION.—The issuance (or non-issuance) of guidance under subparagraph (A) shall not preclude the review of, or action on, an application submitted under this subsection.

(D) REQUIREMENT FOR PRODUCT CLASS-SPECIFIC GUIDANCE.—If the Secretary issues product class-specific guidance under subparagraph (A), such guidance shall include a description of—

(i) the criteria that the Secretary will use to determine whether a biological product is highly similar to a reference product in such product class; and

(ii) the criteria, if available, that the Secretary will use to determine whether a biological product meets the standards described in paragraph (4).

(E) CERTAIN PRODUCT CLASSES.—

(i) GUIDANCE.—The Secretary may indicate in a guidance document that the science and experience, as of the date of such guidance, with respect to a product or product class (not including any recombinant protein) does not allow approval of an application for a license as provided under this subsection for such product or product class.

(ii) MODIFICATION OR REVERSAL.—The Secretary may issue a subsequent guidance document under subparagraph (A) to modify or reverse a guidance document under clause (i).

(iii) NO EFFECT ON ABILITY TO DENY LICENSE.—Clause (i) shall not be construed to require the Secretary to approve a product with respect to which the Secretary has not indicated in a guidance document that the science and experience, as described in clause (i), does not allow approval of such an application.

(9) PUBLIC LISTING.—

(A) IN GENERAL.—

(i) INITIAL PUBLICATION.—Not later than 180 days after the date of enactment of this paragraph, the Sec-

retary shall publish and make available to the public in a searchable, electronic format—

(I) a list of each biological product, by nonproprietary name (proper name), for which, as of such date of enactment, a biologics license under subsection (a) or this subsection is in effect, or that, as of such date of enactment, is deemed to be licensed under this section pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009;

(II) the date of licensure of the marketing application and the application number; and

(III) with respect to each biological product described in subclause (I), the licensure status, and, as available, the marketing status.

(ii) REVISIONS.—Every 30 days after the publication of the first list under clause (i), the Secretary shall revise the list to include each biological product which has been licensed under subsection (a) or this subsection during the 30-day period or deemed licensed under this section pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009.

(iii) PATENT INFORMATION.—Not later than 30 days after a list of patents under subsection (l)(3)(A), or a supplement to such list under subsection (l)(7), has been provided by the reference product sponsor to the subsection (k) applicant respecting a biological product included on the list published under this subparagraph, the reference product sponsor shall provide such list of patents (or supplement thereto) and their corresponding expiry dates to the Secretary, and the Secretary shall, in revisions made under clause (ii), include such information for such biological product. Within 30 days of providing any subsequent or supplemental list of patents to any subsequent subsection (k) applicant under subsection (l)(3)(A) or (l)(7), the reference product sponsor shall update the information provided to the Secretary under this clause with any additional patents from such subsequent or supplemental list and their corresponding expiry dates.

(iv) LISTING OF EXCLUSIVITIES.—For each biological product included on the list published under this subparagraph, the Secretary shall specify each exclusivity period under paragraph (6) or paragraph (7) for which the Secretary has determined such biological product to be eligible and that has not concluded.

(B) REVOCATION OR SUSPENSION OF LICENSE.—If the license of a biological product is determined by the Secretary to have been revoked or suspended for safety, purity, or potency reasons, it may not be published in the list under subparagraph (A). If such revocation or suspension occurred after inclusion of such biological product in the

list published under subparagraph (A), the reference product sponsor shall notify the Secretary that—

(i) the biological product shall be immediately removed from such list for the same period as the revocation or suspension; and

(ii) a notice of the removal shall be published in the Federal Register.

(l) PATENTS.—

(1) CONFIDENTIAL ACCESS TO SUBSECTION (k) APPLICATION.—

(A) APPLICATION OF PARAGRAPH.—Unless otherwise agreed to by a person that submits an application under subsection (k) (referred to in this subsection as the "subsection (k) applicant") and the sponsor of the application for the reference product (referred to in this subsection as the "reference product sponsor"), the provisions of this paragraph shall apply to the exchange of information described in this subsection.

(B) IN GENERAL.—

(i) PROVISION OF CONFIDENTIAL INFORMATION.—When a subsection (k) applicant submits an application under subsection (k), such applicant shall provide to the persons described in clause (ii), subject to the terms of this paragraph, confidential access to the information required to be produced pursuant to paragraph (2) and any other information that the subsection (k) applicant determines, in its sole discretion, to be appropriate (referred to in this subsection as the "confidential information").

(ii) RECIPIENTS OF INFORMATION.—The persons described in this clause are the following:

(I) OUTSIDE COUNSEL.—One or more attorneys designated by the reference product sponsor who are employees of an entity other than the reference product sponsor (referred to in this paragraph as the "outside counsel"), provided that such attorneys do not engage, formally or informally, in patent prosecution relevant or related to the reference product.

(II) IN-HOUSE COUNSEL.—One attorney that represents the reference product sponsor who is an employee of the reference product sponsor, provided that such attorney does not engage, formally or informally, in patent prosecution relevant or related to the reference product.

(iii) PATENT OWNER ACCESS.—A representative of the owner of a patent exclusively licensed to a reference product sponsor with respect to the reference product and who has retained a right to assert the patent or participate in litigation concerning the patent may be provided the confidential information, provided that the representative informs the reference product sponsor and the subsection (k) applicant of his or her agreement to be subject to the confidentiality

provisions set forth in this paragraph, including those under clause (ii).

(C) LIMITATION ON DISCLOSURE.—No person that receives confidential information pursuant to subparagraph (B) shall disclose any confidential information to any other person or entity, including the reference product sponsor employees, outside scientific consultants, or other outside counsel retained by the reference product sponsor, without the prior written consent of the subsection (k) applicant, which shall not be unreasonably withheld.

(D) USE OF CONFIDENTIAL INFORMATION.—Confidential information shall be used for the sole and exclusive purpose of determining, with respect to each patent assigned to or exclusively licensed by the reference product sponsor, whether a claim of patent infringement could reasonably be asserted if the subsection (k) applicant engaged in the manufacture, use, offering for sale, sale, or importation into the United States of the biological product that is the subject of the application under subsection (k).

(E) OWNERSHIP OF CONFIDENTIAL INFORMATION.—The confidential information disclosed under this paragraph is, and shall remain, the property of the subsection (k) applicant. By providing the confidential information pursuant to this paragraph, the subsection (k) applicant does not provide the reference product sponsor or the outside counsel any interest in or license to use the confidential information, for purposes other than those specified in subparagraph (D).

(F) EFFECT OF INFRINGEMENT ACTION.—In the event that the reference product sponsor files a patent infringement suit, the use of confidential information shall continue to be governed by the terms of this paragraph until such time as a court enters a protective order regarding the information. Upon entry of such order, the subsection (k) applicant may redesignate confidential information in accordance with the terms of that order. No confidential information shall be included in any publicly-available complaint or other pleading. In the event that the reference product sponsor does not file an infringement action by the date specified in paragraph (6), the reference product sponsor shall return or destroy all confidential information received under this paragraph, provided that if the reference product sponsor opts to destroy such information, it will confirm destruction in writing to the subsection (k) applicant.

(G) RULE OF CONSTRUCTION.—Nothing in this paragraph shall be construed—

(i) as an admission by the subsection (k) applicant regarding the validity, enforceability, or infringement of any patent; or

(ii) as an agreement or admission by the subsection (k) applicant with respect to the competency, relevance, or materiality of any confidential information.

(H) EFFECT OF VIOLATION.—The disclosure of any confidential information in violation of this paragraph shall be deemed to cause the subsection (k) applicant to suffer irreparable harm for which there is no adequate legal remedy and the court shall consider immediate injunctive relief to be an appropriate and necessary remedy for any violation or threatened violation of this paragraph.

(2) SUBSECTION (k) APPLICATION INFORMATION.—Not later than 20 days after the Secretary notifies the subsection (k) applicant that the application has been accepted for review, the subsection (k) applicant—

(A) shall provide to the reference product sponsor a copy of the application submitted to the Secretary under subsection (k), and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application; and

(B) may provide to the reference product sponsor additional information requested by or on behalf of the reference product sponsor.

(3) LIST AND DESCRIPTION OF PATENTS.—

(A) LIST BY REFERENCE PRODUCT SPONSOR.—Not later than 60 days after the receipt of the application and information under paragraph (2), the reference product sponsor shall provide to the subsection (k) applicant—

(i) a list of patents for which the reference product sponsor believes a claim of patent infringement could reasonably be asserted by the reference product sponsor, or by a patent owner that has granted an exclusive license to the reference product sponsor with respect to the reference product, if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application; and

(ii) an identification of the patents on such list that the reference product sponsor would be prepared to license to the subsection (k) applicant.

(B) LIST AND DESCRIPTION BY SUBSECTION (k) APPLICANT.—Not later than 60 days after receipt of the list under subparagraph (A), the subsection (k) applicant—

(i) may provide to the reference product sponsor a list of patents to which the subsection (k) applicant believes a claim of patent infringement could reasonably be asserted by the reference product sponsor if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application;

(ii) shall provide to the reference product sponsor, with respect to each patent listed by the reference product sponsor under subparagraph (A) or listed by the subsection (k) applicant under clause (i)—

(I) a detailed statement that describes, on a claim by claim basis, the factual and legal basis of

the opinion of the subsection (k) applicant that such patent is invalid, unenforceable, or will not be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application; or

(II) a statement that the subsection (k) applicant does not intend to begin commercial marketing of the biological product before the date that such patent expires; and

(iii) shall provide to the reference product sponsor a response regarding each patent identified by the reference product sponsor under subparagraph (A)(ii).

(C) DESCRIPTION BY REFERENCE PRODUCT SPONSOR.—Not later than 60 days after receipt of the list and statement under subparagraph (B), the reference product sponsor shall provide to the subsection (k) applicant a detailed statement that describes, with respect to each patent described in subparagraph (B)(ii)(I), on a claim by claim basis, the factual and legal basis of the opinion of the reference product sponsor that such patent will be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application and a response to the statement concerning validity and enforceability provided under subparagraph (B)(ii)(I).

(4) PATENT RESOLUTION NEGOTIATIONS.—

(A) IN GENERAL.—After receipt by the subsection (k) applicant of the statement under paragraph (3)(C), the reference product sponsor and the subsection (k) applicant shall engage in good faith negotiations to agree on which, if any, patents listed under paragraph (3) by the subsection (k) applicant or the reference product sponsor shall be the subject of an action for patent infringement under paragraph (6).

(B) FAILURE TO REACH AGREEMENT.—If, within 15 days of beginning negotiations under subparagraph (A), the subsection (k) applicant and the reference product sponsor fail to agree on a final and complete list of which, if any, patents listed under paragraph (3) by the subsection (k) applicant or the reference product sponsor shall be the subject of an action for patent infringement under paragraph (6), the provisions of paragraph (5) shall apply to the parties.

(5) PATENT RESOLUTION IF NO AGREEMENT.—

(A) NUMBER OF PATENTS.—The subsection (k) applicant shall notify the reference product sponsor of the number of patents that such applicant will provide to the reference product sponsor under subparagraph (B)(i)(I).

(B) EXCHANGE OF PATENT LISTS.—

(i) IN GENERAL.—On a date agreed to by the subsection (k) applicant and the reference product sponsor, but in no case later than 5 days after the subsection (k) applicant notifies the reference product sponsor under subparagraph (A), the subsection (k) applicant and the reference product sponsor shall simultaneously exchange—

(I) the list of patents that the subsection (k) applicant believes should be the subject of an action for patent infringement under paragraph (6); and

(II) the list of patents, in accordance with clause (ii), that the reference product sponsor believes should be the subject of an action for patent infringement under paragraph (6).

(ii) NUMBER OF PATENTS LISTED BY REFERENCE PRODUCT SPONSOR.—

(I) IN GENERAL.—Subject to subclause (II), the number of patents listed by the reference product sponsor under clause (i)(II) may not exceed the number of patents listed by the subsection (k) applicant under clause (i)(I).

(II) EXCEPTION.—If a subsection (k) applicant does not list any patent under clause (i)(I), the reference product sponsor may list 1 patent under clause (i)(II).

(6) IMMEDIATE PATENT INFRINGEMENT ACTION.—

(A) ACTION IF AGREEMENT ON PATENT LIST.—If the subsection (k) applicant and the reference product sponsor agree on patents as described in paragraph (4), not later than 30 days after such agreement, the reference product sponsor shall bring an action for patent infringement with respect to each such patent.

(B) ACTION IF NO AGREEMENT ON PATENT LIST.—If the provisions of paragraph (5) apply to the parties as described in paragraph (4)(B), not later than 30 days after the exchange of lists under paragraph (5)(B), the reference product sponsor shall bring an action for patent infringement with respect to each patent that is included on such lists.

(C) NOTIFICATION AND PUBLICATION OF COMPLAINT.—

(i) NOTIFICATION TO SECRETARY.—Not later than 30 days after a complaint is served to a subsection (k) applicant in an action for patent infringement described under this paragraph, the subsection (k) applicant shall provide the Secretary with notice and a copy of such complaint.

(ii) PUBLICATION BY SECRETARY.—The Secretary shall publish in the Federal Register notice of a complaint received under clause (i).

(7) NEWLY ISSUED OR LICENSED PATENTS.—In the case of a patent that—

(A) is issued to, or exclusively licensed by, the reference product sponsor after the date that the reference product sponsor provided the list to the subsection (k) applicant under paragraph (3)(A); and

(B) the reference product sponsor reasonably believes that, due to the issuance of such patent, a claim of patent infringement could reasonably be asserted by the reference product sponsor if a person not licensed by the reference product sponsor engaged in the making, using, offering to

sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application,

not later than 30 days after such issuance or licensing, the reference product sponsor shall provide to the subsection (k) applicant a supplement to the list provided by the reference product sponsor under paragraph (3)(A) that includes such patent, not later than 30 days after such supplement is provided, the subsection (k) applicant shall provide a statement to the reference product sponsor in accordance with paragraph (3)(B), and such patent shall be subject to paragraph (8).

(8) NOTICE OF COMMERCIAL MARKETING AND PRELIMINARY INJUNCTION.—

(A) NOTICE OF COMMERCIAL MARKETING.—The subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k).

(B) PRELIMINARY INJUNCTION.—After receiving the notice under subparagraph (A) and before such date of the first commercial marketing of such biological product, the reference product sponsor may seek a preliminary injunction prohibiting the subsection (k) applicant from engaging in the commercial manufacture or sale of such biological product until the court decides the issue of patent validity, enforcement, and infringement with respect to any patent that is—

(i) included in the list provided by the reference product sponsor under paragraph (3)(A) or in the list provided by the subsection (k) applicant under paragraph (3)(B); and

(ii) not included, as applicable, on—

(I) the list of patents described in paragraph (4); or

(II) the lists of patents described in paragraph (5)(B).

(C) REASONABLE COOPERATION.—If the reference product sponsor has sought a preliminary injunction under subparagraph (B), the reference product sponsor and the subsection (k) applicant shall reasonably cooperate to expedite such further discovery as is needed in connection with the preliminary injunction motion.

(9) LIMITATION ON DECLARATORY JUDGMENT ACTION.—

(A) SUBSECTION (k) APPLICATION PROVIDED.—If a subsection (k) applicant provides the application and information required under paragraph (2)(A), neither the reference product sponsor nor the subsection (k) applicant may, prior to the date notice is received under paragraph (8)(A), bring any action under section 2201 of title 28, United States Code, for a declaration of infringement, validity, or enforceability of any patent that is described in clauses (i) and (ii) of paragraph (8)(B).

(B) SUBSEQUENT FAILURE TO ACT BY SUBSECTION (k) APPLICANT.—If a subsection (k) applicant fails to complete

an action required of the subsection (k) applicant under paragraph (3)(B)(ii), paragraph (5), paragraph (6)(C)(i), paragraph (7), or paragraph (8)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28, United States Code, for a declaration of infringement, validity, or enforceability of any patent included in the list described in paragraph (3)(A), including as provided under paragraph (7).

(C) SUBSECTION (k) APPLICATION NOT PROVIDED.—If a subsection (k) applicant fails to provide the application and information required under paragraph (2)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28, United States Code, for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product.

(m) PEDIATRIC STUDIES.—

(1) APPLICATION OF CERTAIN PROVISIONS.—The provisions of subsections (a), (d), (e), (f), (h), (i), (j), (k), (l), (n), and (p) of section 505A of the Federal Food, Drug, and Cosmetic Act shall apply with respect to the extension of a period under paragraphs (2) and (3) to the same extent and in the same manner as such provisions apply with respect to the extension of a period under subsection (b) or (c) of section 505A of the Federal Food, Drug, and Cosmetic Act.

(2) MARKET EXCLUSIVITY FOR NEW BIOLOGICAL PRODUCTS.—If, prior to approval of an application that is submitted under subsection (a), the Secretary determines that information relating to the use of a new biological product in the pediatric population may produce health benefits in that population, the Secretary makes a written request for pediatric studies (which shall include a timeframe for completing such studies), the applicant agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe, and the reports thereof are submitted and accepted in accordance with section 505A(d)(4) of the Federal Food, Drug, and Cosmetic Act—

(A) the periods for such biological product referred to in subsection (k)(7) are deemed to be 4 years and 6 months rather than 4 years and 12 years and 6 months rather than 12 years; and

(B) if the biological product is designated under section 526 for a rare disease or condition, the period for such biological product referred to in section 527(a) is deemed to be 7 years and 6 months rather than 7 years.

(3) MARKET EXCLUSIVITY FOR ALREADY-MARKETED BIOLOGICAL PRODUCTS.—If the Secretary determines that information relating to the use of a licensed biological product in the pediatric population may produce health benefits in that population and makes a written request to the holder of an approved application under subsection (a) for pediatric studies (which shall include a timeframe for completing such studies), the holder agrees to the request, such studies are completed using appropriate formulations for each age group for which

the study is requested within any such timeframe, and the reports thereof are submitted and accepted in accordance with section 505A(d)(4) of the Federal Food, Drug, and Cosmetic Act—

(A) the periods for such biological product referred to in subsection (k)(7) are deemed to be 4 years and 6 months rather than 4 years and 12 years and 6 months rather than 12 years; and

(B) if the biological product is designated under section 526 for a rare disease or condition, the period for such biological product referred to in section 527(a) is deemed to be 7 years and 6 months rather than 7 years.

(4) EXCEPTION.—The Secretary shall not extend a period referred to in paragraph (2)(A), (2)(B), (3)(A), or (3)(B) if the determination under section 505A(d)(4) is made later than 9 months prior to the expiration of such period.

(n) DATE OF APPROVAL IN THE CASE OF RECOMMENDED CONTROLS UNDER THE CSA.—

(1) IN GENERAL.—In the case of an application under subsection (a) with respect to a biological product for which the Secretary provides notice to the sponsor that the Secretary intends to issue a scientific and medical evaluation and recommend controls under the Controlled Substances Act, approval of such application shall not take effect until the interim final rule controlling the biological product is issued in accordance with section 201(j) of the Controlled Substances Act.

(2) DATE OF APPROVAL.—For purposes of this section, with respect to an application described in paragraph (1), references to the date of approval of such application, or licensure of the product subject to such application, shall mean the later of—

(A) the date an application is approved under subsection (a); or

(B) the date of issuance of the interim final rule controlling the biological product.

SEC. 351A. [262a] ENHANCED CONTROL OF DANGEROUS BIOLOGICAL AGENTS AND TOXINS.[59]

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

(1) LIST OF BIOLOGICAL AGENTS AND TOXINS.—

(A) IN GENERAL.—The Secretary shall by regulation establish and maintain a list of each biological agent and each toxin that has the potential to pose a severe threat to public health and safety.

(B) CRITERIA.—In determining whether to include an agent or toxin on the list under subparagraph (A), the Secretary shall—

(i) consider—

[59] A program is carried out by the Secretary of Agriculture with respect to each biological agent and each toxin that the Secretary determines has the potential to pose a severe threat to animal or plant health, or to animal or plant products. Such program has requirements and authorities similar to those established in section 351A above. See subtitle B of title II of Public Law 107–188 (section 211 et seq.; 116 Stat. 647). Subtitle C of such title (section 221 et seq.; 116 Stat. 657) relates to interagency coordination of the two programs.

(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, including with respect to notification requirements under this section, of—

(i) individuals who are involved in the handling and use of such agents and toxins, including appropriate skills to handle such agents and toxins;

(ii) individuals whose responsibilities routinely place them in close proximity to laboratory facilities in which such agents and toxins are being transferred, possessed, or used; and

(iii) individuals who perform administrative or oversight functions of the facility related to the transfer, possession, or use of such agents and toxins on behalf of registered persons;

(B) proper laboratory facilities to contain and dispose of such agents and toxins;

(2) the establishment and enforcement of safeguard and security measures to prevent access to such agents and toxins for use in domestic or international terrorism or for any other criminal purpose;

(3) the establishment of procedures to protect the public safety in the event of a transfer or potential transfer of such an agent or toxin in violation of the safety procedures established under paragraph (1) or the safeguard and security measures established under paragraph (2); and

(4) appropriate availability of biological agents and toxins for research, education, and other legitimate purposes.

(c) POSSESSION AND USE OF LISTED AGENTS AND TOXINS.—The Secretary shall by regulation provide for the establishment and enforcement of standards and procedures governing the possession

and use of listed agents and toxins, including the provisions described in paragraphs (1) through (4) of subsection (b), in order to protect the public health and safety.

(d) REGISTRATION; IDENTIFICATION; DATABASE.—

(1) REGISTRATION.—Regulations under subsections (b) and (c) shall require registration with the Secretary of the possession, use, and transfer of listed agents and toxins, and shall include provisions to ensure that persons seeking to register under such regulations have a lawful purpose to possess, use, or transfer such agents and toxins, including provisions in accordance with subsection (e)(6).

(2) IDENTIFICATION; DATABASE.—Regulations under subsections (b) and (c) shall require that registration include (if available to the person registering) information regarding the characterization of listed agents and toxins to facilitate their identification, including their source. The Secretary shall maintain a national database that includes the names and locations of registered persons, the listed agents and toxins such persons are possessing, using, or transferring, and information regarding the characterization of such agents and toxins.

(e) SAFEGUARD AND SECURITY REQUIREMENTS FOR REGISTERED PERSONS.—

(1) IN GENERAL.—Regulations under subsections (b) and (c) shall include appropriate safeguard and security requirements for persons possessing, using, or transferring a listed agent or toxin commensurate with the risk such agent or toxin poses to public health and safety (including risks posed by the release, theft, or loss of such agent or toxin, or 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 Secretary,

after review of whether such exemption remains necessary, may provide one extension of an additional 30 days.

(4) AGRICULTURAL EMERGENCIES.—Upon request of the Secretary of Agriculture, after the granting by such Secretary of an exemption under section 212(g)(1)(D) of the Agricultural Bioterrorism Protection Act of 2002 pursuant to a finding that there is an agricultural emergency, the Secretary of Health and Human Services may temporarily exempt a person from the applicability of the requirements of this section, in whole or in part, to provide for the timely participation of the person in a response to the agricultural emergency. With respect to the emergency involved, the exemption under this paragraph for a person may not exceed 30 days, except that upon request of the Secretary of Agriculture, the Secretary of Health and Human Services may, after review of whether such exemption remains necessary, provide one extension of an additional 30 days.

(h) DISCLOSURE OF INFORMATION.—

(1) NONDISCLOSURE OF CERTAIN INFORMATION.—No Federal agency specified in paragraph (2) shall disclose under section 552 of title 5, United States Code, any of the following:

(A) Any registration or transfer documentation submitted under subsections (b) and (c) for the possession, use, or transfer of a listed agent or toxin; or information derived therefrom to the extent that it identifies the listed agent or toxin possessed, used, or transferred by a specific registered person or discloses the identity or location of a specific registered person.

(B) The national database developed pursuant to subsection (d), or any other compilation of the registration or transfer information submitted under subsections (b) and (c) to the extent that such compilation discloses site-specific registration or transfer information.

(C) Any portion of a record that discloses the site-specific or transfer-specific safeguard and security measures used by a registered person to prevent unauthorized access to listed agents and toxins.

(D) Any notification of a release of a listed agent or toxin submitted under subsections (b) and (c), or any notification of theft or loss submitted under such subsections.

(E) Any portion of an evaluation or report of an inspection of a specific registered person conducted under subsection (f) that identifies the listed agent or toxin possessed by a specific registered person or that discloses the identity or location of a specific registered person if the agency determines that public disclosure of the information would endanger public health or safety.

(2) COVERED AGENCIES.—For purposes of paragraph (1) only, the Federal agencies specified in this paragraph are the following:

(A) The Department of Health and Human Services, the Department of Justice, the Department of Agriculture, and the Department of Transportation.

(B) Any Federal agency to which information specified in paragraph (1) is transferred by any agency specified in subparagraph (A) of this paragraph.

(C) Any Federal agency that is a registered person, or has a sub-agency component that is a registered person.

(D) Any Federal agency that awards grants or enters into contracts or cooperative agreements involving listed agents and toxins to or with a registered person, and to which information specified in paragraph (1) is transferred by any such registered person.

(3) OTHER EXEMPTIONS.—This subsection may not be construed as altering the application of any exemptions to public disclosure under section 552 of title 5, United States Code, except as to subsection 552(b)(3) of such title, to any of the information specified in paragraph (1).

(4) RULE OF CONSTRUCTION.—Except as specifically provided in paragraph (1), this subsection may not be construed as altering the authority of any Federal agency to withhold under section 552 of title 5, United States Code, or the obligation of any Federal agency to disclose under section 552 of title 5, United States Code, any information, including information relating to—

(A) listed agents and toxins, or individuals seeking access to such agents and toxins;

(B) registered persons, or persons seeking to register their possession, use, or transfer of such agents and toxins;

(C) general safeguard and security policies and requirements under regulations under subsections (b) and (c); or

(D) summary or statistical information concerning registrations, registrants, denials or revocations of registrations, listed agents and toxins, inspection evaluations and reports, or individuals seeking access to such agents and toxins.

(5) DISCLOSURES TO CONGRESS; OTHER DISCLOSURES.—This subsection may not be construed as providing any authority—

(A) to withhold information from the Congress or any committee or subcommittee thereof; or

(B) to withhold information from any person under any other Federal law or treaty.

(i) CIVIL MONEY PENALTY.—[60]

(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),

[60] 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 406 of title 5, United States Code.

(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.—

(1) NOTIFICATION WITH RESPECT TO FEDERAL FACILITIES.—In the event of the release, loss, or theft of an agent or toxin listed by the Secretary pursuant to subsection (a)(1), or by the Secretary of Agriculture pursuant to section 212(a)(1) of the Agricultural Bioterrorism Protection Act of 2002, from or within a laboratory facility owned or operated by the Department of Health and Human Services, or other Federal laboratory facility subject to the requirements of this section, the Secretary, in a manner that does not compromise national security, shall—

(A) not later than 72 hours after such event is reported to the Secretary, notify the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives of such event, including—

(i) the Federal laboratory facility in which such release, loss, or theft occurred; and

(ii) the circumstances of such release, loss, or theft; and

(B) not later than 14 days after such notification, update such Committees on—

(i) any actions taken or planned by the Secretary to mitigate any potential threat such release, loss, or theft may pose to public health and safety; and

(ii) any actions taken or planned by the Secretary to review the circumstances of such release, loss, or theft, and prevent similar events.

(2) ANNUAL REPORT.—The Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives on an annual basis a report—

(A) summarizing the number and nature of notifications received under subsection (e)(8) (relating to theft or loss) and subsection (j) (relating to releases), during the preceding fiscal year;

(B) describing actions taken by the Secretary to address such incidents, such as any corrective action plans required and steps taken to promote adherence to, and compliance with, safety and security best practices, standards, and regulations; and

(C) describing any gaps, challenges, or limitations with respect to ensuring that such safety and security practices are consistently applied and adhered to, and actions taken to address such gaps, challenges, or limitations.

(3) IMPLEMENTATION OF RECOMMENDATIONS OF THE FEDERAL EXPERTS SECURITY ADVISORY PANEL AND THE FAST TRACK ACTION COMMITTEE ON SELECT AGENT REGULATIONS.—

(A) IN GENERAL.—Not later than 1 year after the date of the enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019, the Secretary shall report to the congressional committees of jurisdiction on the implementation of recommendations of the Federal Experts Security Advisory Panel concerning the select agent program.

(B) CONTINUED UPDATES.—The Secretary shall report to the congressional committees of jurisdiction annually following the submission of the report under subparagraph (A) until the recommendations described in such subparagraph are fully implemented, or a justification is provided for the delay in, or lack of, implementation.

(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 2023 through 2027.

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.

SEC. 352A. [263-1] EDUCATION ON BIOLOGICAL PRODUCTS.

(a) INTERNET WEBSITE.—

(1) IN GENERAL.—The Secretary may maintain and operate an internet website to provide educational materials for health care providers, patients, and caregivers, regarding the meaning of the terms, and the standards for review and licensing of, biological products, including biosimilar biological products and interchangeable biosimilar biological products.

(2) CONTENT.—Educational materials provided under paragraph (1) may include—

(A) explanations of key statutory and regulatory terms, including "biosimilar" and "interchangeable", and clarification regarding the use of interchangeable biosimilar biological products;

(B) information related to development programs for biological products, including biosimilar biological products and interchangeable biosimilar biological products and relevant clinical considerations for prescribers, which may include, as appropriate and applicable, information related to the comparability of such biological products;

(C) an explanation of the process for reporting adverse events for biological products, including biosimilar biological products and interchangeable biosimilar biological products; and

(D) an explanation of the relationship between biosimilar biological products and interchangeable biosimilar biological products licensed under section 351(k) and reference products (as defined in section 351(i)), including the standards for review and licensing of each such type of biological product.

(3) FORMAT.—The educational materials provided under paragraph (1) may be—

(A) in formats such as webinars, continuing education modules, videos, fact sheets, infographics, stakeholder toolkits, or other formats as appropriate and applicable; and

(B) tailored for the unique needs of health care providers, patients, caregivers, and other audiences, as the Secretary determines appropriate.

(4) OTHER INFORMATION.—In addition to the information described in paragraph (2), the Secretary shall continue to publish—

(A) the action package of each biological product licensed under subsection (a) or (k) of section 351; or

(B) the summary review of each biological product licensed under subsection (a) or (k) of section 351.

(5) CONFIDENTIAL AND TRADE SECRET INFORMATION.—This subsection does not authorize the disclosure of any trade secret, confidential commercial or financial information, or other matter described in section 552(b) of title 5.

(b) CONTINUING EDUCATION.—The Secretary shall advance education and awareness among health care providers regarding biological products, including biosimilar biological products and interchangeable biosimilar biological products, as appropriate, including by developing or improving continuing education programs that advance the education of such providers on the prescribing of, and relevant clinical considerations with respect to, biological products, including biosimilar biological products and interchangeable biosimilar biological products.

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 performing the laboratory examinations and other procedures, and

(iii) that contains such other information as the Secretary may require to determine compliance with this section, and

the laboratory agrees to provide to the Secretary (or if the laboratory is accredited, to the accreditation body which accredited it) a description of any change in the information submitted under clause (ii) not later than 6 months after the change was put into effect,

(B) the laboratory provides the Secretary—

(i) with satisfactory assurances that the laboratory will be operated in accordance with standards issued by the Secretary under subsection (f), or

(ii) with proof of accreditation under subsection (e),

(C) the laboratory agrees to permit inspections by the Secretary under subsection (g),

(D) the laboratory agrees to make records available and submit reports to the Secretary as the Secretary may reasonably require, and

(E) the laboratory agrees to treat proficiency testing samples in the same manner as it treats materials derived from the human body referred to it for laboratory examinations or other procedures in the ordinary course of business, except that no proficiency testing sample shall be referred to another laboratory for analysis as prohibited under subsection (i)(4).

(2) REQUIREMENTS FOR CERTIFICATES OF WAIVER.—

(A) IN GENERAL.—A laboratory which only performs laboratory examinations and procedures described in paragraph (3) shall be issued a certificate of waiver or have its certificate of waiver renewed if—

(i) the laboratory submits an application—

(I) in such form and manner as the Secretary shall prescribe,

(II) that describes the characteristics of the laboratory examinations and other procedures performed by the laboratory, including the number and types of laboratory examinations and other procedures performed, the methodologies for laboratory examinations and other procedures employed, and the qualifications (educational background, training, and experience) of the personnel

directing and supervising the laboratory and performing the laboratory examinations and other procedures, and

(III) that contains such other information as the Secretary may reasonably require to determine compliance with this section, and

(ii) the laboratory agrees to make records available and submit reports to the Secretary as the Secretary may require.

(B) CHANGES.—If a laboratory makes changes in the examinations and other procedures performed by it only with respect to examinations and procedures which are described in paragraph (3), the laboratory shall report such changes to the Secretary not later than 6 months after the change has been put into effect. If a laboratory proposes to make changes in the examinations and procedures performed by it such that the laboratory will perform an examination or procedure not described in paragraph (3), the laboratory shall report such change to the Secretary before the change takes effect.

(C) EFFECT.—Subsections (f) and (g) shall not apply to a laboratory to which has been issued a certificate of waiver.

(3) EXAMINATIONS AND PROCEDURES.—The examinations and procedures identified in paragraph (2) are laboratory examinations and procedures that have been approved by the Food and Drug Administration for home use or that, as determined by the Secretary, are simple laboratory examinations and procedures that have an insignificant risk of an erroneous result, including those that—

(A) employ methodologies that are so simple and accurate as to render the likelihood of erroneous results by the user negligible, or

(B) the Secretary has determined pose no unreasonable risk of harm to the patient if performed incorrectly.

(4) DEFINITION.—As used in this section, the term "certificate" includes a certificate of waiver issued under paragraph (2).

(e) ACCREDITATION.—

(1) IN GENERAL.—A laboratory may be accredited for purposes of obtaining a certificate if the laboratory—

(A) meets the standards of an approved accreditation body, and

(B) authorizes the accreditation body to submit to the Secretary (or such State agency as the Secretary may designate) such records or other information as the Secretary may require.

(2) APPROVAL OF ACCREDITATION BODIES.—

(A) IN GENERAL.—The Secretary may approve a private nonprofit organization to be an accreditation body for the accreditation of laboratories if—

(i) using inspectors qualified to evaluate the methodologies used by the laboratories in performing laboratory examinations and other procedures, the ac-

creditation body agrees to inspect a laboratory for purposes of accreditation with such frequency as determined by Secretary, [61]

(ii) the standards applied by the body in determining whether or not to accredit a laboratory are equal to or more stringent than the standards issued by the Secretary under subsection (f),

(iii) there is adequate provision for assuring that the standards of the accreditation body continue to be met by the laboratory,

(iv) in the case of any laboratory accredited by the body which has had its accreditation denied, suspended, withdrawn, or revoked or which has had any other action taken against it by the accrediting body, the accrediting body agrees to submit to the Secretary the name of such laboratory within 30 days of the action taken,

(v) the accreditation body agrees to notify the Secretary at least 30 days before it changes its standards, and

(vi) if the accreditation body has its approval withdrawn by the Secretary, the body agrees to notify each laboratory accredited by the body of the withdrawal within 10 days of the withdrawal.

(B) CRITERIA AND PROCEDURES.—The Secretary shall promulgate criteria and procedures for approving an accreditation body and for withdrawing such approval if the Secretary determines that the accreditation body does not meet the requirements of subparagraph (A).

(C) EFFECT OF WITHDRAWAL OF APPROVAL.—If the Secretary withdraws the approval of an accreditation body under subparagraph (B), the certificate of any laboratory accredited by the body shall continue in effect for 60 days after the laboratory receives notification of the withdrawal of the approval, except that the Secretary may extend such period for a laboratory if it [61] 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

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

(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)[62] STANDARDS.—

(1) IN GENERAL.—The Secretary shall issue standards to assure consistent performance by laboratories issued a certificate under this section of valid and reliable laboratory examinations and other procedures. Such standards shall require each laboratory issued a certificate under this section—

(A) to maintain a quality assurance and quality control program adequate and appropriate for the validity and reliability of the laboratory examinations and other procedures of the laboratory and to meet requirements relating to the proper collection, transportation, and storage of specimens and the reporting of results,

(B) to maintain records, equipment, and facilities necessary for the proper and effective operation of the laboratory,

(C) in performing and carrying out its laboratory examinations and other procedures, to use only personnel meeting such qualifications as the Secretary may establish for the direction, supervision, and performance of examinations and procedures within the laboratory, which qualifications shall take into consideration competency, training, experience, job performance, and education and which qualifications shall, as appropriate, be different on the basis of the type of examinations and procedures being 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,

[62] Section 3 of Public Law 100–578 provides that, with respect to subsection (g)(1) and subsections (h) through (m), any reference made in any of such subsections to the standards established under subsection (f) "shall be considered a reference to the standards established under subsection (d) [of section 353], as in effect on December 31, 1988.".

(E) the calibration and quality control requirements of the instruments used,

(F) the type of training required to operate the instruments used in the methodology, and

(G) such other factors as the Secretary considers relevant.

(3) PROFICIENCY TESTING PROGRAM.—

(A) IN GENERAL.—The Secretary shall establish standards for the proficiency testing programs for laboratories issued a certificate under this section which are conducted by the Secretary, conducted by an organization approved under subparagraph (C), or conducted by an approved accrediting body. The standards shall require that a laboratory issued a certificate under this section be tested for each examination and procedure conducted within a category of examinations or procedures for which it has received a certificate, except for examinations and procedures for which the Secretary has determined that a proficiency test cannot reasonably be developed. The testing shall be conducted on a quarterly basis, except where the Secretary determines for technical and scientific reasons that a particular examination or procedure may be tested less frequently (but not less often than twice per year).

(B) CRITERIA.—The standards established under subparagraph (A) shall include uniform criteria for acceptable performance under a proficiency testing program, based on the available technology and the clinical relevance of the laboratory examination or other procedure subject to such program. The criteria shall be established for all examinations and procedures and shall be uniform for each examination and procedure. The standards shall also include a system for grading proficiency testing performance to determine whether a laboratory has performed acceptably for a particular quarter and acceptably for a particular 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 [63] TESTING.—The Secretary shall perform, or shall direct a program approved under subparagraph (C) to perform, onsite proficiency testing to assure compli-

[63] So in law. Probably should not be hyphenated. Compare with text of subparagraph (D).

ance with the requirements of subsection (d)(5)[64]. The Secretary shall perform, on an onsite or other basis, proficiency testing to evaluate the performance of a proficiency testing program approved under subparagraph (C) and to assure quality performance by a laboratory.

(E) TRAINING, TECHNICAL ASSISTANCE, AND ENHANCED PROFICIENCY TESTING.—The Secretary may, in lieu of or in addition to actions authorized under subsection (h), (i), or (j), require any laboratory which fails to perform acceptably on an individual examination and procedure or a category of examination and procedures—

(i) to undertake training and to obtain the necessary technical assistance to meet the requirements of the proficency[65] 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,

[64] So in law. Probably should be "(d)(1)(E)".
[65] So in law. Probably should be "proficiency".

(iv) periodic confirmation and evaluation of the proficiency of individuals involved in screening or interpreting cytological preparations, including announced and unannounced on-site[66] proficiency testing of such individuals, with such testing to take place, to the extent practicable, under normal working conditions,

(v) procedures for detecting inadequately prepared slides, for assuring that no cytological diagnosis is rendered on such slides, and for notifying referring physicians of such slides,

(vi) requirements that all cytological screening be done on the premises of a laboratory that is certified under this section,

(vii) requirements for the retention of cytology slides by laboratories for such periods of time as the Secretary considers appropriate, and

(viii) standards requiring periodic inspection of cytology services by persons capable of evaluating the quality of cytology services.

(g) INSPECTIONS.—

(1) IN GENERAL.—The Secretary may, on an announced or unannounced basis, enter and inspect, during regular hours of operation, laboratories which have been issued a certificate under this section. In conducting such inspections the Secretary shall have access to all facilities, equipment, materials, records, and information that the Secretary determines have a bearing on whether the laboratory is being operated in accordance with this section. As part of such an inspection the Secretary may copy any such material or require to it be[67] 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 inter-

[66] See footnote 1 for paragraph (3)(D).
[67] So in law. Probably should be "require it to be".

mediate sanctions in lieu of the actions authorized by subsection (i).

(2) TYPES OF SANCTIONS.—The intermediate sanctions which may be imposed under paragraph (1) shall consist of—

(A) directed plans of correction,

(B) civil money penalties in an amount not to exceed $10,000 for each violation listed in subsection (i)(1) or for each day of substantial noncompliance with the requirements of this section,

(C) payment for the costs of onsite monitoring, or

(D) any combination of the actions described in subparagraphs (A), (B), and (C).

(3) PROCEDURES.—The Secretary shall develop and implement procedures with respect to when and how each of the intermediate sanctions is to be imposed under paragraph (1). Such procedures shall provide for notice to the laboratory and a reasonable opportunity to respond to the proposed sanction and appropriate procedures for appealing determinations relating to the imposition of intermediate sanctions [68]

(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

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

(G) has not complied with an intermediate sanction imposed under subsection (h).

(2) ACTION BEFORE A HEARING.—If the Secretary determines that—

(A) the failure of a laboratory to comply with the standards of the Secretary under subsection (f) presents an imminent and serious risk to human health, or

(B) a laboratory has engaged in an action described in subparagraph (D) or (E) of paragraph (1),

the Secretary may suspend or limit the certificate of the laboratory before holding a hearing under paragraph (1) regarding such failure or refusal. The opportunity for a hearing shall be provided no later than 60 days from the effective date of the suspension or limitation. A suspension or limitation under this paragraph shall stay in effect until the decision of the Secretary made after the hearing under paragraph (1).

(3) INELIGIBILITY TO OWN OR OPERATE LABORATORIES AFTER REVOCATION.—No person who has owned or operated a laboratory which has had its certificate revoked may, within 2 years of the revocation of the certificate, own or operate a laboratory for which a certificate has been issued under this section, except that if the revocation occurs pursuant to paragraph (4) the Secretary may substitute intermediate sanctions under subsection (h) instead of the 2-year prohibition against ownership or operation which would otherwise apply under this paragraph. The certificate of a laboratory which has been excluded from participation under the medicare program under title XVIII of the Social Security Act because of actions relating to the quality of the laboratory shall be suspended for the period the laboratory is so excluded.

(4) IMPROPER REFERRALS.—Any laboratory that the Secretary determines intentionally refers its proficiency testing samples to another laboratory for analysis may have its certificate revoked for at least one year and shall be subject to appropriate fines and penalties as provided for in subsection (h).

(j) INJUNCTIONS.—Whenever the Secretary has reason to believe that continuation of any activity by a laboratory would constitute a significant hazard to the public health the Secretary may bring suit in the district court of the United States for the district in which such laboratory is situated to enjoin continuation of such activity. Upon proper showing, a temporary injunction or restraining order against continuation of such activity pending issuance of a final order under this subsection shall be granted without bond by such court.

(k) JUDICIAL REVIEW.—

(1) PETITION.—Any laboratory which has had an intermediate sanction imposed under subsection (h) or has had its certificate suspended, revoked, or limited under subsection (i) may, at any time within 60 days after the date the action of the Secretary under subsection (i) or (h) becomes final, file a petition with the United States court of appeals for the circuit wherein the laboratory has its principal place of business for judicial review of such action. As soon as practicable after receipt of the petition, the clerk of the court shall transmit a

copy of the petition to the Secretary or other officer designated by the Secretary for that purpose. As soon as practicable after receipt of the copy, the Secretary shall file in the court the record on which the action of the Secretary is based, as provided in section 2112 of title 28, United States Code.

(2) ADDITIONAL EVIDENCE.—If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence (and evidence in rebuttal of such additional evidence) to be taken before the Secretary, and to be adduced upon the hearing in such manner and upon such terms and conditions as the court may deem proper. The Secretary may modify the findings of the Secretary as to the facts, or make new findings, by reason of the additional evidence so taken, and the Secretary shall file such modified or new findings, and the recommendations of the Secretary, if any, for the modification or setting aside of his original action, with the return of such additional evidence.

(3) JUDGMENT OF COURT.—Upon the filing of the petition referred to in paragraph (1), the court shall have jurisdiction to affirm the action, or to set it aside in whole or in part, temporarily or permanently. The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive.

(4) FINALITY OF JUDGMENT.—The judgment of the court affirming or setting aside, in whole or in part, any such action of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28, United States Code.

(l) SANCTIONS.—Any person who intentionally violates any requirement of this section or any regulation promulgated thereunder shall be imprisoned for not more than one year or fined under title 18, United States Code or both, except that if the conviction is for a second or subsequent violation of such a requirement such person shall be imprisoned for not more than 3 years or fined in accordance with title 18, United States Code or both.

(m) FEES.—

(1) CERTIFICATE FEES.—The Secretary shall require payment of fees for the issuance and renewal of certificates, except that the Secretary shall only require a nominal fee for the issuance and renewal of certificates of waiver.

(2) ADDITIONAL FEES.—The Secretary shall require the payment of fees for inspections of laboratories which are not accredited and for the cost of performing proficiency testing on laboratories which do not participate in proficiency testing programs approved under subsection (f)(3)(C).

(3) CRITERIA.—

(A) FEES UNDER PARAGRAPH (1).—Fees imposed under paragraph (1) shall be sufficient to cover the general costs of administering this section, including evaluating and monitoring proficiency testing programs approved under

subsection (f) and accrediting bodies and implementing and monitoring compliance with the requirements of this section.

(B) FEES UNDER PARAGRAPH (2).—Fees imposed under paragraph (2) shall be sufficient to cover the cost of the Secretary in carrying out the inspections and proficiency testing described in paragraph (2).

(C) FEES IMPOSED UNDER PARAGRAPHS (1) AND (2).—Fees imposed under paragraphs (1) and (2) shall vary by group or classification of laboratory, based on such considerations as the Secretary determines are relevant, which may include the dollar volume and scope of the testing being performed by the laboratories.

(n) INFORMATION.—On April 1, 1990 and annually thereafter, the Secretary shall compile and make available to physicians and the general public information, based on the previous calendar year, which the Secretary determines is useful in evaluating the performance of a laboratory, including—

(1) a list of laboratories which have been convicted under Federal or State laws relating to fraud and abuse, false billings, or kickbacks,

(2) a list of laboratories—

(A) which have had their certificates revoked, suspended, or limited under subsection (i), or

(B) which have been the subject of a sanction under subsection (l),

together with a statement of the reasons for the revocation, suspension, limitation, or sanction,

(3) a list of laboratories subject to intermediate sanctions under subsection (h) together with a statement of the reasons for the sanctions,

(4) a list of laboratories whose accreditation has been withdrawn or revoked together with a statement of the reasons for the withdrawal or revocation,

(5) a list of laboratories against which the Secretary has taken action under subsection (j) together with a statement of the reasons for such action, and

(6) a list of laboratories which have been excluded from participation under title XVIII or XIX of the Social Security Act.

The information to be compiled under paragraphs (1) through (6) shall be information for the calendar year preceding the date the information is to be made available to the public and shall be accompanied by such explanatory information as may be appropriate to assist in the interpretation of the information compiled under such paragraphs.

(o) DELEGATION.—In carrying out this section, the Secretary may, pursuant to agreement, use the services or facilities of any Federal or State or local public agency or nonprofit private organization, and may pay therefor in advance or by way of reimbursement, and in such installments, as the Secretary may determine.

(p) STATE LAWS.—

(1) Except as provided in paragraph (2), nothing in this section shall be construed as affecting the power of any State

to enact and enforce laws relating to the matters covered by this section to the extent that such laws are not inconsistent with this section or with the regulations issued under this section.

(2) If a State enacts laws relating to matters covered by this section which provide for requirements equal to or more stringent than the requirements of this section or than the regulations issued under this section, the Secretary may exempt clinical laboratories in that State from compliance with this section.

(q) CONSULTATIONS.—In carrying out this section, the Secretary shall consult with appropriate private organizations and public agencies.

Subpart 3—Mammography Facilities

SEC. 354. [263b] CERTIFICATION OF MAMMOGRAPHY FACILITIES.

(a) DEFINITIONS.—As used in this section:

(1) ACCREDITATION BODY.—The term "accreditation body" means a body that has been approved by the Secretary under subsection (e)(1)(A) to accredit mammography facilities.

(2) CERTIFICATE.—The term "certificate" means the certificate described in subsection (b)(1).

(3) FACILITY.—

(A) IN GENERAL.—The term "facility" means a hospital, outpatient department, clinic, radiology practice, or mobile unit, an office of a physician, or other facility as determined by the Secretary, that conducts breast cancer screening or diagnosis through mammography activities. Such term does not include a facility of the Department of Veterans Affairs.

(B) ACTIVITIES.—For the purposes of this section, the activities of a facility include the operation of equipment to produce the mammogram, the processing of the film, the initial interpretation of the mammogram and the viewing conditions for that interpretation. Where procedures such as the film processing, or the interpretation of the 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 [69] (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 [70] 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:

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

[70] 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).

(A) The facility has submitted the required materials to the accreditation body within the established time frames for the submission of such materials but the accreditation body is unable to complete the reaccreditation process before the certification expires.

(B) The facility has acquired additional or replacement equipment, or has had significant personnel changes or other unforeseen situations that have caused the facility to be unable to meet reaccreditation timeframes, but in the opinion of the accreditation body have not compromised the quality of mammography.

(3) LIMITED PROVISIONAL CERTIFICATE.—The Secretary may, upon the request of an accreditation body, issue a limited provisional certificate to an entity to enable the entity to conduct examinations for educational purposes while an onsite visit from an accreditation body is in progress. Such certificate shall be valid only during the time the site visit team from the accreditation body is physically in the facility, and in no case shall be valid for longer than 72 hours. The issuance of a certificate under this paragraph, shall not preclude the entity from qualifying for a provisional certificate under paragraph (4).

(4) PROVISIONAL CERTIFICATE.—The Secretary may issue a provisional certificate for an entity to enable the entity to qualify as a facility. The applicant for a provisional certificate shall meet the requirements of subsection (d)(1), except providing information required by clauses (iii) and (iv) of subsection (d)(1)(A). A provisional certificate may be in effect no longer than 6 months from the date it is issued, except that it may be extended once for a period of not more than 90 days if the owner, lessor, or agent of the facility demonstrates to the Secretary that without such extension access to mammography in the geographic area served by the facility would be significantly reduced and if the owner, lessor, or agent of the facility will describe in a report to the Secretary steps that will be taken to qualify the facility for certification under subsection (b)(1).

(d) APPLICATION FOR CERTIFICATE.—

(1) SUBMISSION.—The Secretary may issue or renew a certificate for a facility if—

(A) the person who owns or leases the facility or an authorized agent of the person, submits to the Secretary, in such form and manner as the Secretary shall prescribe, an application that contains at a minimum—

(i) a description of the manufacturer, model, and type of each x-ray machine, image receptor, and processor operated in the performance of mammography by the facility;

(ii) a description of the procedures currently used to provide mammography at the facility, including—

(I) the types of procedures performed and the number of such procedures performed in the prior 12 months;

(II) the methodologies for mammography; and

(III) the names and qualifications (educational background, training, and experience) of the personnel performing mammography and the physicians reading and interpreting the results from the procedures;

(iii) proof of on-site survey by a qualified medical physicist as described in subsection (f)(1)(E); and

(iv) proof of accreditation in such manner as the Secretary shall prescribe; and

(B) the person or agent submits to the Secretary—

(i) a satisfactory assurance that the facility will be operated in accordance with standards established by the Secretary under subsection (f) to assure the safety and accuracy of mammography;

(ii) a satisfactory assurance that the facility will—

(I) permit inspections under subsection (g);

(II) make such records and information available, and submit such reports, to the Secretary as the Secretary may require; and

(III) update the information submitted under subparagraph (A) or assurances submitted under this subparagraph on a timely basis as required by the Secretary; and

(iii) such other information as the Secretary may require.

An applicant shall not be required to provide in an application under subparagraph (A) any information which the applicant has supplied to the accreditation body which accredited the applicant, except as required by the Secretary.

(2) APPEAL.—If the Secretary denies an application for the certification of a facility submitted under paragraph (1)(A), the Secretary shall provide the owner or lessor of the facility or the agent of the owner or lessor who submitted such application—

(A) a statement of the grounds on which the denial is based, and

(B) an opportunity for an appeal in accordance with the procedures set forth in regulations of the Secretary published at part 498 of title 42, Code of Federal Regulations.

(3) EFFECT OF DENIAL.—If the application for the certification of a facility is denied, the facility may not operate unless the denial of the application is overturned at the conclusion of the administrative appeals process provided in the regulations referred to in paragraph (2)(B).

(e) ACCREDITATION.—

(1) APPROVAL OF ACCREDITATION BODIES.—

(A) IN GENERAL.—The Secretary may approve a private nonprofit organization or State agency to accredit facilities for purposes of subsection (d)(1)(A)(iv) if the accreditation body meets the standards for accreditation established by the Secretary as described in subparagraph (B) and provides the assurances required by subparagraph (C).

(B) STANDARDS.—The Secretary shall establish standards for accreditation bodies, including—

(i) standards that require an accreditation body to perform—

(I) a review of clinical images from each facility accredited by such body not less often than every 3 years which review will be made by qualified review physicians; and

(II) a review of a random sample of clinical images from such facilities in each 3-year period beginning October 1, 1994, which review will be made by qualified review physicians;

(ii) standards that prohibit individuals conducting the reviews described in clause (i) from maintaining any relationship to the facility undergoing review which would constitute a conflict of interest;

(iii) standards that limit the imposition of fees for accreditation to reasonable amounts;

(iv) standards that require as a condition of accreditation that each facility undergo a survey at least annually by a medical physicist as described in subsection (f)(1)(E) to ensure that the facility meets the standards described in subparagraphs (A) and (B) of subsection (f)(1);

(v) standards that require monitoring and evaluation of such survey, as prescribed by the Secretary;

(vi) standards that are equal to standards established under subsection (f) which are relevant to accreditation as determined by the Secretary; and

(vii) such additional standards as the Secretary may require.

(C) ASSURANCES.—The accrediting body shall provide the Secretary satisfactory assurances that the body will—

(i) comply with the standards as described in subparagraph (B);

(ii) comply with the requirements described in paragraph (4);

(iii) submit to the Secretary the name of any facility for which the accreditation body denies, suspends, or revokes accreditation;

(iv) notify the Secretary in a timely manner before the accreditation body changes the standards of the body;

(v) notify each facility accredited by the accreditation body if the Secretary withdraws approval of the accreditation body under paragraph (2) in a timely manner; and

(vi) provide such other additional information as the Secretary may require.

(D) REGULATIONS.—Not later than 9 months after the date of the enactment of this section, the Secretary shall promulgate regulations under which the Secretary may approve an accreditation body.

(2) WITHDRAWAL OF APPROVAL.—

(A) IN GENERAL.—The Secretary shall promulgate regulations under which the Secretary may withdraw the ap-

proval 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 agen-

cies 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 Com-

mittee (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 re-

quirements of such paragraph. The Secretary shall promulgate regulations for the implementation of this subparagraph.

(B) EFFECT OF WITHDRAWAL.—If the Secretary withdraws the approval of a State under subparagraph (A), the certificate of any facility certified by the State shall continue in effect until the expiration of a reasonable period, as determined by the Secretary, for such facility to obtain certification by the Secretary.

(r) FUNDING.—

(1) FEES.—

(A) IN GENERAL.—The Secretary shall, in accordance with this paragraph assess and collect fees from persons described in subsection (d)(1)(A) (other than persons who are governmental entities, as determined by the Secretary) to cover the costs of inspections conducted under subsection (g)(1) by the Secretary or a State acting under a delegation under subparagraph (A) of such subsection. Fees may be assessed and collected under this paragraph only in such manner as would result in an aggregate amount of fees collected during any fiscal year which equals the aggregate amount of costs for such fiscal year for inspections of facilities of such persons under subsection (g)(1). A person's liability for fees shall be reasonably based on the proportion of the inspection costs which relate to such person.

(B) DEPOSIT AND APPROPRIATIONS.—

(i) DEPOSIT AND AVAILABILITY.—Fees collected under subparagraph (A) shall be deposited as an offsetting collection to the appropriations for the Department of Health and Human Services as provided in appropriation Acts and shall remain available without fiscal year limitation.

(ii) APPROPRIATIONS.—Fees collected under subparagraph (A) shall be collected and available only to the extent provided in advance in appropriation Acts.

(2) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section—

(A) to award research grants under subsection (p), such sums as may be necessary for each of the fiscal years 1993 through 2007; and

(B) for the Secretary to carry out other activities which are not supported by fees authorized and collected under paragraph (1), such sums as may be necessary for fiscal years 1993 through 2007.

PART G—QUARANTINE AND INSPECTION

CONTROL OF COMMUNICABLE DISEASES

SEC. 361. [264] (a) The Surgeon General, with the approval of the Secretary is authorized to make and enforce such regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into

any other State or possession. For purposes of carrying out and enforcing such regulations, the Surgeon General may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, as in his judgment may be necessary.

(b) Regulations prescribed under this section shall not provide for the apprehension, detention, or conditional release of individuals except for the purpose of preventing the introduction, transmission, or spread of such communicable diseases as may be specified from time to time in Executive orders of the President upon the recommendation of the Secretary, in consultation with the Surgeon General, [71].

(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 Gen-

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

eral, in accordance with regulations approved by the President, shall have the power to prohibit, in whole or in part, the introduction of persons and property from such countries or places as he shall designate in order to avert such danger, and for such period of time as he may deem necessary for such purpose.

SPECIAL POWERS IN TIME OF WAR

SEC. 363.[72] [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),[73] 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.

[72] 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".

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

(c) The Surgeon General shall fix a reasonable rate of extra compensation for overtime services of employees of the United States Public Health Service, Foreign Quarantine Division, performing overtime duties including the operation of vessels, in connection with the inspection or quarantine treatment of persons (passengers and crews), conveyances, or goods arriving by land, water, or air in the United States or any place subject to the jurisdiction thereof, hereinafter referred to as "employees of the Public Health Service", when required to be on duty between the hours of 6 o'clock postmeridian and 6 o'clock antemeridian (or between the hours of 7 o'clock postmeridian and 7 o'clock antemeridian at stations which have a declared workday of from 7 o'clock antemeridian to 7 o'clock postmeridian), or on Sundays or holidays, such rate, in lieu of compensation under any other provision of law, to be fixed at two times the basic hourly rate for each hour that the overtime extends beyond 6 o'clock (or 7 o'clock as the case may be) postmeridian, and two times the basic hourly rate for each overtime hour worked on Sundays or holidays. As used in this subsection, the term "basic hourly rate" shall mean the regular basic rate of pay which is applicable to such employees for work performed within their regular scheduled tour of duty.

(d)(1) The said extra compensation shall be paid to the United States by the owner, agent, consignee, operator, or master or other person in charge of any conveyance, for whom, at his request, services as described in this subsection (hereinafter referred to as overtime service) are performed. If such employees have been ordered to report for duty and have so reported, and the requested services are not performed by reason of circumstances beyond the control of the employees concerned, such extra compensation shall be paid on the same basis as though the overtime services had actually been performed during the period between the time the employees were ordered to report for duty and did so report, and the time they were notified that their services would not be required, and in any case as though their services had continued for not less than one hour. The Surgeon General with the approval of the Secretary of Health, Education, and Welfare may prescribe regulations requiring the owner, agent, consignee, operator, or master or other person for whom the overtime services are performed to file a bond in such amounts and containing such conditions and with such sureties, or in lieu of a bond, to deposit money or obligations of the United States in such amount, as will assure the payment of charges under this subsection, which bond or deposit may cover one or more transactions or all transactions during a specified period: *Provided,* That no charges shall be made for services performed in connection with the inspection of (1) persons arriving by international highways, ferries, bridges, or tunnels, or the conveyances in which they arrive, or (2) persons arriving by aircraft or railroad trains, the operations of which are covered by published schedules, or the aircraft or trains in which they arrive, or (3) persons arriving by vessels operated between Canadian ports and ports on Puget Sound or operated on the Great Lakes and connecting waterways, the operations of which are covered by published schedules, or the vessels in which they arrive.

(2) Moneys collected under this subsection shall be deposited in the Treasury of the United States to the credit of the appropriation charged with the expense of the services, and the appropriations so credited shall be available for the payment of such compensation to the said employees for services so rendered.

CERTAIN DUTIES OF CONSULAR AND OTHER OFFICERS

SEC. 365. [268] (a) Any consular or medical officer of the United States, designated for such purpose by the Secretary, shall make reports to the Surgeon General, on such forms and at such intervals as the Surgeon General may prescribe, of the health conditions at the port or place at which such officer is stationed.

(b) It shall be the duty of the customs officers and of Coast Guard officers to aid in the enforcement of quarantine rules and regulations; but no additional compensation, except actual and necessary traveling expenses, shall be allowed any such officer by reason of such services.

BILLS OF HEALTH

SEC. 366. [269] (a) Except as otherwise prescribed in regulations, any vessel at any foreign port or place clearing or departing for any port or place in a State or possession shall be required to obtain from the consular officer of the United States or from the Public Health Service officer, or other medical officer of the United States designated by the Surgeon General, at the port or place of departure, a bill of health in duplicate, in the form prescribed by the Surgeon General. The President, from time to time, shall specify the ports at which a medical officer shall be stationed for this purpose. Such bill of health shall set forth the sanitary history and condition of said vessel, and shall state that it has in all respects complied with the regulations prescribed pursuant to subsection (c). Before granting such duplicate bill of health, such consular or 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[74]

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) 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)[75] and—

(A) is a nonprofit entity,

(B) has accounting and other fiscal procedures (as specified by the Secretary) necessary to assure the fiscal stability of the organization,

(C) has an agreement with the Secretary to be reimbursed under title XVIII of the Social Security Act for the procurement of kidneys,

(D) notwithstanding any other provision of law, has met the other requirements of this section and has been certified or recertified by the Secretary within the previous 4-year period as meeting the performance standards to be a qualified organ procurement organization through a process that either—

(i) granted certification or recertification within such 4-year period with such certification or recertification in effect as of January 1, 2000, and remaining in effect through the earlier of—

(I) January 1, 2002; or

(II) the completion of recertification under the requirements of clause (ii); or

(ii) is defined through regulations that are promulgated by the Secretary by not later than January 1, 2002, that—

(I) require recertifications of qualified organ procurement organizations not more frequently than once every 4 years;

(II) rely on outcome and process performance measures that are based on empirical evidence, obtained through reasonable efforts, of organ donor po-

[74] See section 301 of the National Organ Transplant Act (Public Law 98-507; 42 U.S.C. 274e) for the prohibition against acquiring, receiving, or transferring a human organ for valuable consideration for use in human transplantation.

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

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

(F) 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,

(G) 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 histocompatibility 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 (3)(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 (3), 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,[76] 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)[77].

[76] Enacted November 16, 1990. See section 201(d) of Public Law 101–616.

[77] The reference in paragraph (2)(A) to "paragraph (1)(E)" should be "paragraph (1)(F)" pursuant to the redesignation of subparagraph (E) of paragraph (1) as subparagraph (F) by section 701(c)(1) of Pub. L. 106–505 and section 1(a)(1) [title II, § 219(b)(1)] of Pub. L. 106–554.

(B) Not later than 1 year after the date of enactment of this paragraph,[76] the Secretary shall publish in the Federal Register a final rule to establish the criteria described in subparagraph (A).

(3) An organ procurement organization shall—

(A) have effective agreements, to identify potential organ donors, with a substantial majority of the hospitals and other health care entities in its service area which have facilities for organ donations,

(B) conduct and participate in systematic efforts, including professional education, to acquire all usable organs from potential donors,

(C) arrange for the acquisition and preservation of donated organs and provide quality standards for the acquisition of organs which are consistent with the standards adopted by the Organ Procurement and Transplantation Network under section 372(b)(2)(E), including arranging for testing with respect to identifying organs that are infected with human immunodeficiency virus (HIV),

(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) IN GENERAL—The Secretary shall provide for the continued operation of an Organ Procurement and Transplantation Network which meets the requirements of subsection (b). The Secretary may award grants, contracts, or cooperative agreements, as the Secretary determines appropriate, for purposes of carrying out this section.

(b) COMPOSITION.—

(1) IN GENERAL.—The Organ Procurement and Transplantation Network shall—

(A) be operated through awards to public or private entities made by the Secretary that are distinct from the awards made to support the organization tasked with supporting the board of directors described in subparagraph (B); and

(B)[78] 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 24-hour telephone or information technology 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;

(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;

[78] The margin of subparagraph (B) of section 372(b)(1) is so in law. Should be moved to the right to align with subparagraph (A) (as so amended by section 2(2) of Public Law 118–14).

(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) recognize the differences in health and in organ transplantation issues between children and adults throughout the system and adopt criteria, polices, and procedures that address the unique health care needs of children;

(N) carry out studies and demonstration projects for the purpose of improving procedures for organ donation procurement and allocation, including but not limited to projects to examine and attempt to increase transplantation among populations with special needs, including children and individuals who are members of racial or ethnic minority groups, and among populations with limited access to transportation;

(O) provide that for purposes of this paragraph, the term "children" refers to individuals who are under the age of 18;

(P) encourage the integration of electronic health records systems through application programming interfaces (or successor technologies) among hospitals, organ procurement organizations, and transplant centers, including the use of automated electronic hospital referrals and the grant of remote, electronic access to hospital electronic health records of potential donors by organ procurement organizations, in a manner that complies with the privacy regulations promulgated under the Health Insurance Portability and Accountability Act of 1996, at part 160 of title 45, Code of Federal Regulations, and subparts A, C, and E of part 164 of such title (or any successor regulations); and

(Q) consider establishing a dashboard to display the number of transplants performed, the types of transplants performed, the number and types of organs that entered the Organ Procurement and Transplantation Network system and failed to be transplanted, and other appropriate statistics, which should be updated more frequently than annually.

(3) CLARIFICATION.—In adopting and using standards of quality under paragraph (2)(E), the Organ Procurement and Transplantation Network may adopt and use such standards with respect to organs infected with human immunodeficiency virus (in this paragraph referred to as "HIV"), provided that any such standards ensure that organs infected with HIV may be transplanted only into individuals who—

(A) are infected with HIV before receiving such organ; and

(B)(i) are participating in clinical research approved by an institutional review board under the criteria, standards, and regulations described in subsections (a) and (b) of section 377E; or

(ii) if the Secretary has determined under section 377E(c) that participation in such clinical research, as a requirement for such transplants, is no longer warranted, are receiving a transplant under the standards and regulations under section 377E(c).

(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.

(d) REGISTRATION FEES.—

(1) IN GENERAL.—The Secretary may collect registration fees from any member of the Organ Procurement and Transplantation Network for each transplant candidate such member places on the list described in subsection (b)(2)(A)(i). Such registration fees shall be collected and distributed only to support the operation of the Organ Procurement and Transplantation Network. Such registration fees are authorized to remain available until expended.

(2) COLLECTION.—The Secretary may collect the registration fees under paragraph (1) directly or through awards made under subsection (b)(1)(A).

(3) DISTRIBUTION.—Any amounts collected under this subsection shall—

(A) be credited to the currently applicable appropriation, account, or fund of the Department of Health and Human Services as discretionary offsetting collections; and

(B) be available, only to the extent and in the amounts provided in advance in appropriations Acts, to distribute such fees among awardees described in subsection (b)(1)(A).

(4) TRANSPARENCY.—The Secretary shall—

(A) promptly post on the website of the Organ Procurement and Transplantation Network—

(i) the amount of registration fees collected under this subsection from each member of the Organ Procurement and Transplantation Network; and

(ii) a list of activities such fees are used to support; and

(B) update the information posted pursuant to subparagraph (A), as applicable for each calendar quarter for which fees are collected under paragraph (1).

(5) GAO REVIEW.—Not later than 2 years after the date of enactment of this subsection, the Comptroller General of the United States shall, to the extent data are available—

(A) conduct a review concerning the activities under this subsection; and

(B) submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Finance of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report on such review, including related recommendations, as applicable.

(6) SUNSET.—The authority to collect registration fees under paragraph (1) shall expire on the date that is 3 years after the date of enactment of the Consolidated Appropriations Act, 2026.

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, 372, or 373 shall keep such records as the Secretary shall prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of such grant or contract, the total cost of the undertaking in connection with which such grant or contract was made, and the amount of that portion of the cost of the undertaking supplied by other sources, and such other records as will facilitate an effective audit.

(B) The Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of the recipient of a grant or contract under section 371, 372, 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—

(A) to patients, their families, and their physicians about transplantation; and

(B) 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 2 years after the date of enactment of the Securing the U.S. Organ Procurement and Transplantation Network Act and every 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 Health, Education, Labor, and Pensions of the Senate, a report on the scientific and clinical status of organ transplantation. The Secretary shall consult with the Director of the National Institutes of Health and the Commissioner of the Food and Drug Administration in the preparation of the report.

SEC. 377. [274f] REIMBURSEMENT OF TRAVEL AND SUBSISTENCE EXPENSES INCURRED TOWARD LIVING ORGAN DONATION.

(a) IN GENERAL.—The Secretary may award grants to States, transplant centers, qualified organ procurement organizations under section 371, or other public or private entities for the purpose of—

(1) providing for the reimbursement of travel and subsistence expenses incurred by individuals toward making living donations of their organs (in this section referred to as "donating individuals"); and

(2) providing for the reimbursement of such incidental nonmedical expenses that are so incurred as the Secretary determines by regulation to be appropriate.

(b) PREFERENCE.—The Secretary shall, in carrying out subsection (a), give preference to those individuals that the Secretary

determines are more likely to be otherwise unable to meet such expenses.

(c) NO CONSIDERATION OF INCOME OF ORGAN RECIPIENT.—The recipient of a grant under this section, in providing reimbursement to a donating individual through such grant, shall not give any consideration to the income of the organ recipient.

(d) 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).

(e) 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; or

(2) by an entity that provides health services on a prepaid basis.

(f) 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 (d)(1).

(2) The term "qualifying expenses" means the expenses authorized for purposes of subsection (a), subject to subsection (d)(2).

(g) 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.

(h) ANNUAL REPORT.—Not later than December 31 of each year, beginning in fiscal year 2027, the Secretary shall—

(1) prepare, submit to the Congress, and make public a report on whether grants under this section provided adequate funding during the preceding fiscal year to reimburse all donating individuals participating in the grant program under this section for all qualifying expenses; and

(2) include in each such report—

(A) the estimated number of all donating individuals participating in the grant program under this section who did not receive reimbursement for all qualifying expenses during the preceding fiscal year; and

(B) the total amount of funding that is estimated to be necessary to fully reimburse all donating individuals par-

ticipating in the grant program under this section for all qualifying expenses.

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. 377E. [274f–5] CRITERIA, STANDARDS, AND REGULATIONS WITH RESPECT TO ORGANS INFECTED WITH HIV.

(a) IN GENERAL.—Not later than 2 years after the date of the enactment of the HIV Organ Policy Equity Act, the Secretary shall develop and publish criteria for the conduct of research relating to transplantation of organs from donors infected with human immunodeficiency virus (in this section referred to as "HIV") into individuals who are infected with HIV before receiving such organ.

(b) CORRESPONDING CHANGES TO STANDARDS AND REGULATIONS APPLICABLE TO RESEARCH.—Not later than 2 years after the date

of the enactment of the HIV Organ Policy Equity Act, to the extent determined by the Secretary to be necessary to allow the conduct of research in accordance with the criteria developed under subsection (a)—

(1) the Organ Procurement and Transplantation Network shall revise the standards of quality adopted under section 372(b)(2)(E); and

(2) the Secretary shall revise section 121.6 of title 42, Code of Federal Regulations (or any successor regulations).

(c) REVISION OF STANDARDS AND REGULATIONS GENERALLY.—Not later than 4 years after the date of the enactment of the HIV Organ Policy Equity Act, and annually thereafter, the Secretary, shall—

(1) review the results of scientific research in conjunction with the Organ Procurement and Transplantation Network to determine whether the results warrant revision of the standards of quality adopted under section 372(b)(2)(E) with respect to donated organs infected with HIV and with respect to the safety of transplanting an organ with a particular strain of HIV into a recipient with a different strain of HIV;

(2) if the Secretary determines under paragraph (1) that such results warrant revision of the standards of quality adopted under section 372(b)(2)(E) with respect to donated organs infected with HIV and with respect to transplanting an organ with a particular strain of HIV into a recipient with a different strain of HIV, direct the Organ Procurement and Transplantation Network to revise such standards, consistent with section 372 and in a way that ensures the changes will not reduce the safety of organ transplantation; and

(3) in conjunction with any revision of such standards under paragraph (2), revise section 121.6 of title 42, Code of Federal Regulations (or any successor regulations).

SEC. 378. [274g] AUTHORIZATION OF APPROPRIATIONS.

For the purpose of carrying out this part, there are authorized to be appropriated $8,000,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 and 1993.

PART I—C.W. BILL YOUNG CELL TRANSPLANTATION PROGRAM

SEC. 379. [274k] NATIONAL PROGRAM.

(a) ESTABLISHMENT.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall by one or more contracts establish and maintain a C.W. Bill Young Cell Transplantation Program (referred to in this section as the "Program"), successor to the National Bone Marrow Donor Registry, that has the purpose of increasing the number of transplants for recipients suitably matched to biologically unrelated donors of bone marrow and cord blood, and that meets the requirements of this section. The Secretary may award a separate contract to perform each of the major functions of the Program described in paragraphs (1) and (2) of subsection (d) if deemed necessary by the Secretary to operate an effective and efficient system that is in the

best interest of patients. The Secretary shall conduct a separate competition for the initial establishment of the cord blood functions of the Program. The Program shall be under the general supervision of the Secretary. The Secretary shall establish an Advisory Council to advise, assist, consult with, and make recommendations to the Secretary on matters related to the activities carried out by the Program. The members of the Advisory Council shall be appointed in accordance with the following:

(1) Each member of the Advisory Council shall serve for a term of 2 years, and each such member may serve as many as 3 consecutive 2-year terms, except that—

(A) such limitations shall not apply to the Chair of the Advisory Council (or the Chair-elect) or to the member of the Advisory Council who most recently served as the Chair; and

(B) one additional consecutive 2-year term may be served by any member of the Advisory Council who has no employment, governance, or financial affiliation with any donor center, recruitment organization, transplant center, or cord blood bank.

(2) A member of the Advisory Council may continue to serve after the expiration of the term of such member until a successor is appointed.

(3) In order to ensure the continuity of the Advisory Council, the Advisory Council shall be appointed so that each year the terms of approximately one-third of the members of the Advisory Council expire.

(4) The membership of the Advisory Council—

(A) shall include as voting members a balanced number of representatives including representatives of marrow donor centers and marrow transplant centers, representatives of cord blood banks and participating birthing hospitals, recipients of a bone marrow transplant, recipients of a cord blood transplant, persons who require such transplants, family members of such a recipient or family members of a patient who has requested the assistance of the Program in searching for an unrelated donor of bone marrow or cord blood, persons with expertise in bone marrow and cord blood transplantation, persons with expertise in typing, matching, and transplant outcome data analysis, persons with expertise in the social sciences, basic scientists with expertise in the biology of adult stem cells, and members of the general public; and

(B) shall include as nonvoting members representatives from the Department of Defense Marrow Donor Recruitment and Research Program operated by the Department of the Navy, the Division of Transplantation of the Health Resources and Services Administration, the Food and Drug Administration, and the National Institutes of Health.

(5) Members of the Advisory Council shall be chosen so as to ensure objectivity and balance and reduce the potential for conflicts of interest. The Secretary shall establish bylaws and procedures—

(A) to prohibit any member of the Advisory Council who has an employment, governance, or financial affiliation with a donor center, recruitment organization, transplant center, or cord blood bank from participating in any decision that materially affects the center, recruitment organization, transplant center, or cord blood bank; and

(B) to limit the number of members of the Advisory Council with any such affiliation.

(6) The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall submit to Congress an annual report on the activities carried out under this section.

(7) The Secretary shall convene the Advisory Council at least two times each calendar year.

(b) ACCREDITATION.—The Secretary shall, through a public process, recognize one or more accreditation entities for the accreditation of cord blood banks.

(c) INFORMED CONSENT.—The Secretary shall, through a public process, examine issues of informed consent, including—

(1) the appropriate timing of such consent; and

(2) the information provided to the maternal donor regarding all of her medically appropriate cord blood options.

Based on such examination, the Secretary shall require that the standards used by the accreditation entities recognized under subsection (b) ensure that a cord blood unit is acquired with the informed consent of the maternal donor.

(d) FUNCTIONS.— [79]

(1) BONE MARROW FUNCTIONS.—With respect to bone marrow, the Program shall—

(A) operate a system for identifying, matching, and facilitating the distribution of bone marrow that is suitably matched to candidate patients;

---

[79] Section 5 of Public Law 105–196 (112 Stat. 636) provides as follows:

"SEC. 5. STUDY BY GENERAL ACCOUNTING OFFICE.

"(a) IN GENERAL.—During the period indicated pursuant to subsection (b), the Comptroller General of the United States shall conduct a study of the National Bone Marrow Donor Registry under section 379 of the Public Health Service Act for purposes of making determinations of the following:

"(1) The extent to which, relative to the effective date of this Act, such Registry has increased the representation of racial and ethnic minority groups (including persons of mixed ancestry) among potential donors of bone marrow who are enrolled with the Registry, and whether the extent of increase results in a level of representation that meets the standard established in subsection (c)(1)(A) of such section 379 (as added by section 2(c) of this Act).

"(2) The extent to which patients in need of a transplant of bone marrow from a biologically unrelated donor, and the physicians of such patients, have been utilizing the Registry in the search for such a donor.

"(3) The number of such patients for whom the Registry began a preliminary search but for whom the full search process was not completed, and the reasons underlying such circumstances.

"(4) The extent to which the plan required in section 2(b)(2) of this Act (relating to the relationship between the Registry and donor centers) has been implemented.

"(5) The extent to which the Registry, donor centers, donor registries, collection centers, transplant centers, and other appropriate entities have been complying with the standards, criteria, and procedures under subsection (e) of such section 379 (as redesignated by section 2(c) of this Act).

"(b) REPORT.—A report describing the findings of the study under subsection (a) shall be submitted to the Congress not later than October 1, 2001. The report may not be submitted before January 1, 2001.".

(B) consistent with paragraph (3), permit transplant physicians, other appropriate health care professionals, and patients to search by means of electronic access all available bone marrow donors listed in the Program;

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

(D) maintain and expand medical contingency response capabilities, in coordination with Federal programs, to prepare for and respond effectively to biological, chemical, or radiological attacks, and other public health emergencies that can damage marrow, so that the capability of supporting patients with marrow damage from disease can be used to support casualties with marrow damage;

(E) carry out informational and educational activities in accordance with subsection (e);

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

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

(H) provide case management services for any potential donor of bone marrow to whom the Program has provided a notice that the potential donor may be suitably matched to a particular patient through the office established under subsection (h);

(I) with respect to searches for unrelated donors of bone marrow that are conducted through the system under subparagraph (A), collect, analyze, and publish data in a standardized electronic format on the number and percentage of patients at each of the various stages of the search process, including data regarding the furthest stage reached, the number and percentage of patients who are unable to complete the search process, and the reasons underlying such circumstances;

(J) support studies and demonstration and outreach projects for the purpose of increasing the number of individuals who are willing to be marrow donors to ensure a genetically diverse donor pool; and

(K) facilitate research with the appropriate Federal agencies to improve the availability, efficiency, safety, and cost of transplants from unrelated donors and the effectiveness of Program operations.

(2) CORD BLOOD FUNCTIONS.—

(A) IN GENERAL.—With respect to cord blood, the Program shall—

(i)[80] operate a system for identifying, matching, and facilitating the distribution of donated cord blood units

[80] Margin so in law. The amendment by section 2(b)(2)(A)(ii) of Public Law 111–264 redesignates subpargraphs (A)–(H) as clauses (i)–(viii); however, the amendment did not move the margins of such clauses to the right so that it appears indented 6 ems from the left margin (except

Continued

that are suitably matched to candidate patients and meet all applicable Federal and State regulations (including informed consent and Food and Drug Administration regulations) from a qualified cord blood bank;

(ii)[80] consistent with paragraph (3), allow transplant physicians, other appropriate health care professionals, and patients to search by means of electronic access all available cord blood units made available through the Program;

(iii)[80] allow transplant physicians and other appropriate health care professionals to reserve, as defined by the Secretary, a cord blood unit for transplantation;

(iv) support and expand new and existing studies and demonstration and outreach projects for the purpose of increasing cord blood unit donation and collection from a genetically diverse population and expanding the number of cord blood unit collection sites partnering with cord blood banks receiving a contract under the National Cord Blood Inventory program under section 2 of the Stem Cell Therapeutic and Research Act of 2005, including such studies and projects that focus on—

(I) remote collection of cord blood units, consistent with the requirements under the Program and the National Cord Blood Inventory program goal described in section 2(a) of the Stem Cell Therapeutic and Research Act of 2005; and

(II) exploring novel approaches or incentives to encourage innovative technological advances that could be used to collect cord blood units, consistent with the requirements under the Program and such National Cord Blood Inventory program goal;

(v)[80] provide for a system of patient advocacy through the office established under subsection (h);

(vi)[80] coordinate with the qualified cord blood banks to support informational and educational activities in accordance with subsection (g);

(vii)[80] maintain and expand medical contingency response capabilities, in coordination with Federal programs, to prepare for and respond effectively to biological, chemical, or radiological attacks, and other public health emergencies that can damage marrow, so that the capability of supporting patients with marrow damage from disease can be used to support casualties with marrow damage; and

(viii)[80] with respect to the system under subparagraph (A), collect, analyze, and publish data in a standardized electronic format, as required by the Secretary, on the number and percentage of patients at each of the various stages of the search process, including data regarding the furthest stage reached, the number and percentage of pa-

for clause (iv) which was amended in its entirety by section 2(b)(2)(A)(iii) of such Public Law and as rewritten appears on the correct margin).

tients who are unable to complete the search process, and the reasons underlying such circumstances.

(B) EFFORTS TO INCREASE COLLECTION OF HIGH QUALITY CORD BLOOD UNITS.—In carrying out subparagraph (A)(iv), not later than 1 year after the date of enactment of the Stem Cell Therapeutic and Research Reauthorization Act of 2010 and annually thereafter, the Secretary shall set an annual goal of increasing collections of high quality cord blood units, including remote collection, consistent with the inventory goal described in section 2(a) of the Stem Cell Therapeutic and Research Act of 2005 (referred to in this subparagraph as the "inventory goal"), and shall identify at least one project under subparagraph (A)(iv) to replicate and expand nationwide, as appropriate.

(C) DEFINITION.—In this paragraph, the term "remote collection" means the collection of cord blood units at locations that do not have written contracts with cord blood banks for collection support.

(3) SINGLE POINT OF ACCESS; STANDARD DATA.—

(A) SINGLE POINT OF ACCESS.—The Secretary shall ensure that health care professionals and patients are able to search electronically for and facilitate access to, in the manner and to the extent defined by the Secretary and consistent with the functions described in paragraphs (1)(A) and (2)(A)(i), cells from bone marrow donors and cord blood units through a single point of access.

(B) STANDARD DATA.—The Secretary shall require all recipients of contracts under this section to make available a standard dataset for purposes of subparagraph (A) in a standardized electronic format that enables transplant physicians to compare among and between bone marrow donors and cord blood units to ensure the best possible match for the patient.

(4) DEFINITION.—The term "qualified cord blood bank" means a cord blood bank that—

(A) has obtained all applicable Federal and State licenses, certifications, registrations (including pursuant to the regulations of the Food and Drug Administration), and other authorizations required to operate and maintain a cord blood bank;

(B) has implemented donor screening, cord blood collection practices, and processing methods intended to protect the health and safety of donors and transplant recipients to improve transplant outcomes, including with respect to the transmission of potentially harmful infections and other diseases;

(C) is accredited by an accreditation entity recognized by the Secretary under subsection (b);

(D) has established a system of strict confidentiality to protect the identity and privacy of patients and donors in accordance with existing Federal and State law;

(E) has established a system for encouraging donation by a genetically diverse group of donors; and

(F) has established a system to confidentially maintain linkage between a cord blood unit and a maternal donor.

(e) BONE MARROW RECRUITMENT; PRIORITIES; INFORMATION AND EDUCATION.—

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

(A) The Program shall give priority to carrying out activities under this part to increase representation for such populations in order to enable a member of such a population, to the extent practicable, to have a probability of finding a suitable unrelated donor that is comparable to the probability that an individual who is not a member of an underrepresented population would have.

(B) The Program shall consider racial and ethnic minority groups (including persons of mixed ancestry) to be populations that have been identified for purposes of this paragraph, and shall carry out subparagraph (A) with respect to such populations.

(2) INFORMATION AND EDUCATION REGARDING RECRUITMENT; TESTING AND ENROLLMENT.—

(A) IN GENERAL.—The Program shall carry out informational and educational activities, in coordination with organ donation public awareness campaigns operated through the Department of Health and Human Services, for purposes of recruiting individuals to serve as donors of bone marrow, and shall test and enroll with the Program potential bone marrow donors. Such information and educational activities shall include the following:

(i) Making information available to the general public, including information describing the needs of patients with respect to donors of bone marrow.

(ii) Educating and providing information to individuals who are willing to serve as potential bone marrow donors.

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

(B) PRIORITIES.—In carrying out informational and educational activities under subparagraph (A), the Program shall give priority to recruiting individuals to serve as donors of bone marrow for populations that are identified under paragraph (1).

(3) TRANSPLANTATION AS TREATMENT OPTION.—In addition to activities regarding recruitment, the recruitment program under paragraph (1) shall provide information to physicians, other health care professionals, and the public regarding bone marrow transplants from unrelated donors as a treatment option.

(4) IMPLEMENTATION OF SUBSECTION.—The requirements of this subsection shall be carried out by the entity that has been

awarded a contract by the Secretary under subsection (a) to carry out the functions described in subsection (d)(1).

(f) BONE MARROW CRITERIA, STANDARDS, AND PROCEDURES.—The Secretary shall enforce, for participating entities, including the Program, individual marrow donor centers, marrow donor registries, marrow collection centers, and marrow transplant centers—

(1) quality standards and standards for tissue typing, obtaining the informed consent of donors, and providing patient advocacy;

(2) donor selection criteria, based on established medical criteria, to protect both the donor and the recipient and to prevent the transmission of potentially harmful infectious diseases such as the viruses that cause hepatitis and the etiologic agent for Acquired Immune Deficiency Syndrome;

(3) procedures to ensure the proper collection and transportation of the marrow;

(4) standards for the system for patient advocacy operated under subsection (h), including standards requiring the provision of appropriate information (at the start of the search process and throughout the process) to patients and their families and physicians;

(5) standards that—

(A) require the establishment of a system of strict confidentiality to protect the identity and privacy of patients and donors in accordance with Federal and State law; and

(B) prescribe the purposes for which the records described in subparagraph (A) may be disclosed, and the circumstances and extent of the disclosure; and

(6) in the case of a marrow donor center or marrow donor registry participating in the program, procedures to ensure the establishment of a method for integrating donor files, searches, and general procedures of the center or registry with the Program.

(g) CORD BLOOD RECRUITMENT; PRIORITIES; INFORMATION AND EDUCATION.—

(1) RECRUITMENT; PRIORITIES.—The Program shall support activities, in cooperation with qualified cord blood banks, for the recruitment of cord blood donors. Such recruitment program shall identify populations that are underrepresented among cord blood donors. In the case of populations that are identified under the preceding sentence:

(A) The Program shall give priority to supporting activities under this part to increase representation for such populations in order to enable a member of such a population, to the extent practicable, to have a probability of finding a suitable cord blood unit that is comparable to the probability that an individual who is not a member of an underrepresented population would have.

(B) The Program shall consider racial and ethnic minority groups (including persons of mixed ancestry) to be populations that have been identified for purposes of this paragraph, and shall support activities under subparagraph (A) with respect to such populations.

(2) INFORMATION AND EDUCATION REGARDING RECRUITMENT; TESTING AND DONATION.—

(A) IN GENERAL.—In carrying out the recruitment program under paragraph (1), the Program shall support informational and educational activities in coordination with qualified cord blood banks and organ donation public awareness campaigns operated through the Department of Health and Human Services, for purposes of recruiting pregnant women to serve as donors of cord blood. Such information and educational activities shall include the following:

(i) Making information available to the general public, including information describing the needs of patients with respect to cord blood units.

(ii) Educating and providing information to pregnant women who are willing to donate cord blood units.

(iii) Training individuals in requesting pregnant women to serve as cord blood donors.

(B) PRIORITIES.—In carrying out informational and educational activities under subparagraph (A), the Program shall give priority to supporting the recruitment of pregnant women to serve as donors of cord blood for populations that are identified under paragraph (1).

(3) TRANSPLANTATION AS TREATMENT OPTION.—In addition to activities regarding recruitment, the recruitment program under paragraph (1) shall provide information to physicians, other health care professionals, and the public regarding cord blood transplants from donors as a treatment option.

(4) IMPLEMENTATION OF SUBSECTION.—The requirements of this subsection shall be carried out by the entity that has been awarded a contract by the Secretary under subsection (a) to carry out the functions described in subsection (d)(2).

(h) PATIENT ADVOCACY AND CASE MANAGEMENT FOR BONE MARROW AND CORD BLOOD.—

(1) IN GENERAL.—The Secretary shall establish and maintain, through a contract or other means determined appropriate by the Secretary, an office of patient advocacy (in this subsection referred to as the "Office").

(2) GENERAL FUNCTIONS.—The Office shall meet the following requirements:

(A) The Office shall be headed by a director.

(B) The Office shall be staffed by individuals with expertise in bone marrow and cord blood therapy covered under the Program.

(C) The Office shall operate a system for patient advocacy, which shall be separate from mechanisms for donor advocacy, and which shall serve patients for whom the Program is conducting, or has been requested to conduct, a search for a bone marrow donor or cord blood unit.

(D) In the case of such a patient, the Office shall serve as an advocate for the patient by directly providing to the patient (or family members, physicians, or other individuals acting on behalf of the patient) individualized services

with respect to efficiently utilizing the system under paragraphs (1) and (2) of subsection (d) to conduct an ongoing search for a bone marrow donor or cord blood unit and assist with information regarding third party payor matters.

(E) In carrying out subparagraph (D), the Office shall monitor the system under paragraphs (1) and (2) of subsection (d) to determine whether the search needs of the patient involved are being met, including with respect to the following:

(i) Periodically providing to the patient (or an individual acting on behalf of the patient) information regarding bone marrow donors or cord blood units that are suitably matched to the patient, and other information regarding the progress being made in the search.

(ii) Informing the patient (or such other individual) if the search has been interrupted or discontinued.

(iii) Identifying and resolving problems in the search, to the extent practicable.

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

(i) The resources available through the Program.

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

(iii) The post-transplant outcomes for individual transplant centers.

(iv) Information concerning issues that patients may face after a transplant.

(v) Such other information as the Program determines to be appropriate.

(G) The Office shall conduct surveys of patients (or family members, physicians, or other individuals acting on behalf of patients) to determine the extent of satisfaction with the system for patient advocacy under this subsection, and to identify ways in which the system can be improved to best meet the needs of patients.

(3) CASE MANAGEMENT.—

(A) IN GENERAL.—In serving as an advocate for a patient under paragraph (2), the Office shall provide individualized case management services directly to the patient (or family members, physicians, or other individuals acting on behalf of the patient), including—

(i) individualized case assessment; and

(ii) the functions described in paragraph (2)(D) (relating to progress in the search process).

(B) POSTSEARCH FUNCTIONS.—In addition to the case management services described in paragraph (1) for patients, the Office shall, on behalf of patients who have completed the search for a bone marrow donor or cord blood unit, provide information and education on the process of receiving a transplant, including the post-transplant process.

(i) COMMENT PROCEDURES.—The Secretary shall establish and provide information to the public on procedures under which the Secretary shall receive and consider comments from interested persons relating to the manner in which the Program is carrying out the duties of the Program. The Secretary may promulgate regulations under this section.

(j) CONSULTATION.—In developing policies affecting the Program, the Secretary shall consult with the Advisory Council, the Department of Defense Marrow Donor Recruitment and Research Program operated by the Department of the Navy, and the board of directors of each entity awarded a contract under this section.

(k) CONTRACTS.—

(1) APPLICATION.—To be eligible to enter into a contract under this section, an entity shall submit to the Secretary and obtain approval of an application at such time, in such manner, and containing such information as the Secretary shall by regulation prescribe.

(2) CONSIDERATIONS.—In awarding contracts under this section, the Secretary shall give consideration to the continued safety of donors and patients and other factors deemed appropriate by the Secretary.

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

(m) RECORDS.—

(1) RECORDKEEPING.—Each recipient of a contract or subcontract under subsection (a) shall keep such records as the Secretary shall prescribe, including records that fully disclose the amount and disposition by the recipient of the proceeds of the contract, the total cost of the undertaking in connection with which the contract was made, and the amount of the portion of the cost of the undertaking supplied by other sources, and such other records as will facilitate an effective audit.

(2) EXAMINATION OF RECORDS.—The Secretary and the Comptroller General of the United States shall have access to any books, documents, papers, and records of the recipient of a contract or subcontract entered into under this section that are pertinent to the contract, for the purpose of conducting audits and examinations.

(n) PENALTIES FOR DISCLOSURE.—Any person who discloses the content of any record referred to in subsection (d)(4)(D) or (f)(5)(A) without the prior written consent of the donor or potential donor with respect to whom the record is maintained, or in violation of the standards described in subsection (f)(5)(B), shall be imprisoned for not more than 2 years or fined in accordance with title 18, United States Code, or both.

(o) PERIODIC REVIEW OF STATE OF SCIENCE.—

(1) REVIEW.—Not less frequently than every 2 years, the Secretary, in consultation with the Director of the National Institutes of Health, the Commissioner of Food and Drugs, the Administrator of the Health Resources and Services Administration, the Advisory Council, and other stakeholders, where appropriate given relevant expertise, shall conduct a review of the state of the science of using adult stem cells and birthing tissues to develop new types of therapies for patients, for the

purpose of considering the potential inclusion of such new types of therapies in the Program.

(2) RECOMMENDATIONS.—Not later than June 30, 2025, the Secretary shall—

(A) complete the second review required by paragraph (1); and

(B) informed by such review, submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives recommendations on the appropriateness of the inclusion of new types of therapies in the Program.

SEC. 379A. [274l] STEM CELL THERAPEUTIC OUTCOMES DATABASE.

(a) ESTABLISHMENT.—The Secretary shall by contract establish and maintain a scientific database of information relating to patients who have been recipients of a stem cell therapeutics product (including bone marrow, cord blood, or other such product) from a donor.

(b) INFORMATION.—The outcomes database shall include information in a standardized electronic format with respect to patients described in subsection (a), diagnosis, transplant procedures, results, long-term follow-up, and such other information as the Secretary determines to be appropriate, to conduct an ongoing evaluation of the scientific and clinical status of transplantation involving recipients of a stem cell therapeutics product from a donor.

(c) ANNUAL REPORT ON PATIENT OUTCOMES.—The Secretary shall require the entity awarded a contract under this section to submit to the Secretary an annual report concerning patient outcomes with respect to each transplant center, based on data collected and maintained by the entity pursuant to this section.

(d) PUBLICLY AVAILABLE DATA.—The outcomes database shall make relevant scientific information not containing individually identifiable information available to the public in the form of summaries and data sets to encourage medical research and to provide information to transplant programs, physicians, patients, entities awarded a contract under section 379 donor registries, and cord blood banks.

SEC. 379A–1. [274l–1] DEFINITIONS.

In this part:

(1) The term "Advisory Council" means the advisory council established by the Secretary under section 379(a)(1).

(2) The term "bone marrow" means the cells found in adult bone marrow and peripheral blood.

(3) The term "outcomes database" means the database established by the Secretary under section 379A.

(4) The term "Program" means the C.W. Bill Young Cell Transplantation Program established under section 379.

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

For the purpose of carrying out this part, there are authorized to be appropriated $31,009,000 for each of fiscal years 2022 through 2026.

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[81] 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–0] (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.

[81] So in law. Probably should read "...diagnosis, and treatment...".

SEC. 392A. [280b–1] PREVENTING OVERDOSES OF CONTROLLED SUBSTANCES.

(a) EVIDENCE-BASED PREVENTION GRANTS.—

(1) IN GENERAL.—The Director of the Centers for Disease Control and Prevention may—

(A) to the extent practicable, carry out and expand any evidence-based prevention activities described in paragraph (2);

(B) provide training and technical assistance to States, localities, and Indian Tribes for purposes of carrying out such activity; and

(C) award grants to States, localities, and Indian Tribes for purposes of carrying out such activity.

(2) EVIDENCE-BASED PREVENTION ACTIVITIES.—An evidence-based prevention activity described in this paragraph is any of the following activities:

(A) Improving the efficiency and use of a new or currently operating prescription drug monitoring program, including by—

(i) encouraging all authorized users (as specified by the State or other entity) to register with and use the program;

(ii) enabling such users to access any updates to information collected by the program in as close to real-time as possible;

(iii) improving the ease of use of such program;

(iv) providing for a mechanism for the program to notify authorized users of any potential misuse or abuse of controlled substances and any detection of inappropriate prescribing or dispensing practices relating to such substances;

(v) encouraging the analysis of prescription drug monitoring data for purposes of providing de-identified, aggregate reports based on such analysis to State public health agencies, State substance abuse agencies, State licensing boards, and other appropriate State agencies, as permitted under applicable Federal and State law and the policies of the prescription drug monitoring program and not containing any protected health information, to prevent inappropriate prescribing, drug diversion, or abuse and misuse of controlled substances, and to facilitate better coordination among agencies;

(vi) enhancing interoperability between the program and any health information technology (including certified health information technology), including by integrating program data into such technology;

(vii) updating program capabilities to respond to technological innovation for purposes of appropriately addressing the occurrence and evolution of controlled substance overdoses;

(viii) facilitating and encouraging data exchange between the program and the prescription drug monitoring programs of other States;

(ix) enhancing data collection and quality, including improving patient matching and proactively monitoring data quality;

(x) providing prescriber and dispenser practice tools, including prescriber practice insight reports for practitioners to review their prescribing patterns in comparison to such patterns of other practitioners in the specialty; and

(xi) meeting the purpose of the program established under section 399O, as described in section 399O(a).

(B) Promoting community or health system interventions.

(C) Evaluating interventions to prevent controlled substance overdoses and associated risks.

(D) Implementing projects to advance an innovative prevention approach with respect to new and emerging public health crises and opportunities to address such crises, such as enhancing public education and awareness on the risks associated with substances causing overdose.

(3) ADDITIONAL GRANTS.—The Director may award grants to States, localities, and Indian Tribes for the following purposes:

(A) To carry out innovative projects for grantees to detect, identify, and rapidly respond to controlled substance misuse, abuse, and overdoses, and associated risk factors, including changes in patterns of such controlled substance use. Such projects may include the use of innovative, evidence-based strategies for detecting such patterns, such as wastewater surveillance, if proven to support actionable prevention strategies, in a manner consistent with applicable Federal and State privacy laws.

(B) For any other evidence-based activity for preventing controlled substance misuse, abuse, and overdoses as the Director determines appropriate.

(4) RESEARCH.—The Director, in coordination with the Assistant Secretary for Mental Health and Substance Use and the National Mental Health and Substance Use Policy Laboratory established under section 501A, as appropriate and applicable, may conduct studies and evaluations to address substance use disorders, including preventing substance use disorders or other related topics the Director determines appropriate.

(b) ENHANCED CONTROLLED SUBSTANCE OVERDOSE DATA COLLECTION, ANALYSIS, AND DISSEMINATION GRANTS.—

(1) IN GENERAL.—The Director of the Centers for Disease Control and Prevention may—

(A) to the extent practicable, carry out any controlled substance overdose data collection activities described in paragraph (2);

(B) provide training and technical assistance to States, localities, and Indian Tribes for purposes of carrying out such activity;

(C) award grants to States, localities, and Indian Tribes for purposes of carrying out such activity; and

(D) coordinate with the Assistant Secretary for Mental Health and Substance Use to collect data pursuant to section 505(d)(1)(A) (relating to the number of individuals admitted to emergency departments as a result of the abuse of alcohol or other drugs).

(2) CONTROLLED SUBSTANCE OVERDOSE DATA COLLECTION AND ANALYSIS ACTIVITIES.—A controlled substance overdose data collection, analysis, and dissemination activity described in this paragraph is any of the following activities:

(A) Improving the timeliness of reporting data to the public, including data on fatal and nonfatal overdoses of controlled substances.

(B) Enhancing the comprehensiveness of controlled substance overdose data by collecting information on such overdoses, and associated risk factors, from appropriate sources such as toxicology reports, autopsy reports, death scene investigations, and emergency departments.

(C) Modernizing the system for monitoring and identifying causes of death related to controlled substance overdoses to use an electronic-based system.

(D) Using data to help identify risk factors associated with controlled substance overdoses.

(E) Supporting entities involved in providing information on controlled substance overdoses, such as coroners, medical examiners, and public health laboratories, to improve accurate testing and standardized reporting of causes and contributing factors to controlled substances overdoses and analysis of various opioid analogues and other emerging substances related to controlled substance overdoses.

(F) Working to enable and encourage the access, exchange, and use of information regarding controlled substance overdoses and associated risk factors among data sources and entities.

(c) PRIORITY.—In awarding grants to States under subsections (a) and (b), the Director of the Centers for Disease Control and Prevention may give priority to jurisdictions with a disproportionately high rate of drug overdoses or drug overdose deaths, as applicable.

(d) DEFINITIONS.—In this section:

(1) CONTROLLED SUBSTANCE.—The term "controlled substance" has the meaning given that term in section 102 of the Controlled Substances Act.

(2) INDIAN TRIBE.—The term "Indian tribe" has the meaning given that term in section 4 of the Indian Self-Determination and Education Assistance Act.

(e) AUTHORIZATION OF APPROPRIATIONS.—For purposes of carrying out this section, section 399O of this Act, and section 102 of the Comprehensive Addiction and Recovery Act of 2016 (Public Law 114–198), there is authorized to be appropriated $505,579,000 for each of fiscal years 2026 through 2030.

INTERPERSONAL VIOLENCE WITHIN FAMILIES AND AMONG ACQUAINTANCES

SEC. 393. [280b–1a] (a) With respect to activities that are authorized in sections 391 and 392, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall carry out such activities with respect to interpersonal violence within families and among acquaintances. Activities authorized in the preceding sentence include the following:

(1) Collecting data relating to the incidence of such violence.

(2) Making grants to public and nonprofit private entities for the evaluation of programs whose purpose is to prevent such violence, including the evaluation of demonstration projects under paragraph (6).

(3) Making grants to public and nonprofit private entities for the conduct of research on identifying effective strategies for preventing such violence.

(4) Providing to the public information and education on such violence, including information and education to increase awareness of the public health consequences of such violence.

(5) Training health care providers as follows:

(A) To identify individuals whose medical conditions or statements indicate that the individuals are victims of such violence.

(B) To routinely determine, in examining patients, whether the medical conditions or statements of the patients so indicate.

(C) To refer individuals so identified to entities that provide services regarding such violence, including referrals for counseling, housing, legal services, and services of community organizations.

(6) Making grants to public and nonprofit private entities for demonstration projects with respect to such violence, including with respect to prevention.

(b) For purposes of this part, the term "interpersonal violence within families and among acquaintances" includes behavior commonly referred to as domestic violence, sexual assault, spousal abuse, woman battering, partner abuse, elder abuse, and acquaintance rape.

SEC. 393A. [280b–1b] USE OF ALLOTMENTS FOR RAPE PREVENTION EDUCATION.

(a) PERMITTED USE.—The Secretary, acting through the National Center for Injury Prevention and Control at the Centers for Disease Control and Prevention, shall award targeted grants to States to be used for rape prevention and education programs conducted by rape crisis centers, State, territorial or tribal sexual assault coalitions, and other public and private nonprofit entities for—

(1) educational seminars;

(2) the operation of hotlines or utilization of other communication technologies for purposes related to such a hotline;

(3) training programs for professionals, including school-based professionals, to identify and refer students who may have experienced or are at risk of experiencing sexual violence;

(4) the preparation of informational material;

(5) education and training programs for students and campus personnel designed to reduce the incidence of sexual assault at colleges and universities;

(6) education to increase awareness about drugs and alcohol used to facilitate rapes or sexual assaults; and

(7) other efforts to increase awareness of the facts about, or to help prevent, sexual violence, sexual assault, and sexual harassment, 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)) and Deaf[82] individuals.

(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) MEANINGFUL INVOLVEMENT OF STATE SEXUAL ASSAULT COALITIONS, CULTURALLY SPECIFIC ORGANIZATIONS, AND UNDERSERVED COMMUNITIES.—In awarding funds to States under this section, the Secretary shall set forth procedures designed to ensure meaningful involvement of sexual assault coalitions, culturally specific organizations, and representatives from underserved communities of the State or territory in the application for, and implementation of, funding.

(d) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—There is authorized to be appropriated to carry out this section $100,000,000 for each of fiscal years 2023 through 2027.

(2) NATIONAL SEXUAL VIOLENCE RESOURCE CENTER ALLOTMENT.—Of the total amount made available under this subsection in each fiscal year, not less than $1,500,000 shall be available for allotment under subsection (b).

(3) BASELINE FUNDING FOR STATES, THE DISTRICT OF COLUMBIA, AND PUERTO RICO.—A minimum allocation of $150,000 shall be awarded in each fiscal year for each of the States, the District of Columbia, and Puerto Rico. A minimum allocation of $35,000 shall be awarded in each fiscal year for each Territory. Any unused or remaining funds shall be allotted to each State, the District of Columbia, and Puerto Rico on the basis of population. Not less than 80 percent of the total amount

[82] So in law. Probably should read "deaf".

made available under this subsection in each fiscal year shall be awarded in accordance with this paragraph.

(4) STATE, TERRITORIAL, AND TRIBAL SEXUAL ASSAULT COALITION ALLOTMENT.—

(A) IN GENERAL.—Of the total amount appropriated under this subsection for a fiscal year, not less than 15 percent shall be allocated to State, territorial, and Tribal sexual assault coalitions for the purposes of coordinating and providing prevention activities, providing assistance to prevention programs, and collaborating and coordinating with applicable Federal, State, Tribal, and local entities engaged in sexual violence prevention, in accordance with this paragraph.

(B) ALLOCATIONS.—Of the total amount appropriated under this subsection and allocated to making awards to sexual assault coalitions, as described in subparagraph (A), for a fiscal year—

(i) not less than 10 percent shall be made available to Tribal sexual assault coalitions; and

(ii) any remaining amounts shall be made available, in equal amounts, to each State coalition and each territorial coalition.

(C) CLARIFICATION.—Receipt of an award under this subsection by a sexual assault coalition shall not preclude the coalition from receiving additional grants or administering funds to carry out the purposes described in subsection (a).

(e) 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.

(f) REPORT.—Not later than 1 year after the date of the enactment of the Violence Against Women Act Reauthorization Act of 2022, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall submit to the Committee on Appropriations, the Committee on Energy and Commerce, and the Committee on the Judiciary of the House of Representatives and the Committee on Appropriations, the Committee on Health, Education, Labor, and Pensions, and the Committee on the Judiciary of the Senate a report on the activities funded by grants awarded under this section and best practices relating to rape prevention and education.

PREVENTION OF TRAUMATIC BRAIN INJURY

SEC. 393B. [280b–1c] (a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Pre-

vention, 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 2020, commonly referred to as Healthy People 2020), including—

(A) the national dissemination of information on—

(i) incidence and prevalence; and

(ii) information relating to traumatic brain injury and the sequelae of secondary conditions arising from traumatic brain injury upon discharge from hospitals and emergency departments; and

(B) the provision of information in primary care settings, including emergency rooms and trauma centers, concerning the availability of State level services and resources.

(c) COORDINATION OF ACTIVITIES.—The Secretary shall ensure that activities under this section are coordinated as appropriate with other agencies of the Public Health Service that carry out activities regarding traumatic brain injury.

(d) DEFINITION.—For purposes of this section, the term "traumatic brain injury" means an acquired injury to the brain. Such term does not include brain dysfunction caused by congenital or degenerative disorders, nor birth trauma, but may include brain injuries caused by anoxia due to trauma. The Secretary may revise the definition of such term as the Secretary determines necessary, after consultation with States and other appropriate public or nonprofit private entities.

NATIONAL PROGRAM FOR TRAUMATIC BRAIN INJURY SURVEILLANCE AND REGISTRIES

SEC. 393C.[83] [280b–1d] (a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make grants to States or their designees to develop or operate the State's traumatic brain injury surveillance system or registry to determine the incidence and prevalence of traumatic brain injury and related disability, to ensure the uniformity

[83] The amendment by section 2(3) of Public Law 110–206 to redesignate section 393B (relating to traumatic brain injury registeries) as section 393C could not be executed because such section had already been redesignated as section 393C by section 2(1) of Public Law 110–202.

of reporting under such system or registry, to link individuals with traumatic brain injury to services and supports, and to link such individuals with academic institutions to conduct applied research that will support the development of such surveillance systems and registries as may be necessary. A surveillance system or registry under this section shall provide for the collection of data concerning—

(1) demographic information about each traumatic brain injury;

(2) information about the circumstances surrounding the injury event associated with each traumatic brain injury;

(3) administrative information about the source of the collected information, dates of hospitalization and treatment, and the date of injury; and

(4) information characterizing the clinical aspects of the traumatic brain injury, including the severity of the injury, outcomes of the injury, the types of treatments received, and the types of services utilized.

(b) Not later than 18 months after the date of enactment of the Traumatic Brain Injury Act of 2008, the Secretary, acting through the Director of the Centers for Disease Control and Prevention and the Director of the National Institutes of Health and in consultation with the Secretary of Defense and the Secretary of Veterans Affairs, shall submit to the relevant committees of Congress a report that contains the findings derived from an evaluation concerning activities and procedures that can be implemented by the Centers for Disease Control and Prevention to improve the collection and dissemination of compatible epidemiological studies on the incidence and prevalence of traumatic brain injury in individuals who were formerly in the military. The report shall include recommendations on the manner in which such agencies can further collaborate on the development and improvement of traumatic brain injury diagnostic tools and treatments.

(c) NATIONAL CONCUSSION DATA COLLECTION AND ANALYSIS.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may implement concussion data collection and analysis to determine the prevalence and incidence of concussion.

SEC. 393D. [28b–1f] PREVENTION OF FALLS AMONG OLDER ADULTS.

(a) PUBLIC EDUCATION.—The Secretary may—

(1) oversee and support a national education campaign to be carried out by a nonprofit organization with experience in designing and implementing national injury prevention programs, that is directed principally to older adults, their families, and health care providers, and that focuses on reducing falls among older adults and preventing repeat falls; and

(2) award grants, contracts, or cooperative agreements to qualified organizations, institutions, or consortia of qualified organizations and institutions, specializing, or demonstrating expertise, in falls or fall prevention, for the purpose of organizing State-level coalitions of appropriate State and local agencies, safety, health, senior citizen, and other organizations

to design and carry out local education campaigns, focusing on reducing falls among older adults and preventing repeat falls.

(b) RESEARCH.—

(1) IN GENERAL.—The Secretary may—

(A) conduct and support research to—

(i) improve the identification of older adults who have a high risk of falling;

(ii) improve data collection and analysis to identify fall risk and protective factors;

(iii) design, implement, and evaluate the most effective fall prevention interventions;

(iv) improve strategies that are proven to be effective in reducing falls by tailoring these strategies to specific populations of older adults;

(v) conduct research in order to maximize the dissemination of proven, effective fall prevention interventions;

(vi) intensify proven interventions to prevent falls among older adults;

(vii) improve the diagnosis, treatment, and rehabilitation of elderly fall victims and older adults at high risk for falls; and

(viii) assess the risk of falls occurring in various settings;

(B) conduct research concerning barriers to the adoption of proven interventions with respect to the prevention of falls among older adults;

(C) conduct research to develop, implement, and evaluate the most effective approaches to reducing falls among high-risk older adults living in communities and long-term care and assisted living facilities; and

(D) evaluate the effectiveness of community programs designed to prevent falls among older adults.

(2) EDUCATIONAL SUPPORT.—The Secretary, either directly or through awarding grants, contracts, or cooperative agreements to qualified organizations, institutions, or consortia of qualified organizations and institutions, specializing, or demonstrating expertise, in falls or fall prevention, may provide professional education for physicians and allied health professionals, and aging service providers in fall prevention, evaluation, and management.

(c) DEMONSTRATION PROJECTS.—The Secretary may carry out the following:

(1) Oversee and support demonstration and research projects to be carried out by qualified organizations, institutions, or consortia of qualified organizations and institutions, specializing, or demonstrating expertise, in falls or fall prevention, in the following areas:

(A) A multistate demonstration project assessing the utility of targeted fall risk screening and referral programs.

(B) Programs designed for community-dwelling older adults that utilize multicomponent fall intervention approaches, including physical activity, medication assess-

ment and reduction when possible, vision enhancement, and home modification strategies.

(C) Programs that are targeted to new fall victims who are at a high risk for second falls and which are designed to maximize independence and quality of life for older adults, particularly those older adults with functional limitations.

(D) Private sector and public-private partnerships to develop technologies to prevent falls among older adults and prevent or reduce injuries if falls occur.

(2)(A) Award grants, contracts, or cooperative agreements to qualified organizations, institutions, or consortia of qualified organizations and institutions, specializing, or demonstrating expertise, in falls or fall prevention, to design, implement, and evaluate fall prevention programs using proven intervention strategies in residential and institutional settings.

(B) Award 1 or more grants, contracts, or cooperative agreements to 1 or more qualified organizations, institutions, or consortia of qualified organizations and institutions, specializing, or demonstrating expertise, in falls or fall prevention, in order to carry out a multistate demonstration project to implement and evaluate fall prevention programs using proven intervention strategies designed for single and multifamily residential settings with high concentrations of older adults, including—

(i) identifying high-risk populations;

(ii) evaluating residential facilities;

(iii) conducting screening to identify high-risk individuals;

(iv) providing fall assessment and risk reduction interventions and counseling;

(v) coordinating services with health care and social service providers; and

(vi) coordinating post-fall treatment and rehabilitation.

(3) Award 1 or more grants, contracts, or cooperative agreements to qualified organizations, institutions, or consortia of qualified organizations and institutions, specializing, or demonstrating expertise, in falls or fall prevention, to conduct evaluations of the effectiveness of the demonstration projects described in this subsection.

(d) PRIORITY.—In awarding grants, contracts, or cooperative agreements under this section, the Secretary may give priority to entities that explore the use of cost-sharing with respect to activities funded under the grant, contract, or agreement to ensure the institutional commitment of the recipients of such assistance to the projects funded under the grant, contract, or agreement. Such non-Federal cost sharing contributions may be provided directly or through donations from public or private entities and may be in cash or in-kind, fairly evaluated, including plant, equipment, or services.

(e) STUDY OF EFFECTS OF FALLS ON HEALTH CARE COSTS.—

(1) IN GENERAL.—The Secretary may conduct a review of the effects of falls on health care costs, the potential for reduc-

ing falls, and the most effective strategies for reducing health care costs associated with falls.

(2) REPORT.—If the Secretary conducts the review under paragraph (1), the Secretary shall, not later than 36 months after the date of enactment of the Safety of Seniors Act of 2007, submit to Congress a report describing the findings of the Secretary in conducting such review.

GENERAL PROVISIONS

SEC. 394. [280b–2] (a) The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish an advisory committee to advise the Secretary and such Director with respect to the prevention and control of injuries.

(b) The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may provide technical assistance to public and nonprofit private entities with respect to the planning, development, and operation of any program or service carried out pursuant to this part. The Secretary may provide such technical assistance directly or through grants or contracts.

(c) Not later than February 1 of 1995 and of every second year thereafter, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report describing the activities carried out under this part during the preceding 2 fiscal years. Such report shall include a description of such activities that were carried out with respect to interpersonal violence within families and among acquaintances and with respect to rural areas.

SEC. 394A. [280b–3] AUTHORIZATIONS OF APPROPRIATIONS.

(a) IN GENERAL.—For the purpose of carrying out this part, there are authorized to be appropriated $50,000,000 for fiscal year 1994, and[84] 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.

(b) TRAUMATIC BRAIN INJURY.—To carry out sections 393B and 393C, there are authorized to be appropriated $11,750,000 for each of fiscal years 2020 through 2024.

PART K—HEALTH CARE SERVICES IN THE HOME AND PUBLIC HEALTH PROGRAMS FOR DEMENTIA[85]

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

[84] 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".)

[85] The style or formatting of the heading of Park K, as amended by section 2(1) of Public Law 115–406 and carried out above, reflects the original traditional style of such part heading.

the purpose of assisting grantees in carrying out demonstration projects—

(1) to identify low-income individuals who can avoid institutionalization or prolonged hospitalization if[86] skilled nursing care services, homemaker or home health aide services, or personal care services are provided in the homes of the individuals;

(2) to pay the costs of the provision of such services in the homes of such individuals; and

(3) to coordinate the provision by public and private entities of such services, and other long-term care services, in the homes of such individuals.

(b) REQUIREMENT WITH RESPECT TO AGE OF RECIPIENTS OF SERVICES.—The Secretary may not make a grant under subsection (a) to a State unless the State agrees to ensure that—

(1) not less than 25 percent of the grant is expended to provide services under such subsection to individuals who are not less than 65 years of age; and

(2) of the portion of the grant reserved by the State for purposes of complying with paragraph (1), not less than 10 percent is expended to provide such services to individuals who are not less than 85 years of age.

(c) RELATIONSHIP TO ITEMS AND SERVICES UNDER OTHER PROGRAMS.—A State may not make payments from a grant under subsection (a) for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to such item or service—

(1) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program; or

(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.

[86] Section 2(f) of Public Law 102–108 (105 Stat. 550) provides as follows: "(f) PUBLIC HEALTH SERVICE ACT TECHNICAL AMENDMENTS.—Section 395. [280c](a)(1) after the word 'if' insert the words 'skilled medical services,'". The text of such section 2(f) does not provide sufficient amendatory instructions to execute an amendment. The apparent intent of the Congress was to amend section 395(a)(1) of the Public Health Service Act (42 U.S.C. 280c(a)(1)).

(2) 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—Programs With Respect to Alzheimer's Disease and Related Dementias

SEC. 398. [280c–3] COOPERATIVE AGREEMENTS TO STATES AND PUBLIC HEALTH DEPARTMENTS FOR ALZHEIMER'S DISEASE AND RELATED DEMENTIAS.

(a) IN GENERAL.—The Secretary, in coordination with the Director of the Centers for Disease Control and Prevention and the heads of other agencies, as appropriate, shall award cooperative agreements to health departments of States, political subdivisions of States, and Indian tribes and tribal organizations, to address Alzheimer's disease and related dementias, including by reducing cognitive decline, helping meet the needs of caregivers, and addressing unique aspects of Alzheimer's disease and related dementias to support the development and implementation of evidence-based interventions with respect to—

(1) educating and informing the public, based on evidence-based public health research and data, about Alzheimer's disease and related dementias;

(2) supporting early detection and diagnosis;

(3) reducing the risk of potentially avoidable hospitalizations for individuals with Alzheimer's disease and related dementias;

(4) reducing the risk of cognitive decline and cognitive impairment associated with Alzheimer's disease and related dementias;

(5) improving support to meet the needs of caregivers of individuals with Alzheimer's disease and related dementias;

(6) supporting care planning and management for individuals with Alzheimer's disease and related dementias.

(7) supporting other relevant activities identified by the Secretary or the Director of the Centers for Disease Control and Prevention, as appropriate

(b) PREFERENCE.—In awarding cooperative agreements under this section, the Secretary shall give preference to applications that focus on addressing health disparities, including populations and geographic areas that have the highest prevalence of Alzheimer's disease and related dementias.

(c) ELIGIBILITY.—To be eligible to receive a cooperative agreement under this section, an eligible entity (pursuant to subsection (a)) shall prepare and submit to the Secretary an application at

such time, in such manner, and containing such information as the Secretary may require, including a plan that describes—

(1) how the applicant proposes to develop or expand, programs to educate individuals through partnership engagement, workforce development, guidance and support for programmatic efforts, and evaluation with respect to Alzheimer's disease and related dementias, and in the case of a cooperative agreement under this section, how the applicant proposes to support other relevant activities identified by the Secretary or Director of the Centers for Disease Control and Prevention, as appropriate.

(2) the manner in which the applicant will coordinate with Federal, tribal, and State programs related to Alzheimer's disease and related dementias, and appropriate State, tribal, and local agencies, as well as other relevant public and private organizations or agencies; and

(3) the manner in which the applicant will evaluate the effectiveness of any program carried out under the cooperative agreement.

(d) MATCHING REQUIREMENT.—Each health department that is awarded a cooperative agreement under subsection (a) shall provide, from non-Federal sources, an amount equal to 30 percent of the amount provided under such agreement (which may be provided in cash or in-kind) to carry out the activities supported by the cooperative agreement.

(e) WAIVER AUTHORITY.—The Secretary may waive all or part of the matching requirement described in subsection (d) for any fiscal year for a health department of a State, political subdivision of a State, or Indian tribe and tribal organization (including those located in a rural area or frontier area), if the Secretary determines that applying such matching requirement would result in serious hardship or an inability to carry out the purposes of the cooperative agreement awarded to such health department of a State, political subdivision of a State, or Indian tribe and tribal organization.

(g) RELATIONSHIP TO ITEMS AND SERVICES UNDER OTHER PROGRAMS.—A State may not make payments from a grant[87] 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.

(f)[88] NON-DUPLICATION OF EFFORT.—The Secretary shall ensure that activities under any cooperative agreement awarded under this subpart do not unnecessarily duplicate efforts of other

[87] Section 3(6) of Public Law 115–406 provides as follows: "(6) in subsection (f) (as so redesignated), by striking 'grant' and inserting 'cooperative agreement'". The amendment was not carried out because it probably should have been made to subsection (g) (as so redesignated).

[88] The placement of subsection (f) (as added to the end of the section by section 3(7) of Public Law 115–406) is so in law. The amendment probably should have been made to insert this new subsection before subsection (g) (as redesignated).

agencies and offices within the Department of Health and Human Services related to—

(1) activities of centers of excellence with respect to Alzheimer's disease and related dementias described in section 398A; and

(2) activities of public health departments with respect to Alzheimer's disease and related dementias described in this section.

SEC. 398A. [280c–4] PROMOTION OF PUBLIC HEALTH KNOWLEDGE AND AWARENESS OF ALZHEIMER'S DISEASE AND RELATED DEMENTIAS.

(a) ALZHEIMER'S DISEASE AND RELATED DEMENTIAS PUBLIC HEALTH CENTERS OF EXCELLENCE.—

(1) IN GENERAL.—The Secretary, in coordination with the Director of the Centers for Disease Control and Prevention and the heads of other agencies as appropriate, shall award grants, contracts, or cooperative agreements to eligible entities, such as institutions of higher education, State, tribal, and local health departments, Indian tribes, tribal organizations, associations, or other appropriate entities for the establishment or support of regional centers to address Alzheimer's disease and related dementias by—

(A) advancing the awareness of public health officials, health care professionals, and the public, on the most current information and research related to Alzheimer's disease and related dementias, including cognitive decline, brain health, and associated health disparities;

(B) identifying and translating promising research findings, such as findings from research and activities conducted or supported by the National Institutes of Health, including Alzheimer's Disease Research Centers authorized by section 445, into evidence-based programmatic interventions for populations with Alzheimer's disease and related dementias and caregivers for such populations; and

(C) expanding activities, including through public-private partnerships related to Alzheimer's disease and related dementias and associated health disparities.

(2) REQUIREMENTS.—To be eligible to receive a grant, contract, or cooperative agreement under this subsection, an entity shall submit to the Secretary an application containing such agreements and information as the Secretary may require, including a description of how the entity will—

(A) coordinate, as applicable, with existing Federal, State, and tribal programs related to Alzheimer's disease and related dementias;

(B) examine, evaluate, and promote evidence-based interventions for individuals with Alzheimer's disease and related dementias, including underserved populations with such conditions, and those who provide care for such individuals; and

(C) prioritize activities relating to—

(i) expanding efforts, as appropriate, to implement evidence-based practices to address Alzheimer's disease and related dementias, including through the

training of State, local, and tribal public health officials and other health professionals on such practices;

(ii) supporting early detection and diagnosis of Alzheimer's disease and related dementias;

(iii) reducing the risk of potentially avoidable hospitalizations of individuals with Alzheimer's disease and related dementias;

(iv) reducing the risk of cognitive decline and cognitive impairment associated with Alzheimer's disease and related dementias;

(v) enhancing support to meet the needs of caregivers of individuals with Alzheimer's disease and related dementias;

(vi) reducing health disparities related to the care and support of individuals with Alzheimer's disease and related dementias;

(vii) supporting care planning and management for individuals with Alzheimer's disease and related dementias; and

(viii) supporting other relevant activities identified by the Secretary or the Director of the Centers for Disease Control and Prevention, as appropriate.

(3) CONSIDERATIONS.—In awarding grants, contracts, and cooperative agreements under this subsection, the Secretary shall consider, among other factors, whether the entity—

(A) provides services to rural areas or other underserved populations;

(B) is able to build on an existing infrastructure of services and public health research; and

(C) has experience with providing care or caregiver support, or has experience conducting research related to Alzheimer's disease and related dementias.

(4) DISTRIBUTION OF AWARDS.—In awarding grants, contracts, or cooperative agreements under this subsection, the Secretary, to the extent practicable, shall ensure equitable distribution of awards based on geographic area, including consideration of rural areas, and the burden of the disease within sub-populations.

(5) DATA REPORTING AND PROGRAM OVERSIGHT.—With respect to a grant, contract, or cooperative agreement awarded under this subsection, not later than 90 days after the end of the first year of the period of assistance, and annually thereafter for the duration of the grant, contract, or agreement (including the duration of any renewal period as provided for under paragraph (5)), the entity shall submit data, as appropriate, to the Secretary regarding—

(A) the programs and activities funded under the grant, contract, or agreement; and

(B) outcomes related to such programs and activities.

(b) IMPROVING DATA ON STATE AND NATIONAL PREVALENCE OF ALZHEIMER'S DISEASE AND RELATED DEMENTIAS.—

(1) IN GENERAL.—The Secretary shall, as appropriate, improve the analysis and timely reporting of data on the incidence and prevalence of Alzheimer's disease and related de-

mentias. Such data may include, as appropriate, information on cognitive decline, caregiving, and health disparities experienced by individuals with cognitive decline and their caregivers. The Secretary may award grants, contracts, or cooperative agreements to eligible entities for activities under this paragraph.

(2) ELIGIBILITY.—To be eligible to receive a grant, contract, or cooperative agreement under this subsection, an entity shall be a public or nonprofit private entity, including institutions of higher education, State, local, and tribal health departments, and Indian tribes and tribal organizations, and submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

(3) DATA SOURCES.—The analysis, timely public reporting, and dissemination of data under this subsection may be carried out using data sources such as the following:

(A) The Behavioral Risk Factor Surveillance System.

(B) The National Health and Nutrition Examination Survey.

(C) The National Health Interview Survey.

(c) IMPROVED COORDINATION.—The Secretary shall ensure that activities and programs related to dementia under this section do not unnecessarily duplicate activities and programs of other agencies and offices within the Department of Health and Human Services.

SEC. 398B. [280c–5] GENERAL PROVISIONS.

(a) LIMITATION ON ADMINISTRATIVE EXPENSES.—The Secretary may not make a grant or cooperative agreement under sections 398 or 398A to an entity unless the entity agrees that not more than 5 percent of the grant or cooperative agreement will be expended for administrative expenses with respect to the grant or cooperative agreement.

(b) REQUIREMENT OF APPLICATION.—The Secretary may not make a grant under sections 398 or 398A to an entity unless the entity has submitted to the Secretary an application for the grant. The application shall—

(1) contain the description of intended expenditures;

(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.

(c) EVALUATIONS AND REPORT BY SECRETARY.—The Secretary shall—

(1) provide for an evaluation of the activities for which an award is made under sections 398 or 398A; and

(2) not later than 1 year after the completion of such evaluations, submit to the Congress a report describing the findings made as a result of the evaluations.

(d) DEFINITION.—In this subpart, the terms "Indian tribe" and "tribal organization" have the meanings given such terms in section 4 of the Indian Health Care Improvement Act.

(e) AUTHORIZATIONS OF APPROPRIATIONS.—For the purpose of carrying out this subpart, there are authorized to be appropriated $20,000,000 for each of fiscal years 2020 through 2024 and $33,000,000 for each of fiscal years 2025 through 2029.

Subpart III—Grants for Home Visiting Services for At-Risk Families

SEC. 399. [280c–6] PROJECTS TO IMPROVE MATERNAL, INFANT, AND CHILD HEALTH.

(a) IN GENERAL.—

(1) ESTABLISHMENT OF PROGRAM.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall make grants to eligible entities to pay the Federal share of the cost of providing the services specified in subsection (b) to families in which a member is—

(A) a pregnant woman at risk of delivering an infant with a health or developmental complication; or

(B) a child less than 3 years of age—

(i) who is experiencing or is at risk of a health or developmental complication, or of child abuse or neglect; or

(ii) who has been prenatally exposed to maternal substance abuse.

(2) MINIMUM PERIOD OF AWARDS; ADMINISTRATIVE CONSULTATIONS.—

(A) The Secretary shall award grants under paragraph (1) for periods of at least three years.

(B) The Administrator of the Administration for Children, Youth, and Families and the Director of the National Commission to Prevent Infant Mortality shall be consulted regarding the promulgation of program guidelines and funding priorities under this section.

(3) REQUIREMENT OF STATUS AS MEDICAID PROVIDER.—

(A) Subject to subparagraph (B), the Secretary may make a grant under paragraph (1) only if, in the case of any service under such paragraph that is covered in the State plan approved under title XIX of the Social Security Act for the State involved—

(i) the entity involved will provide the service directly, and the entity has entered into a participation agreement under the State plan and is qualified to receive payments under such plan; or

(ii) the entity will enter into an agreement with an organization under which the organization will provide the service, and the organization has entered into such a participation agreement and is qualified to receive such payments.

(B)(i) In the case of an organization making an agreement under subparagraph (A)(ii) regarding the provision of services under paragraph (1), the requirement established in such subparagraph regarding a participation agreement shall be waived by the Secretary if the organization does not, in providing health or mental health services, impose a charge or accept reimbursement available from any

third-party payor, including reimbursement under any insurance policy or under any Federal or State health benefits program.

(ii) A determination by the Secretary of whether an organization referred to in clause (i) meets the criteria for a waiver under such clause shall be made without regard to whether the organization accepts voluntary donations regarding the provision of services to the public.

(b) HOME VISITING SERVICES FOR ELIGIBLE FAMILIES.—With respect to an eligible family, each of the following services shall, directly or through arrangement with other public or nonprofit private entities, be available (as applicable to the family member involved) in each project operated with a grant under subsection (a):

(1) Prenatal and postnatal health care.

(2) Primary health care for the children, including developmental assessments.

(3) Education for the parents concerning infant care and child development, including the development and utilization of parent and teacher resource networks and other family resource and support networks where such networks are available.

(4) Upon the request of a parent, providing the education described in paragraph (3) to other individuals who have responsibility for caring for the children.

(5) Education for the parents concerning behaviors that adversely affect health.

(6) Assistance in obtaining necessary health, mental health, developmental, social, housing, and nutrition services and other assistance, including services and other assistance under maternal and child health programs; the special supplemental nutrition program for women, infants, and children; section 17 of the Child Nutrition Act of 1966; title V of the Social Security Act; title XIX of such Act (including the program for early and periodic screening, diagnostic, and treatment services described in section 1905(r) of such Act); titles IV and XIX of the Social Security Act; housing programs; other food assistance programs; and appropriate alcohol and drug dependency treatment programs, according to need.

(c) CONSIDERATIONS IN MAKING GRANTS.—In awarding grants under subsection (a), the Secretary shall take into consideration—

(1) the ability of the entity involved to provide, either directly or through linkages, a broad range of preventive and primary health care services and related social, family support, and developmental services;

(2) different combinations of professional and lay home visitors utilized within programs that are reflective of the identified service needs and characteristics of target populations;

(3) the extent to which the population to be targeted has limited access to health care, and related social, family support, and developmental services; and

(4) whether such grants are equitably distributed among urban and rural settings and whether entities serving Native American communities are represented among the grantees.

(d) FEDERAL SHARE.—With respect to the costs of carrying out a project under subsection (a), a grant under such subsection for the project may not exceed 90 percent of such costs. To be eligible to receive such a grant, an applicant must provide assurances that the applicant will obtain at least 10 percent of such costs from non-Federal funds (and such contributions to such costs may be in cash or in-kind, including facilities and personnel).

(e) RULE OF CONSTRUCTION REGARDING AT-RISK BIRTHS.—For purposes of subsection (a)(1), a pregnant woman shall be considered to be at risk of delivering an infant with a health or developmental complication if during the pregnancy the woman—

(1) lacks appropriate access to, or information concerning, early and routine prenatal care;

(2) lacks the transportation necessary to gain access to the services described in subsection (b);

(3) lacks appropriate child care assistance, which results in impeding the ability of such woman to utilize health and related social services;

(4) is fearful of accessing substance abuse services or child and family support services; or

(5) is a minor with a low income.

(f) DELIVERY OF SERVICES AND CASE MANAGEMENT.—

(1) CASE MANAGEMENT MODEL.—Home visiting services provided under this section shall be delivered according to a case management model, and a registered nurse, licensed social worker, or other licensed health care professional with experience and expertise in providing health and related social services in home and community settings shall be assigned as the case manager for individual cases under such model.

(2) CASE MANAGER.—A case manager assigned under paragraph (1) shall have primary responsibility for coordinating and overseeing the development of a plan for each family that is to receive home visiting services under this section, and for coordinating the delivery of such services provided through appropriate personnel.

(3) APPROPRIATE PERSONNEL.—In determining which personnel shall be utilized in the delivery of services, the case manager shall consider—

(A) the stated objective of the project to be operated with the grant, as determined after considering identified gaps in the current service delivery system; and

(B) the nature of the needs of the family to be served, as determined at the initial assessment of the family that is conducted by the case manager, and through follow-up contacts by other providers of home visiting services.

(4) FAMILY SERVICE PLAN.—A case manager, in consultation with a team established in accordance with paragraph (5) for the family involved, shall develop a plan for the family following the initial visit to the home of the family. Such plan shall reflect—

(A) an assessment of the health and related social service needs of the family;

(B) a structured plan for the delivery of home visiting services to meet the identified needs of the family;

(C) the frequency with which such services are to be provided to the family;

(D) ongoing revisions made as the needs of family members change; and

(E) the continuing voluntary participation of the family in the plan.

(5) HOME VISITING SERVICES TEAM.—The team to be consulted under paragraph (4) on behalf of a family shall include, as appropriate, other nursing professionals, physician assistants, social workers, child welfare professionals, infant and early childhood specialists, nutritionists, and laypersons trained as home visitors. The case manager shall ensure that the plan is coordinated with those physician services that may be required by the mother or child.

(g) OUTREACH.—Each grantee under subsection (a) shall provide outreach and casefinding services to inform eligible families of the availability of home visiting services from the project.

(h) CONFIDENTIALITY.—In accordance with applicable State law, an entity receiving a grant under subsection (a) shall maintain confidentiality with respect to services provided to families under this section.

(i) CERTAIN ASSURANCES.—The Secretary may award a grant under subsection (a) only if the entity involved provides assurances satisfactory to the Secretary that—

(1) the entity will provide home visiting services with reasonable frequency—

(A) to families with pregnant women, as early in the pregnancy as is practicable, and until the infant reaches at least 2 years of age; and

(B) to other eligible families, for at least 2 years; and

(2) the entity will coordinate with public health and related social service agencies to prevent duplication of effort and improve the delivery of comprehensive health and related social services.

(j) SUBMISSION TO SECRETARY OF CERTAIN INFORMATION.—The Secretary may award a grant under subsection (a) only if the entity involved submits to the Secretary—

(1) a description of the population to be targeted for home visiting services and methods of outreach and casefinding for identifying eligible families, including the use of lay home visitors where appropriate;

(2) a description of the types and qualifications of home visitors used by the entity and the process by which the entity will provide continuing training and sufficient support to the home visitors; and

(3) such other information as the Secretary determines to be appropriate.

(k) LIMITATION REGARDING ADMINISTRATIVE EXPENSES.—Not more than 10 percent of a grant under subsection (a) may be expended for administrative expenses with respect to the grant. The costs of training individuals to serve in the project involved are not subject to the preceding sentence.

(l) RESTRICTIONS ON USE OF GRANT.—To be eligible to receive a grant under this section, an entity must agree that the grant will not be expended—

(1) to provide inpatient hospital services;

(2) to make cash payments to intended recipients of services;

(3) to purchase or improve land, purchase, construct, or permanently improve (other than minor remodeling) any building or other facility, or purchase major medical equipment;

(4) to satisfy any requirement for the expenditure of non-Federal funds as a condition for the receipt of Federal funds; or

(5) to provide financial assistance to any entity other than a public or nonprofit private entity.

(m) REPORTS TO SECRETARY.—To be eligible to receive a grant under this section, an entity must agree to submit an annual report on the services provided under this section to the Secretary in such manner and containing such information as the Secretary by regulation requires. At a minimum, the entity shall report information concerning eligible families, including—

(1) the characteristics of the families and children receiving services under this section;

(2) the usage, nature, and location of the provider, of preventive health services, including prenatal, primary infant, and child health care;

(3) the incidence of low birthweight and premature infants;

(4) the length of hospital stays for pre- and post-partum women and their children;

(5) the incidence of substantiated child abuse and neglect for all children within participating families;

(6) the number of emergency room visits for routine health care;

(7) the source of payment for health care services and the extent to which the utilization of health care services, other than routine screening and medical care, available to the individuals under the program established under title XIX of the Social Security Act, and under other Federal, State, and local programs, is reduced;

(8) the number and type of referrals made for health and related social services, including alcohol and drug treatment services, and the utilization of such services provided by the grantee; and

(9) the incidence of developmental disabilities.

(n) REQUIREMENT OF APPLICATION.—The Secretary may make a grant under subsection (a) only if—

(1) an application for the grant is submitted to the Secretary;

(2) the application contains the agreements and assurances required in this section, and the information required in subsection (j);

(3) the application contains evidence that the preparation of the application has been coordinated with the State agencies responsible for maternal and child health and child welfare,

and coordinated with services provided under part C of the Individuals with Disabilities Education Act; and

(4) the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(o) PEER REVIEW.—

(1) REQUIREMENT.—In making determinations for awarding grants under subsection (a), the Secretary shall rely on the recommendations of the peer review panel established under paragraph (2).

(2) COMPOSITION.—The Secretary shall establish a review panel to make recommendations under paragraph (1) that shall be composed of—

(A) national experts in the fields of maternal and child health, child abuse and neglect, and the provision of community-based primary health services; and

(B) representatives of relevant Federal agencies, including the Health Resources and Services Administration, the Substance Abuse and Mental Health Services Administration, the Administration for Children, Youth, and Families, the U.S. Advisory Board on Child Abuse and Neglect, and the National Commission to Prevent Infant Mortality.

(p) EVALUATIONS.—

(1) IN GENERAL.—The Secretary shall, directly or through contracts with public or private entities—

(A) conduct evaluations to determine the effectiveness of projects under subsection (a) in reducing the incidence of children born with health or developmental complications, the incidence among children less than 3 years of age of such complications, and the incidence of child abuse and neglect; and

(B) not less than once during each 3-year period, prepare and submit to the appropriate committees of Congress a report concerning the results of such evaluations.

(2) CONTENTS.—The evaluations conducted under paragraph (1) shall—

(A) include a summary of the data contained in the annual reports submitted under subsection (m);

(B) assess the relative effectiveness of projects under subsection (a) in urban and rural areas, and among programs utilizing differing combinations of professionals and trained home visitors recruited from the community to meet the needs of defined target service populations; and

(C) make further recommendations necessary or desirable to increase the effectiveness of such projects.

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

(1) The term "eligible entity" includes public and nonprofit private entities that provide health or related social services, including community-based organizations, visiting nurse organizations, hospitals, local health departments, community health centers, Native Hawaiian health centers, nurse managed clinics, family service agencies, child welfare agencies, de-

velopmental service providers, family resource and support programs, and resource mothers projects.

(2) The term "eligible family" means a family described in subsection (a).

(3) The term "health or developmental complication", with respect to a child, means—

(A) being born in an unhealthy or potentially unhealthy condition, including premature birth, low birthweight, and prenatal exposure to maternal substance abuse;

(B) a condition arising from a condition described in subparagraph (A);

(C) a physical disability or delay; and

(D) a developmental disability or delay.

(4) The term "home visiting services" means the services specified in subsection (b), provided at the residence of the eligible family involved or provided pursuant to arrangements made for the family (including arrangements for services in community settings).

(5) The term "home visitors" means providers of home visiting services.

(r) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there is authorized to be appropriated $30,000,000 for each of the fiscal years 1993 and 1994.

[Part L [89]—]

SEC. 399A. [280d] GRANTS FOR SERVICES FOR CHILDREN OF SUBSTANCE ABUSERS. [89]

(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

[89] 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.

the Administrator of the Substance Abuse and Mental Health Services Administration shall be consulted regarding the promulgation of program guidelines and funding priorities under this section.

(3) REQUIREMENT OF STATUS AS MEDICAID PROVIDER.—

(A) Subject to subparagraph (B), the Secretary may make a grant under paragraph (1) only if, in the case of any service under such paragraph that is covered in the State plan approved under title XIX of the Social Security Act for the State involved—

(i) the entity involved will provide the service directly, and the entity has entered into a participation agreement under the State plan and is qualified to receive payments under such plan; or

(ii) the entity will enter into an agreement with an organization under which the organization will provide the service, and the organization has entered into such a participation agreement and is qualified to receive such payments.

(B)(i) In the case of an organization making an agreement under subparagraph (A)(ii) regarding the provision of services under paragraph (1), the requirement established in such subparagraph regarding a participation agreement shall be waived by the Secretary if the organization does not, in providing health or mental health services, impose a charge or accept reimbursement available from any third-party payor, including reimbursement under any insurance policy or under any Federal or State health benefits program.

(ii) A determination by the Secretary of whether an organization referred to in clause (i) meets the criteria for a waiver under such clause shall be made without regard to whether the organization accepts voluntary donations regarding the provision of services to the public.

(b) SERVICES FOR CHILDREN OF SUBSTANCE ABUSERS.—The Secretary may make a grant under subsection (a) only if the applicant involved agrees to make available (directly or through agreements with other entities) to children of substance abusers each of the following services:

(1) Periodic evaluation of children for developmental, psychological, and medical problems.

(2) Primary pediatric care.

(3) Other necessary health and mental health services.

(4) Therapeutic intervention services for children, including provision of therapeutic child care.

(5) Preventive counseling services.

(6) Counseling related to the witnessing of chronic violence.

(7) Referrals for, and assistance in establishing eligibility for, services provided under—

(A) education and special education programs;

(B) Head Start programs established under the Head Start Act;

(C) other early childhood programs;

(D) employment and training programs;

(E) public assistance programs provided by Federal, State, or local governments; and

(F) programs offered by vocational rehabilitation agencies, recreation departments, and housing agencies.

(8) Additional developmental services that are consistent with the provision of early intervention services, as such term is defined in part C of the Individuals with Disabilities Education Act.

(c) SERVICES FOR AFFECTED FAMILIES.—The Secretary may make a grant under subsection (a) only if, in the case of families in which a member is a substance abuser, the applicant involved agrees to make available (directly or through agreements with other entities) each of the following services, as applicable to the family member involved:

(1) Services as follows, to be provided by a public health nurse, social worker, or similar professional, or by a trained worker from the community who is supervised by a professional:

(A) Counseling to substance abusers on the benefits and availability of substance abuse treatment services and services for children of substance abusers.

(B) Assistance to substance abusers in obtaining and using substance abuse treatment services and in obtaining the services described in subsection (b) for their children.

(C) Visiting and providing support to substance abusers, especially pregnant women, who are receiving substance abuse treatment services or whose children are receiving services under subsection (b).

(2) In the case of substance abusers:

(A) Encouragement and, where necessary, referrals to participate in appropriate substance abuse treatment.

(B) Primary health care and mental health services, including prenatal and post partum care for pregnant women.

(C) Consultation and referral regarding subsequent pregnancies and life options, including education and career planning.

(D) Where appropriate, counseling regarding family conflict and violence.

(E) Remedial education services.

(F) Referrals for, and assistance in establishing eligibility for, services described in subsection (b)(7).

(3) In the case of substance abusers, spouses of substance abusers, extended family members of substance abusers, caretakers of children of substance abusers, and other people significantly involved in the lives of substance abusers or the children of substance abusers:

(A) An assessment of the strengths and service needs of the family and the assignment of a case manager who will coordinate services for the family.

(B) Therapeutic intervention services, such as parental counseling, joint counseling sessions for families and children, and family therapy.

(C) Child care or other care for the child to enable the parent to attend treatment or other activities and respite care services.

(D) Parenting education services and parent support groups.

(E) Support services, including, where appropriate, transportation services.

(F) Where appropriate, referral of other family members to related services such as job training.

(G) Aftercare services, including continued support through parent groups and home visits.

(d) CONSIDERATIONS IN MAKING GRANTS.—In making grants under subsection (a), the Secretary shall ensure that the grants are reasonably distributed among the following types of entities:

(1) Alcohol and drug treatment programs, especially those providing treatment to pregnant women and mothers and their children.

(2) Public or nonprofit private entities that provide health or social services to disadvantaged populations, and that have—

(A) expertise in applying the services to the particular problems of substance abusers and the children of substance abusers; and

(B) an affiliation or contractual relationship with one or more substance abuse treatment programs.

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

(4) Indian tribes.

(e) FEDERAL SHARE.—The Federal share of a program carried out under subsection (a) shall be 90 percent. The Secretary shall accept the value of in-kind contributions, including facilities and personnel, made by the grant recipient as a part or all of the non-Federal share of grants.

(f) COORDINATION WITH OTHER PROVIDERS.—The Secretary may make a grant under subsection (a) only if the applicant involved agrees to coordinate its activities with those of the State lead agency, and the State Interagency Coordinating Council, under part C of the Individuals with Disabilities Education Act.

(g) RESTRICTIONS ON USE OF GRANT.—The Secretary may make a grant under subsection (a) only if the applicant involved agrees that the grant will not be expended—

(1) to provide inpatient hospital services;

(2) to make cash payments to intended recipients of services;

(3) to purchase or improve land, purchase, construct, or permanently improve (other than minor remodeling) any building or other facility, or purchase major medical equipment;

(4) to satisfy any requirement for the expenditure of non-Federal funds as a condition for the receipt of Federal funds; or

(5) to provide financial assistance to any entity other than a public or nonprofit private entity.

(h) SUBMISSION TO SECRETARY OF CERTAIN INFORMATION.—The Secretary may make a grant under subsection (a) only if the applicant involved submits to the Secretary—

(1) a description of the population that is to receive services under this section and a description of such services that are to be provided and measurable goals and objectives;

(2) a description of the mechanism that will be used to involve the local public agencies responsible for health, mental health, child welfare, education, juvenile justice, developmental disabilities, and substance abuse treatment programs in planning and providing services under this section, as well as evidence that the proposal has been coordinated with the State agencies responsible for administering those programs and the State agency responsible for administering public maternal and child health services;

(3) information demonstrating that the applicant has established a collaborative relationship with child welfare agencies and child protective services that will enable the applicant, where appropriate, to—

(A) provide advocacy on behalf of substance abusers and the children of substance abusers in child protective services cases;

(B) provide services to help prevent the unnecessary placement of children in substitute care; and

(C) promote reunification of families or permanent plans for the placement of the child; and

(4) such other information as the Secretary determines to be appropriate.

(i) REPORTS TO SECRETARY.—The Secretary may make a grant under subsection (a) only if the applicant involved agrees that for each fiscal year for which the applicant receives such a grant the applicant, in accordance with uniform standards developed by the Secretary, will submit to the Secretary a report containing—

(1) a description of specific services and activities provided under the grant;

(2) information regarding progress toward meeting the program's stated goals and objectives;

(3) information concerning the extent of use of services provided under the grant, including the number of referrals to related services and information on other programs or services accessed by children, parents, and other caretakers;

(4) information concerning the extent to which parents were able to access and receive treatment for alcohol and drug abuse and sustain participation in treatment over time until the provider and the individual receiving treatment agree to end such treatment, and the extent to which parents re-enter treatment after the successful or unsuccessful termination of treatment;

(5) information concerning the costs of the services provided and the source of financing for health care services;

(6) information concerning—

(A) the number and characteristics of families, parents, and children served, including a description of the

type and severity of childhood disabilities, and an analysis of the number of children served by age;

(B) the number of children served who remained with their parents during the period in which entities provided services under this section;

(C) the number of children served who were placed in out-of-home care during the period in which entities provided services under this section;

(D) the number of children described in subparagraph (C) who were reunited with their families; and

(E) the number of children described in subparagraph (C) for whom a permanent plan has not been made or for whom the permanent plan is other than family reunification;

(7) information on hospitalization or emergency room use by the family members participating in the program; and

(8) such other information as the Secretary determines to be appropriate.

(j) REQUIREMENT OF APPLICATION.—The Secretary may make any grant under subsection (a) only if—

(1) an application for the grant is submitted to the Secretary;

(2) the application contains the agreements required in this section and the information required in subsection (h); and

(3) the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(k) PEER REVIEW.—

(1) REQUIREMENT.—In making determinations for awarding grants under subsection (a), the Secretary shall rely on the recommendations of the peer review panel established under paragraph (2).

(2) COMPOSITION.—The Secretary shall establish a review panel to make recommendations under paragraph (1) that shall be composed of—

(A) national experts in the fields of maternal and child health, substance abuse treatment, and child welfare; and

(B) representatives of relevant Federal agencies, including the Health Resources and Services Administration, the Substance Abuse and Mental Health Services Administration, and the Administration for Children, Youth, and Families.

(l) EVALUATIONS.—The Secretary shall periodically conduct evaluations to determine the effectiveness of programs supported under subsection (a)—

(1) in reducing the incidence of alcohol and drug abuse among substance abusers participating in the programs;

(2) in preventing adverse health conditions in children of substance abusers;

(3) in promoting better utilization of health and developmental services and improving the health, developmental, and psychological status of children receiving services under the program;

(4) in improving parental and family functioning;

(5) in reducing the incidence of out-of-home placement for children whose parents receive services under the program; and

(6) in facilitating the reunification of families after children have been placed in out-of-home care.

(m) REPORT TO CONGRESS.—Not later than 2 years after the date on which amounts are first appropriated under subjection (o), the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report that contains a description of programs carried out under this section. At a minimum, the report shall contain—

(1) information concerning the number and type of programs receiving grants;

(2) information concerning the type and use of services offered;

(3) information concerning—

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

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

(C) the number of children served who were placed in out-of-home care during the period in which entities provided services under this section;

(D) the number of children described in subparagraph (C) who were reunited with their families; and

(E) the number of children described in subparagraph (C) who were permanently placed in out-of-home care;

analyzed by the type of entity described in subsection (d) that provided services;

(4) an analysis of the access provided to, and use of, related services and alcohol and drug treatment through programs carried out under this section; and

(5) a comparison of the costs of providing services through each of the types of entities described in subsection (d).

(n) DATA COLLECTION.—The Secretary shall periodically collect and report on information concerning the numbers of children in substance abusing families, including information on the age, gender and ethnicity of the children, the composition and income of the family, and the source of health care finances.

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

(1) The term "caretaker", with respect to a child of a substance abuser, means any individual acting in a parental role regarding the child (including any birth parent, foster parent, adoptive parent, relative of such a child, or other individual acting in such a role).

(2) The term "children of substance abusers" means—

(A) children who have lived or are living in a household with a substance abuser who is acting in a parental role regarding the children; and

(B) children who have been prenatally exposed to alcohol or other dangerous drugs.

(3) The term "Indian tribe" means any tribe, band, nation, or other organized group or community of Indians, including any Alaska Native village (as defined in, or established pursuant to, the Alaska Native Claims Settlement Act), that is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians.

(4) The term "public or nonprofit private entities that provide health or social services to disadvantaged populations" includes community-based organizations, local public health departments, community action agencies, hospitals, community health centers, child welfare agencies, developmental disabilities service providers, and family resource and support programs.

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

***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 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)(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 [90] 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 Inter-

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

agency Coordinating Council under part H of the Individuals with Disabilities Education Act; and;[91]

(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 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.

---

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

(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.[92]

analyzed by the type of entity described in subsection (d)[93] *that provided services;*[94]

(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

---

[92] *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.*

[93] *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).*

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

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 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.

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 pro-

viding screening, diagnostic or therapeutic services to patients with respect to cancer;

(ii) a means to assure the complete reporting of cancer cases (as defined in subsection (a)) to the statewide cancer registry by physicians, surgeons, and all other health care practitioners diagnosing or providing treatment for cancer patients, except for cases directly referred to or previously admitted to a hospital or other facility providing screening, diagnostic or therapeutic services to patients in that State and reported by those facilities;

(iii) a means for the statewide cancer registry to access all records of physicians and surgeons, hospitals, outpatient clinics, nursing homes, and all other facilities, individuals, or agencies providing such services to patients which would identify cases of cancer or would establish characteristics of the cancer, treatment of the cancer, or medical status of any identified patient;

(iv) for the reporting of cancer case data to the statewide cancer registry in such a format, with such data elements, and in accordance with such standards of quality timeliness and completeness, as may be established by the Secretary;

(v) for the protection of the confidentiality of all cancer case data reported to the statewide cancer registry, including a prohibition on disclosure to any person of information reported to the statewide cancer registry that identifies, or could lead to the identification of, an individual cancer patient, except for disclosure to other State cancer registries and local and State health officers;

(vi) for a means by which confidential case data may in accordance with State law be disclosed to cancer researchers for the purposes of cancer prevention, control and research;

(vii) for the authorization or the conduct, by the statewide cancer registry or other persons and organizations, of studies utilizing statewide cancer registry data, including studies of the sources and causes of cancer, evaluations of the cost, quality, efficacy, and appropriateness of diagnostic, therapeutic, rehabilitative, and preventative services and programs relating to cancer, and any other clinical, epidemiological, or other cancer research; and

(viii) for protection for individuals complying with the law, including provisions specifying that no person shall be held liable in any civil action with respect to a cancer case report provided to the statewide cancer registry, or with respect to access to cancer case information provided to the statewide cancer registry.

(d) RELATIONSHIP TO CERTAIN PROGRAMS.—

(1) IN GENERAL.—This section may not be construed to act as a replacement for or diminishment of the program carried

out by the Director of the National Cancer Institute and designated by such Director as the Surveillance, Epidemiology, and End Results Program (SEER).

(2) SUPPLANTING OF ACTIVITIES.—In areas where both such programs exist, the Secretary shall ensure that SEER support is not supplanted and that any additional activities are consistent with the guidelines provided for in subsection (c)(2) (C) and (D) and are appropriately coordinated with the existing SEER program.

(3) TRANSFER OF RESPONSIBILITY.—The Secretary may not transfer administration responsibility for such SEER program from such Director.

(4) COORDINATION.—To encourage the greatest possible efficiency and effectiveness of Federally supported efforts with respect to the activities described in this subsection, the Secretary shall take steps to assure the appropriate coordination of programs supported under this part with existing Federally supported cancer registry programs.

(e) REQUIREMENT REGARDING CERTAIN STUDY ON BREAST CANCER.—In the case of a grant under subsection (a) to any State specified in subsection (b) of section 399E, the Secretary may establish such conditions regarding the receipt of the grant as the Secretary determines are necessary to facilitate the collection of data for the study carried out under such section.

SEC. 399C. [280e–1] PLANNING GRANTS REGARDING REGISTRIES.

(a) IN GENERAL.—

(1) STATES.—The Secretary, acting through the Director of the Centers for Disease Control, may make grants to States for the purpose of developing plans that meet the assurances required by the Secretary under section 399B(c)(2).

(2) OTHER ENTITIES.—For the purpose described in paragraph (1), the Secretary may make grants to public entities other than States and to nonprofit private entities. Such a grant may be made to an entity only if the State in which the purpose is to be carried out has certified that the State approves the entity as qualified to carry out the purpose.

(b) APPLICATION.—The Secretary may make a grant under subsection (a) only if an application for the grant is submitted to the Secretary, the application contains the certification required in subsection (a)(2) (if the application is for a grant under such subsection), and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

SEC. 399D. [280e–2] TECHNICAL ASSISTANCE IN OPERATIONS OF STATEWIDE CANCER REGISTRIES.

The Secretary, acting through the Director of the Centers for Disease Control, may, directly or through grants and contracts, or both, provide technical assistance to the States in the establishment and operation of statewide registries, including assistance in the development of model legislation for statewide cancer registries and assistance in establishing a computerized reporting and data processing system.

SEC. 399E. [280e–3] STUDY IN CERTAIN STATES TO DETERMINE THE FACTORS CONTRIBUTING TO THE ELEVATED BREAST CANCER MORTALITY RATES.

(a) IN GENERAL.—Subject to subsections (c) and (d), the Secretary, acting through the Director of the National Cancer Institute, shall conduct a study for the purpose of determining the factors contributing to the fact that breast cancer mortality rates in the States specified in subsection (b) are elevated compared to rates in other States.

(b) RELEVANT STATES.—The States referred to in subsection (a) are Connecticut, Delaware, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Rhode Island, Vermont, and the District of Columbia.

(c) COOPERATION OF STATE.—The Secretary may conduct the study required in subsection (a) in a State only if the State agrees to cooperate with the Secretary in the conduct of the study, including providing information from any registry operated by the State pursuant to section 399B(a).

(d) PLANNING, COMMENCEMENT, AND DURATION.—The Secretary shall, during each of the fiscal years 1993 and 1994, develop a plan for conducting the study required in subsection (a). The study shall be initiated by the Secretary not later than fiscal year 1994, and the collection of data under the study may continue through fiscal year 1998.

SEC. 399E–1. [280e–3a] NATIONAL CHILDHOOD CANCER REGISTRY.

(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make awards to State cancer registries to enhance and expand infrastructure to collect information to better understand the epidemiology of cancer in children, adolescents, and young adults. Such registries may be updated to include each occurrence of such cancers within a period of time designated by the Secretary.

(b) ACTIVITIES.—The grants described in subsection (a) may be used for—

(1) identifying, recruiting, and training potential sources for reporting childhood, adolescent, and young adult cancer cases;

(2) developing practices to ensure early inclusion of childhood, adolescent, and young adult cancer cases in State cancer registries through the use of electronic reporting;

(3) collecting and submitting deidentified data to the Centers for Disease Control and Prevention for inclusion in a national database that includes information on childhood, adolescent, and young adult cancers; and

(4) improving State cancer registries and the database described in paragraph (3), as appropriate, including to support the early inclusion of childhood, adolescent, and young adult cancer cases.

(c) COORDINATION.—To encourage the greatest possible efficiency and effectiveness of federally supported efforts with respect to the activities described in this section, the Secretary shall ensure the appropriate coordination of programs supported under this section with other federally supported cancer registry programs and the activities under section 417E(a), as appropriate.

(d) INFORMED CONSENT AND PRIVACY REQUIREMENTS AND COORDINATION WITH EXISTING PROGRAMS.—The activities described in this section shall be subject to section 552a of title 5, United States Code, the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996, applicable Federal and State informed consent regulations, any other applicable Federal and State laws relating to the privacy of patient information, and section 399B(d)(4) of this Act.

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

(a) REGISTRIES.—For the purpose of carrying out this part (other than section 399E–1), there are authorized to be appropriated $30,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 through 2003. Of the amounts appropriated under the preceding sentence for any such fiscal year, the Secretary may obligate not more than 25 percent for carrying out section 399C, and not more than 10 percent may be expended for assessing the accuracy, completeness and quality of data collected, and not more than 10 percent of which is to be expended under section 399D.

(b) BREAST CANCER STUDY.—Of the amounts appropriated for the National Cancer Institute under subpart 1 of part C of title IV for any fiscal year in which the study required in section 399K[95] is being carried out, the Secretary shall expend not less than $1,000,000 for the study.

PART N—NATIONAL FOUNDATION FOR THE CENTERS FOR DISEASE CONTROL AND PREVENTION

SEC. 399G. [280e–11] ESTABLISHMENT AND DUTIES OF FOUNDATION.

(a) IN GENERAL.—There shall be established in accordance with this section a nonprofit private corporation to be known as the National Foundation for the Centers for Disease Control and Prevention (in this part referred to as the "Foundation"). The Foundation shall not be an agency or instrumentality of the Federal Government, and officers, employees, and members of the board of the Foundation shall not be officers or employees of the Federal Government.

(b) PURPOSE OF FOUNDATION.—The purpose of the Foundation shall be to support and carry out activities for the prevention and control of diseases, disorders, injuries, and disabilities, and for promotion of public health.

(c) ENDOWMENT FUND.—

(1) IN GENERAL.—In carrying out subsection (b), the Foundation shall establish a fund for providing endowments for positions that are associated with the Centers for Disease Control 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

[95] 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".)

earnings of the Foundation and the fund) as the Foundation may elect to transfer to the fund.

(2) AUTHORIZED EXPENDITURES OF FUND.—The provision of endowments under paragraph (1) shall be the exclusive function of the fund established under such paragraph. Such endowments may be expended only for the compensation of individuals holding the positions, for staff, equipment, quarters, travel, and other expenditures that are appropriate in supporting the positions, and for recruiting individuals to hold the positions endowed by the fund.

(d) CERTAIN ACTIVITIES OF FOUNDATION.—In carrying out subsection (b), the Foundation may provide for the following with respect to the purpose described in such subsection:

(1) Programs of fellowships for State and local public health officials to work and study in association with the Centers for Disease Control and Prevention.

(2) Programs of international arrangements to provide opportunities for public health officials of other countries to serve in public health capacities in the United States in association with the Centers for Disease Control and Prevention or elsewhere, or opportunities for employees of such Centers (or other public health officials in the United States) to serve in such capacities in other countries, or both.

(3) Studies, projects, and research (which may include applied research on the effectiveness of prevention activities, demonstration projects, and programs and projects involving international, Federal, State, and local governments).

(4) Forums for government officials and appropriate private entities to exchange information. Participants in such forums may include institutions of higher education and appropriate international organizations.

(5) Meetings, conferences, courses, and training workshops.

(6) Programs to improve the collection and analysis of data on the health status of various populations.

(7) Programs for writing, editing, printing, and publishing of books and other materials.

(8) Other activities to carry out the purpose described in subsection (b).

(e) GENERAL STRUCTURE OF FOUNDATION; NONPROFIT STATUS.—

(1) BOARD OF DIRECTORS.—The Foundation shall have a board of directors (in this part referred to as the "Board"), which shall be established and conducted in accordance with subsection (f). The Board shall establish the general policies of the Foundation for carrying out subsection (b), including the establishment of the bylaws of the Foundation.

(2) EXECUTIVE DIRECTOR.—The Foundation shall have an executive director (in this part referred to as the "Director"), who shall be appointed by the Board, who shall serve at the pleasure of the Board, and for whom the Board shall establish the rate of compensation. Subject to compliance with the policies and bylaws established by the Board pursuant to paragraph (1), the Director shall be responsible for the daily operations of the Foundation in carrying out subsection (b).

(3) NONPROFIT STATUS.—In carrying out subsection (b), the Board shall establish such policies and bylaws under paragraph (1), and the Director shall carry out such activities under paragraph (2), as may be necessary to ensure that the Foundation maintains status as an organization that—

(A) is described in subsection (c)(3) of section 501 of the Internal Revenue Code of 1986; and

(B) is, under subsection (a) of such section, exempt from taxation.

(f) BOARD OF DIRECTORS.—

(1) CERTAIN BYLAWS.—

(A) In establishing bylaws under subsection (e)(1), the Board shall ensure that the bylaws of the Foundation include bylaws for the following:

(i) Policies for the selection of the officers, employees, agents, and contractors of the Foundation.

(ii) Policies, including ethical standards, for the acceptance and disposition of donations to the Foundation and for the disposition of the assets of the Foundation.

(iii) Policies for the conduct of the general operations of the Foundation.

(iv) Policies for writing, editing, printing, and publishing of books and other materials, and the acquisition of patents and licenses for devices and procedures developed by the Foundation.

(B) In establishing bylaws under subsection (e)(1), the Board shall ensure that the bylaws of the Foundation (and activities carried out under the bylaws) do not—

(i) reflect unfavorably upon the ability of the Foundation, or the Centers for Disease Control and Prevention, to carry out its responsibilities or official duties in a fair and objective manner; or

(ii) compromise, or appear to compromise, the integrity of any governmental program or any officer or employee involved in such program.

(2) COMPOSITION.—

(A) Subject to subparagraph (B), the Board shall be composed of 7 individuals, appointed in accordance with paragraph (4), who collectively possess education or experience appropriate for representing the general field of public health, the general field of international health, and the general public. Each such individual shall be a voting member of the Board.

(B) The Board may, through amendments to the bylaws of the Foundation, provide that the number of members of the Board shall be a greater number than the number specified in subparagraph (A).

(3) CHAIR.—The Board shall, from among the members of the Board, designate an individual to serve as the chair of the Board (in this subsection referred to as the "Chair").

(4) APPOINTMENTS, VACANCIES, AND TERMS.—Subject to subsection (j) (regarding the initial membership of the Board), the following shall apply to the Board:

(A) Any vacancy in the membership of the Board shall be filled by appointment by the Board, after consideration of suggestions made by the Chair and the Director regarding the appointments. Any such vacancy shall be filled not later than the expiration of the 180-day period beginning on the date on which the vacancy occurs.

(B) The term of office of each member of the Board appointed under subparagraph (A) shall be 5 years. A member of the Board may continue to serve after the expiration of the term of the member until the expiration of the 180-day period beginning on the date on which the term of the member expires.

(C) A vacancy in the membership of the Board shall not affect the power of the Board to carry out the duties of the Board. If a member of the Board does not serve the full term applicable under subparagraph (B), the individual appointed to fill the resulting vacancy shall be appointed for the remainder of the term of the predecessor of the individual.

(5) COMPENSATION.—Members of the Board may not receive compensation for service on the Board. The members may be reimbursed for travel, subsistence, and other necessary expenses incurred in carrying out the duties of the Board.

(g) CERTAIN RESPONSIBILITIES OF EXECUTIVE DIRECTOR.—In carrying out subsection (e)(2), the Director shall carry out the following functions:

(1) Hire, promote, compensate, and discharge officers and employees of the Foundation, and define the duties of the officers and employees.

(2) Accept and administer donations to the Foundation, and administer the assets of the Foundation.

(3) Establish a process for the selection of candidates for holding endowed positions under subsection (c).

(4) Enter into such financial agreements as are appropriate in carrying out the activities of the Foundation.

(5) Take such action as may be necessary to acquire patents and licenses for devices and procedures developed by the Foundation and the employees of the Foundation.

(6) Adopt, alter, and use a corporate seal, which shall be judicially noticed.

(7) Commence and respond to judicial proceedings in the name of the Foundation.

(8) Other functions that are appropriate in the determination of the Director.

(h) GENERAL PROVISIONS.—

(1) AUTHORITY FOR ACCEPTING FUNDS.—The Director of the Centers for Disease Control and Prevention may accept and utilize, on behalf of the Federal Government, any gift, 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 until such time as the private funding for such individual ends.

(B) The limitation established in subparagraph (A) regarding the period of time in which services may be accepted applies to each individual who is not an employee of the Federal Government and who serves in association with the Centers for Disease Control and Prevention pursuant to financial support from the Foundation.

(3) ADMINISTRATIVE CONTROL.—No officer, employee, or member of the Board of the Foundation may exercise any administrative or managerial control over any Federal employee.

(4) APPLICABILITY OF CERTAIN STANDARDS TO NON-FEDERAL EMPLOYEES.—In the case of any individual who is not an employee of the Federal Government and who serves in association with the Centers for Disease Control and Prevention pursuant to financial support from the Foundation, the Foundation shall negotiate a memorandum of understanding with the individual and the Director of the Centers for Disease Control and Prevention specifying that the individual—

(A) shall be subject to the ethical and procedural standards regulating Federal employment, scientific investigation, and research findings (including publications and patents) that are required of individuals employed by the Centers for Disease Control and Prevention, including standards under this Act, chapter 131 of title 5, United States Code, and the Technology Transfer Act; and

(B) shall be subject to such ethical and procedural standards under chapter 11 of title 18, United States Code (relating to conflicts of interest), as the Director of such Centers determines is appropriate, except such memorandum may not provide that the individual shall be subject to the standards of section 209 of such chapter.

(5) FINANCIAL CONFLICTS OF INTEREST.—Any individual who is an officer, employee, or member of the Board of the Foundation may not directly or indirectly participate in the consideration or determination by the Foundation of any question affecting—

(A) any direct or indirect financial interest of the individual; or

(B) any direct or indirect financial interest of any business organization or other entity of which the individual is an officer or employee or in which the individual has a direct or indirect financial interest.

(6) AUDITS; AVAILABILITY OF RECORDS.—The Foundation shall—

(A) provide for biennial audits of the financial condition of the Foundation; and

(B) make such audits, and all other records, documents, and other papers of the Foundation, available to the Secretary and the Comptroller General of the United States for examination or audit.

(7) REPORTS.—

(A) Not later than February 1 of each fiscal year, the Foundation shall publish a report describing the activities of the Foundation during the preceding fiscal year. Each such report shall include for the fiscal year involved a comprehensive statement of the operations, activities, financial condition, and accomplishments of the Foundation, including an accounting of the use of amounts provided for under subsection (i).

(B) With respect to the financial condition of the Foundation, each report under subparagraph (A) shall include the source, and a description of, all gifts to the Foundation of real or personal property, and the source and amount of all gifts to the Foundation of money. Each such report shall include a specification of any restrictions on the purposes for which gifts to the Foundation may be used.

(C) The Foundation shall make copies of each report submitted under subparagraph (A) available—

(i) for public inspection, and shall upon request provide a copy of the report to any individual for a charge not to exceed the cost of providing the copy; and

(ii) to the appropriate committees of Congress.

(8) LIAISON FROM CENTERS FOR DISEASE CONTROL AND PREVENTION.—The Director of the Centers for Disease Control and Prevention shall serve as the liaison representative of such Centers to the Board and the Foundation.

(i) FEDERAL FUNDING.—

(1) AUTHORITY FOR ANNUAL GRANTS.—

(A) The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall—

(i) for fiscal year 1993, make a grant to an entity described in subsection (j)(9) (relating to the establishment of a committee to establish the Foundation);

(ii) for fiscal year 1994, make a grant to the committee established under such subsection, or if the Foundation has been established, to the Foundation; and

(iii) for fiscal year 1995 and each subsequent fiscal year, make a grant to the Foundation.

(B) A grant under subparagraph (A) may be expended—

(i) in the case of an entity receiving the grant under subparagraph (A)(i), only for the purpose of carrying out the duties established in subsection (j)(9) for the entity;

(ii) in the case of the committee established under such subsection, only for the purpose of carrying out

the duties established in subsection (j) for the committee; and

(iii) in the case of the Foundation, only for the purpose of the administrative expenses of the Foundation.

(C) A grant under subparagraph (A) may not be expended to provide amounts for the fund established under subsection (c).

(D) For the purposes described in subparagraph (B)—

(i) any portion of the grant made under subparagraph (A)(i) for fiscal year 1993 that remains unobligated after the entity receiving the grant completes the duties established in subsection (j)(9) for the entity shall be available to the committee established under such subsection; and

(ii) any portion of a grant under subparagraph (A) made for fiscal year 1993 or 1994 that remains unobligated after such committee completes the duties established in such subsection for the committee shall be available to the Foundation.

(2) FUNDING FOR GRANTS.—

(A) For the purpose of grants under paragraph (1), there is authorized to be appropriated $1,250,000 for each fiscal year.

(B) For the purpose of grants under paragraph (1), the Secretary may for each fiscal year make available not less than $500,000, and not more than $1,250,000 from the amounts appropriated for the fiscal year for the programs of the Department of Health and Human Services. Such amounts may be made available without regard to whether amounts have been appropriated under subparagraph (A).

(3) CERTAIN RESTRICTION.—If the Foundation receives Federal funds for the purpose of serving as a fiscal intermediary between Federal agencies, the Foundation may not receive such funds for the indirect costs of carrying out such purpose in an amount exceeding 10 percent of the direct costs of carrying out such purpose. The preceding sentence may not be construed as authorizing the expenditure of any grant under paragraph (1) for such purpose.

(4) SUPPORT SERVICES.—The Director of the Centers for Disease Control and Prevention may provide facilities, utilities, and support services to the Foundation if it is determined by the Director to be advantageous to the programs of such Centers.

(j) COMMITTEE FOR ESTABLISHMENT OF FOUNDATION.—

(1) IN GENERAL.—There shall be established in accordance with this subsection a committee to carry out the functions 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 Foun-

dation. 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[96].

(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 in the membership of the Committee shall not affect the power

[96] Enacted October 27, 1992.

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[97], 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.

[97] Enacted October 27, 1992.

PART O—FETAL ALCOHOL SPECTRUM DISORDER PREVENTION AND SERVICES PROGRAM

SEC. 399H. [280f] FETAL ALCOHOL SPECTRUM DISORDERS PREVENTION, INTERVENTION, AND SERVICES DELIVERY PROGRAM.

(a) IN GENERAL.—The Secretary shall establish or continue activities to support a comprehensive fetal alcohol spectrum disorders (referred to in this section as "FASD") education, prevention, identification, intervention, and services delivery program, which may include—

(1) an education and public awareness program to support, conduct, and evaluate the effectiveness of—

(A) educational programs targeting health professions 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 infants, children, adolescents, and adults with FASD;

(B) strategies to educate school-age children, including pregnant and high-risk youth, concerning FASD;

(C) public and community awareness programs concerning FASD; 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, agencies providing health services, and agencies involved in education, vocational training, and civil and criminal justice;

(2) supporting and conducting research on FASD, as appropriate, including to—

(A) develop appropriate medical diagnostic methods for identifying FASD; and

(B) develop effective culturally and linguistically appropriate evidence-based or evidence-informed interventions and appropriate supports for preventing prenatal alcohol exposure, which may co-occur with exposure to other substances;

(3) building State and Tribal capacity for the identification, treatment, and support of individuals with FASD and their families, which may include—

(A) utilizing and adapting existing Federal, State, or Tribal programs to include FASD identification and FASD-informed support;

(B) developing and expanding screening and diagnostic capacity for FASD;

(C) developing, implementing, and evaluating targeted FASD-informed intervention programs for FASD;

(D) providing training with respect to FASD for professionals across relevant sectors; and

(E) disseminating information about FASD and support services to affected individuals and their families; and

(4) 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 spectrum disorder or fetal alcohol effect and their families.

(b) GRANTS AND TECHNICAL ASSISTANCE.—

(1) IN GENERAL.—The Secretary may award grants, cooperative agreements and contracts and provide technical assistance to eligible entities to carry out subsection (a).

(2) ELIGIBLE ENTITIES.—To be eligible to receive a grant, or enter into a cooperative agreement or contract, under this section, an entity shall—

(A) be a State, Indian Tribe or Tribal organization, local government, scientific or academic institution, or nonprofit organization; and

(B) 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 description of the activities that the entity intends to carry out using amounts received under this section.

(3) ADDITIONAL APPLICATION CONTENTS.—The Secretary may require that an eligible entity include in the application submitted under paragraph (2)(B)—

(A) a designation of an individual to serve as a FASD State or Tribal coordinator of activities such eligible entity proposes to carry out through a grant, cooperative agreement, or contract under this section; and

(B) a description of an advisory committee the entity will establish to provide guidance for the entity on developing and implementing a statewide or Tribal strategic plan to prevent FASD and provide for the identification, treatment, and support of individuals with FASD and their families.

(c) DEFINITION OF FASD-INFORMED.—For purposes of this section, the term "FASD-informed", with respect to support or an intervention program, means that such support or intervention program uses culturally and linguistically informed evidence-based or practice-based interventions and appropriate resources to support an improved quality of life for an individual with FASD and the family of such individual.

SEC. 399I. [280f–1] STRENGTHENING CAPACITY AND EDUCATION FOR FETAL ALCOHOL SPECTRUM DISORDERS.

(a) IN GENERAL.—The Secretary shall award grants, contracts, or cooperative agreements, as the Secretary determines appropriate, to public or nonprofit private entities with demonstrated expertise in the field of fetal alcohol spectrum disorders (referred to in this section as "FASD"). Such awards shall be for the purposes of building local, Tribal, State, and nationwide capacities to prevent the occurrence of FASD by carrying out the programs described in subsection (b).

(b) PROGRAMS.—An entity receiving an award under subsection (a) may use such award for the following purposes:

(1) Developing and supporting public education and outreach activities to raise public awareness of the risks associated with alcohol consumption during pregnancy.

(2) Acting as a clearinghouse for evidence-based resources on FASD prevention, identification, and culturally and linguistically appropriate best practices to help inform systems of care for individuals with FASD across their lifespan.

(3) Increasing awareness and understanding of efficacious, evidence-based screening tools and culturally and linguistically appropriate evidence-based intervention services and best practices, which may include improving the capacity for State, Tribal, and local affiliates.

(4) Providing technical assistance to recipients of grants, cooperative agreements, or contracts under section 399H, as appropriate.

(c) APPLICATION.—To be eligible for a grant, contract, or cooperative agreement 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.

(d) SUBCONTRACTING.—A public or private nonprofit entity may carry out the following activities required under this section through contracts or cooperative agreements with other public and private nonprofit entities with demonstrated expertise in FASD:

(1) Resource development and dissemination.

(2) Intervention services.

(3) Training and technical assistance.

SEC. 399J. [280f–2] AUTHORIZATION OF APPROPRIATIONS.

There are authorized to be appropriated to carry out this part $12,500,000 for each of fiscal years 2026 through 2030.

PART P—ADDITIONAL PROGRAMS

SEC. 399L. [280g] CHILDREN'S ASTHMA TREATMENT GRANTS PROGRAM.

(a) AUTHORITY TO MAKE GRANTS.—

(1) IN GENERAL.—In addition to any other payments made under this Act or title V of the Social Security Act, the Secretary shall award grants to eligible entities to carry out the following purposes:

(A) To provide access to quality medical care for children who live in areas that have a high prevalence of asthma and who lack access to medical care.

(B) To provide on-site education to parents, children, health care providers, and medical teams to recognize the signs and symptoms of asthma, and to train them in the use of medications to treat asthma and prevent its exacerbations.

(C) To decrease preventable trips to the emergency room by making medication available to individuals who have not previously had access to treatment or education in the management of asthma.

(D) To provide other services, such as smoking cessation programs, home modification, and other direct and support services that ameliorate conditions that exacerbate or induce asthma.

(2) CERTAIN PROJECTS.—In making grants under paragraph (1), the Secretary may make grants designed to develop and expand the following projects:

(A) Projects to provide comprehensive asthma services to children in accordance with the guidelines of the National Asthma Education and Prevention Program (through the National Heart, Lung and Blood Institute), including access to care and treatment for asthma in a community-based setting.

(B) Projects to fully equip mobile health care clinics that provide preventive asthma care including diagnosis, physical examinations, pharmacological therapy, skin testing, peak flow meter testing, and other asthma-related health care services.

(C) Projects to conduct validated asthma management education programs for patients with asthma and their families, including patient education regarding asthma management, family education on asthma management, and the distribution of materials, including displays and videos, to reinforce concepts presented by medical teams.

(2)[98] 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.

[98] 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).

(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.);

(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.—[99]

(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

[99] 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.".

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.

(B) SCOPE.—An authorization granted under subparagraph (A) must allow the student involved to possess and use his or her medication—

(i) while in school;

(ii) while at a school-sponsored activity, such as a sporting event; and

(iii) in transit to or from school or school-sponsored activities.

(C) DURATION OF AUTHORIZATION.—An authorization granted under subparagraph (A)—

(i) must be effective only for the same school and school year for which it is granted; and

(ii) must be renewed by the parent or guardian each subsequent school year in accordance with this subsection.

(D) BACKUP MEDICATION.—The State must require that backup medication, if provided by a student's parent or guardian, be kept at a student's school in a location to which the student has immediate access in the event of an asthma or anaphylaxis emergency.

(E) MAINTENANCE OF INFORMATION.—The State must require that information described in subparagraphs (A)(iii) and (A)(iv) be kept on file at the student's school in a location easily accessible in the event of an asthma or anaphylaxis emergency.

(F) SCHOOL PERSONNEL ADMINISTRATION OF EPINEPHRINE OR SCHOOL COMPREHENSIVE ALLERGIES AND ASTHMA MANAGEMENT PROGRAM.—

(i) IN GENERAL.—In determining the preference (if any) to be given to a State under this subsection, the Secretary shall give additional preference to a State that provides to the Secretary the certification described in subparagraph (G) and that requires that each public elementary school and secondary schoolin the State satisfy the criteria described in clause (ii) or clause (iii).

(ii) CRITERIA FOR SCHOOL PERSONNEL ADMINISTRATION OF EPINEPHRINE.—For purposes of clause (i), the

criteria described in this clause, with respect to each public elementary school and secondary school in the State, are that each such school—

(I) permits trained personnel of the school to administer epinephrine to any student of the school reasonably believed to be having an anaphylactic reaction;

(II) maintains a supply of epinephrine in a secure location that is easily accessible to trained personnel of the school for the purpose of administration to any student of the school reasonably believed to be having an anaphylactic reaction; and

(III) has in place a plan for having on the premises of the school during all operating hours of the school one or more individuals who are trained personnel of the school.

(iii) CRITERIA FOR SCHOOL COMPREHENSIVE ALLERGIES AND ASTHMA MANAGEMENT PROGRAM.—For purposes of clause (i), the criteria described in this clause, with respect to each public elementary school and secondary school in the State, are that each such school—

(I) has in place a plan for having on the premises of the school during all operating hours of the school a school nurse or one or more other individuals who are designated by the principal (or other appropriate administrative staff) of the school to direct and apply the program described in subclause (II) on a voluntary basis outside their scope of employment; and

(II) has in place, under the direction of a school nurse or other individual designated under subclause (I), a comprehensive school-based allergies and asthma management program that includes—

(aa) a method to identify all students of such school with a diagnosis of allergies and asthma;

(bb) an individual student allergies and asthma action plan for each student of such school with a diagnosis of allergies and asthma;

(cc) allergies and asthma education for school staff who are directly responsible for students who have been identified as having allergies or asthma, such as education regarding basics, management, trigger management, and comprehensive emergency responses with respect to allergies and asthma;

(dd) efforts to reduce the presence of environmental triggers of allergies and asthma; and

(ee) a system to support students with a diagnosis of allergies or asthma through coordination with family members of such stu-

dents, primary care providers of such students, primary asthma or allergy care providers of such students, and others as necessary.

(G) CIVIL LIABILITY PROTECTION LAW.—The certification required in subparagraph (F) shall be a certification made by the State attorney general that the State has reviewed any applicable civil liability protection law to determine the application of such law with regard to elementary and secondary school trained personnel who may administer epinephrine to a student reasonably believed to be having an anaphylactic reaction and has concluded that such law provides adequate civil liability protection applicable to such trained personnel. For purposes of the previous sentence, the term "civil liability protection law" means a State law offering legal protection to individuals who give aid on a voluntary basis in an emergency to an individual who is ill, in peril, or otherwise incapacitated.

(2) RULE OF CONSTRUCTION.—Nothing in this subsection creates a cause of action or in any other way increases or diminishes the liability of any person under any other law.

(3) DEFINITIONS.—For purposes of this subsection:

(A) The terms "elementary school" and "secondary school" have the meaning given to those terms in section 8101 of the Elementary and Secondary Education Act of 1965.

(B) The term "health care practitioner" means a person authorized under law to prescribe drugs subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act.

(C) The term "medication" means a drug as that term is defined in section 201 of the Federal Food, Drug, and Cosmetic Act and includes inhaled bronchodilators and auto-injectable epinephrine.

(D) The term "self-administration" means a student's discretionary use of his or her prescribed asthma or anaphylaxis medication, pursuant to a prescription or written direction from a health care practitioner.

(E) The term "trained personnel" means, with respect to an elementary or secondary school, an individual, such as the school nurse—

(i) who has been designated by the school nurse or principal (or other appropriate administrative staff) of the school to administer epinephrine on a voluntary basis outside their scope of employment;

(ii) who has received training in the administration of epinephrine; and

(iii) whose training in the administration of epinephrine meets appropriate medical standards and has been documented by appropriate administrative staff of the school.

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

SEC. 399M. [280g–1] EARLY DETECTION, DIAGNOSIS, AND TREATMENT REGARDING DEAF AND HARD-OF-HEARING NEWBORNS, INFANTS, AND YOUNG CHILDREN.

(a) STATEWIDE NEWBORN, INFANT, AND YOUNG CHILD 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, infant, and young child hearing screening, evaluation, diagnosis, and intervention programs and systems, and to assist in the recruitment, retention, education, and training of qualified personnel and health care providers (including, as appropriate, education and training of family members), for the following purposes:

(1) To develop and monitor the efficacy of statewide programs and systems for hearing screening of newborns, infants, and young children (referred to in this section as "children"); prompt evaluation and diagnosis of children referred from screening programs; and appropriate educational, audiological, medical, and communication (or language acquisition) interventions (including family support), for children identified as deaf or hard-of-hearing, consistent with the following:

(A) Early intervention includes referral to, and delivery of, information and services by organizations such as schools and agencies (including community, consumer, and family-based agencies), in health care settings (including medical homes for children), and in 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 children.

(B) Information provided to families should be accurate, comprehensive, up-to-date, and evidence-based, as appropriate, to allow families to make important decisions for their children in a timely manner, including decisions with respect to the full range of assistive hearing technologies and communications modalities, as appropriate.

(C) Programs and systems under this paragraph shall offer mechanisms that foster family-to-family and deaf and hard-of-hearing consumer-to-family supports.

(2) To continue to provide technical support to States, through one or more technical resource centers, to assist in further developing and enhancing State early hearing detection and intervention programs.

(3) To identify or develop efficient models (educational and medical) to ensure that children who are identified as deaf or hard-of-hearing through screening receive follow-up by qualified early intervention providers or qualified health care providers (including those at medical homes for children), and referrals, as appropriate, including to early intervention services under part C of the Individuals with Disabilities Education Act. State agencies shall be encouraged to effectively increase the rate of such follow-up and referral.

(b) TECHNICAL ASSISTANCE, DATA MANAGEMENT, AND APPLIED RESEARCH.—

(1) CENTERS FOR DISEASE CONTROL AND PREVENTION.—

(A) IN GENERAL.—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 or designated entities of States—

(i) to develop, maintain, and improve data collection systems related to newborn, infant, and young child hearing screening, evaluation (including audiologic, medical, and language acquisition evaluations), diagnosis, and intervention services;

(ii) to conduct applied research related to newborn, infant, and young child hearing screening, evaluation, and intervention programs and outcomes;

(iii) to ensure quality monitoring of hearing screening, evaluation, and intervention programs and systems for newborns, infants, and young children; and

(iv) to support newborn, infant, and young child hearing screening, evaluation, and intervention programs, and information systems.

(B) USE OF AWARDS.—The awards made under subparagraph (A) may be used—

(i) to provide technical assistance on data collection and management, including to coordinate and develop standardized procedures for data management;

(ii) to assess and report on the cost and program effectiveness of newborn, infant, and young child hearing screening, evaluation, and intervention programs and systems;

(iii) to collect data and report on newborn, infant, and young child hearing screening, evaluation, diagnosis, and intervention programs and systems for applied research, program evaluation, and policy improvement;

(iv) to identify the causes and risk factors for congenital hearing loss;

(v) to study the effectiveness of newborn, infant, and young child hearing screening, audiologic and medical evaluations and intervention programs and systems by assessing the health, intellectual and social developmental, cognitive, and hearing status of these children at school age; and

(vi) to promote the integration and interoperability of data regarding early hearing loss across multiple sources to increase the flow of information between clinical care and public health settings, including the ability of States and territories to exchange and share data.

(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—

(A) other Federal agencies;

(B) State and local agencies, including agencies 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;

(C) consumer groups of, and that serve, individuals who are deaf and hard-of-hearing and their families;

(D) appropriate national medical and other health and education specialty organizations;

(E) individuals who are deaf or hard-of-hearing and their families;

(F) 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 children, and their families;

(G) third-party payers and managed care organizations; and

(H) related commercial industries.

(2) POLICY DEVELOPMENT.—The Administrator of the Health Resources and Services Administration, the Director of the Centers for Disease Control and Prevention, and the Director of the National Institutes of Health shall coordinate and collaborate on recommendations for policy development at the Federal and State levels and with the private sector, including consumer, medical and other health and education professional-based organizations, with respect to newborn and infant hearing screening, evaluation, diagnosis, and intervention programs and systems.

(3) STATE EARLY DETECTION, DIAGNOSIS, AND INTERVENTION PROGRAMS AND SYSTEMS; DATA COLLECTION.—The Administrator of the Health Resources and Services Administration and the Director of the Centers for Disease Control and Prevention shall coordinate and collaborate in assisting States—

(A) to establish newborn, infant, and young child hearing screening, evaluation, diagnosis, and intervention programs and systems under subsection (a); and

(B) 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 that do not require the screening for hearing loss of children of parents who object to the screening on the grounds that such screening conflicts with the parent's religious beliefs.

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

(1) The term "audiologic", when used in connection with evaluation, means procedures—

(A) to assess the status of the auditory system;

(B) 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

(C) to identify appropriate treatment and referral options, including—

(i) linkage to State coordinating agencies under part C of the Individuals with Disabilities Education Act or other appropriate agencies;

(ii) medical evaluation;

(iii) assessment for the full range of assistive hearing technologies appropriate for newborns, infants, and young children;

(iv) audiologic rehabilitation treatment; and

(v) referral to national and local consumer, self-help, parent, family, and education organizations, and other family-centered services.

(2) The term "early intervention"means—

(A) providing appropriate services for the child who is deaf or hard-of-hearing, including nonmedical services; and

(B) ensuring that the family of the child is—

(i) provided comprehensive, consumer-oriented information about the full range of family support, training, information services, and language acquisition in oral and visual modalities; and

(ii) given the opportunity to consider and obtain the full range of such appropriate services, educational and program placements, and other options for the child from highly qualified providers.

(3) The term "medical evaluation" means key components performed by a physician including history, examination, and medical decisionmaking 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.

(4) The term "medical intervention"means the process by which a physician provides medical diagnosis and direction for medical or surgical treatment options for hearing loss or other medical disorders associated with hearing loss.

(5) The term "newborn, infant, and young child hearing screening" means objective physiologic procedures to detect possible hearing loss and to identify newborns, infants, and young children under 3 years of age who require further audiologic and medical evaluations.

(f) AUTHORIZATION OF APPROPRIATIONS.—

(1) STATEWIDE NEWBORN AND INFANT HEARING SCREENING, EVALUATION AND INTERVENTION PROGRAMS AND SYSTEMS.—For

the purpose of carrying out subsection (a), there are authorized to be appropriated to the Health Resources and Services Administration $17,818,000 for each of fiscal years 2023 through 2027.

(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 $10,760,000 for each of fiscal years 2023 through 2027.

(3) TECHNICAL ASSISTANCE, DATA MANAGEMENT, AND APPLIED RESEARCH; NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION DISORDERS.—For the purpose of carrying out subsection (b)(2), there are authorized to be appropriated to the National Institute on Deafness and Other Communication Disorders such sums as may be necessary for fiscal years 2011 through 2015.

SEC. 399N. [280g–2] CHILDHOOD MALIGNANCIES.

(a) IN GENERAL.—The Secretary, acting as appropriate through the Director of the Centers for Disease Control and Prevention and the Director of the National Institutes of Health, shall study environmental and other risk factors for childhood cancers (including skeletal malignancies, leukemias, malignant tumors of the central nervous system, lymphomas, soft tissue sarcomas, and other malignant neoplasms) and carry out projects to improve outcomes among children with childhood cancers and resultant secondary conditions, including limb loss, anemia, rehabilitation, and palliative care. Such projects shall be carried out by the Secretary directly and through awards of grants or contracts.

(b) CERTAIN ACTIVITIES.—Activities under subsection (a) include—

(1) the expansion of current demographic data collection and population surveillance efforts to include childhood cancers nationally;

(2) the development of a uniform reporting system under which treating physicians, hospitals, clinics, and States report the diagnosis of childhood cancers, including relevant associated epidemiological data; and

(3) support for the National Limb Loss Information Center to address, in part, the primary and secondary needs of persons who experience childhood cancers in order to prevent or minimize the disabling nature of these cancers.

(c) COORDINATION OF ACTIVITIES.—The Secretary shall assure that activities under this section are coordinated as appropriate with other agencies of the Public Health Service that carry out activities focused on childhood cancers and limb loss.

(d) DEFINITION.—For purposes of this section, the term "childhood cancer" refers to a spectrum of different malignancies that vary by histology, site of disease, origin, race, sex, and age. The Secretary may for purposes of this section revise the definition of such term to the extent determined by the Secretary to be appropriate.

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

SEC. 399O. [280g–3] PRESCRIPTION DRUG MONITORING PROGRAM.

(a) PROGRAM.—

(1) IN GENERAL.—Each fiscal year, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, in coordination with the heads of other departments and agencies as appropriate, shall support States or localities for the purpose of improving the efficiency and use of PDMPs, including—

(A) establishment and implementation of a PDMP;

(B) maintenance of a PDMP;

(C) improvements to a PDMP by—

(i) enhancing functional components to work toward—

(I) universal use of PDMPs among providers and their delegates, to the extent that State laws allow;

(II) more timely inclusion of data within a PDMP;

(III) active management of the PDMP, in part by sending proactive or unsolicited reports to providers to inform prescribing; and

(IV) ensuring the highest level of ease in use of and access to PDMPs by providers and their delegates, to the extent that State laws allow;

(ii) in consultation with the Office of the National Coordinator for Health Information Technology, improving the intrastate interoperability of PDMPs by—

(I) making PDMPs more actionable by integrating PDMPs within electronic health records and health information technology infrastructure; and

(II) linking PDMP data to other data systems within the State, including—

(aa) the data of pharmacy benefit managers, medical examiners and coroners, and the State's Medicaid program;

(bb) worker's compensation data; and

(cc) prescribing data of providers of the Department of Veterans Affairs and the Indian Health Service within the State;

(iii) in consultation with the Office of the National Coordinator for Health Information Technology, improving the interstate interoperability of PDMPs through—

(I) sharing of dispensing data in near-real time across State lines; and

(II) integration of automated queries for multistate PDMP data and analytics into clinical

workflow to improve the use of such data and analytics by practitioners and dispensers; or

(iv) improving the ability to include treatment availability resources and referral capabilities within the PDMP.

(2) LEGISLATION.—As a condition on the receipt of support under this section, the Secretary shall require a State or locality to demonstrate that it has enacted legislation or regulations—

(A) to provide for the implementation of the PDMP; and

(B) to permit the imposition of appropriate penalties for the unauthorized use and disclosure of information maintained by the PDMP.

(b) PDMP STRATEGIES.—The Secretary shall encourage a State or locality, in establishing, improving, or maintaining a PDMP, to implement strategies that improve—

(1) the reporting of dispensing in the State or locality of a controlled substance to an ultimate user so the reporting occurs not later than 24 hours after the dispensing event;

(2) the consultation of the PDMP by each prescribing practitioner, or their designee, in the State or locality before initiating treatment with a controlled substance, or any substance as required by the State to be reported to the PDMP, and over the course of ongoing treatment for each prescribing event;

(3) the consultation of the PDMP before dispensing a controlled substance, or any substance as required by the State to be reported to the PDMP;

(4) the proactive notification to a practitioner when patterns indicative of controlled substance misuse by a patient, including opioid misuse, are detected;

(5) the availability of data in the PDMP to other States, as allowable under State law; and

(6) the availability of nonidentifiable information to the Centers for Disease Control and Prevention for surveillance, epidemiology, statistical research, or educational purposes.

(c) DRUG MISUSE AND ABUSE.—In consultation with practitioners, dispensers, and other relevant and interested stakeholders, a State receiving support under this section—

(1) shall establish a program to notify practitioners and dispensers of information that will help to identify and prevent the unlawful diversion or misuse of controlled substances;

(2) may, to the extent permitted under State law, notify the appropriate authorities responsible for carrying out drug diversion investigations if the State determines that information in the PDMP maintained by the State indicates an unlawful diversion or abuse of a controlled substance;

(3) may conduct analyses of controlled substance program data for purposes of providing appropriate State agencies with aggregate reports based on such analyses in as close to real-time as practicable, regarding prescription patterns flagged as potentially presenting a risk of misuse, abuse, addiction, overdose, and other aggregate information, as appropriate and in compliance with applicable Federal and State laws and pro-

vided that such reports shall not include protected health information; and

(4) may access information about prescriptions, such as claims data, to ensure that such prescribing and dispensing history is updated in as close to real-time as practicable, in compliance with applicable Federal and State laws and provided that such information shall not include protected health information.

(d) EVALUATION AND REPORTING.—As a condition on receipt of support under this section, the State shall report on interoperability with PDMPs of other States and Federal agencies, where appropriate, intrastate interoperability with health information technology systems such as electronic health records, health information exchanges, and e-prescribing, where appropriate, and whether or not the State provides automatic, up-to-date, or daily information about a patient when a practitioner (or the designee of a practitioner, where permitted) requests information about such patient.

(e) EVALUATION AND REPORTING.—A State receiving support under this section shall provide the Secretary with aggregate nonidentifiable information, as permitted by State law, to enable the Secretary—

(1) to evaluate the success of the State's program in achieving the purpose described in subsection (a); or

(2) to prepare and submit to the Congress the report required by subsection (i)(2).

(f) EDUCATION AND ACCESS TO THE MONITORING SYSTEM.—A State receiving support under this section shall take steps to—

(1) facilitate prescribers and dispensers, and their delegates, as permitted by State law, to use the PDMP, to the extent practicable; and

(2) educate prescribers and dispensers, and their delegates on the benefits of the use of PDMPs.

(g) ELECTRONIC FORMAT.—The Secretary may issue guidelines specifying a uniform electronic format for the reporting, sharing, and disclosure of information pursuant to PDMPs. To the extent possible, such guidelines shall be consistent with standards recognized by the Office of the National Coordinator for Health Information Technology.

(h) RULES OF CONSTRUCTION.—

(1) FUNCTIONS OTHERWISE AUTHORIZED BY LAW.—Nothing in this section shall be construed to restrict the ability of any authority, including any local, State, or Federal law enforcement, narcotics control, licensure, disciplinary, or program authority, to perform functions otherwise authorized by law.

(2) ADDITIONAL PRIVACY PROTECTIONS.—Nothing in this section shall be construed as preempting any State from imposing any additional privacy protections.

(3) FEDERAL PRIVACY REQUIREMENTS.—Nothing in this section shall be construed to supersede any Federal privacy or confidentiality requirement, including the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191; 110 Stat. 2033) and section 543 of this Act.

(4) NO FEDERAL PRIVATE CAUSE OF ACTION.—Nothing in this section shall be construed to create a Federal private cause of action.

(5) PROMOTING STATE CHOICE.—Nothing in this section shall be construed to authorize the Secretary to require States to use a specific vendor or a specific interoperability connection other than to align with nationally recognized, consensus-based open standards, such as in accordance with sections 3001 and 3004.

(i) PROGRESS REPORT.—Not later than 3 years after the date of enactment of this section, the Secretary shall—

(1) complete a study that—

(A) determines the progress of grantees in establishing and implementing PDMPs consistent with this section;

(B) provides an analysis of the extent to which the operation of PDMPs has—

(i) reduced inappropriate use, abuse, diversion of, and overdose with, controlled substances;

(ii) established or strengthened initiatives to ensure linkages to substance use disorder treatment services; or

(iii) affected patient access to appropriate care in States operating PDMPs;

(C) determine the progress of grantees in achieving interstate interoperability and intrastate interoperability of PDMPs, including an assessment of technical, legal, and financial barriers to such progress and recommendations for addressing these barriers;

(D) determines the progress of grantees in implementing near real-time electronic PDMPs;

(E) provides an analysis of the privacy protections in place for the information reported to the PDMP in each State or locality receiving support under this section and any recommendations of the Secretary for additional Federal or State requirements for protection of this information;

(F) determines the progress of States or localities in implementing technological alternatives to centralized data storage, such as peer-to-peer file sharing or data pointer systems, in PDMPs and the potential for such alternatives to enhance the privacy and security of individually identifiable data; and

(G) evaluates the penalties that States or localities have enacted for the unauthorized use and disclosure of information maintained in PDMPs, and the criteria used by the Secretary to determine whether such penalties qualify as appropriate for purposes of subsection (a)(2); and

(2) submit a report to the Congress on the results of the study.

(j) ADVISORY COUNCIL.—

(1) ESTABLISHMENT.—A State or locality may establish an advisory council to assist in the establishment, improvement, or maintenance of a PDMP consistent with this section.

(2) LIMITATION.—A State or locality may not use Federal funds for the operations of an advisory council to assist in the establishment, improvement, or maintenance of a PDMP.

(3) SENSE OF CONGRESS.—It is the sense of the Congress that, in establishing an advisory council to assist in the establishment, improvement, or maintenance of a PDMP, a State or locality should consult with appropriate professional boards and other interested parties.

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

(1) The term "controlled substance" means a controlled substance (as defined in section 102 of the Controlled Substances Act) in schedule II, III, or IV of section 202 of such Act.

(2) The term "dispense" means to deliver a controlled substance to an ultimate user by, or pursuant to the lawful order of, a practitioner, irrespective of whether the dispenser uses the Internet or other means to effect such delivery.

(3) The term "dispenser" means a physician, pharmacist, or other person that dispenses a controlled substance to an ultimate user.

(4) The term "interstate interoperability" with respect to a PDMP means the ability of the PDMP to electronically share reported information with another State if the information concerns either the dispensing of a controlled substance to an ultimate user who resides in such other State, or the dispensing of a controlled substance prescribed by a practitioner whose principal place of business is located in such other State.

(5) The term "intrastate interoperability" with respect to a PDMP means the integration of PDMP data within electronic health records and health information technology infrastructure or linking of a PDMP to other data systems within the State, including the State's Medicaid program, workers' compensation programs, and medical examiners or coroners.

(6) The term "nonidentifiable information" means information that does not identify a practitioner, dispenser, or an ultimate user and with respect to which there is no reasonable basis to believe that the information can be used to identify a practitioner, dispenser, or an ultimate user.

(7) The term "PDMP" means a prescription drug monitoring program that is State-controlled.

(8) The term "practitioner" means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which the individual practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

(9) The term "State" means each of the 50 States, the District of Columbia, and any commonwealth or territory of the United States.

(10) The term "ultimate user" means a person who has obtained from a dispenser, and who possesses, a controlled substance for the person's own use, for the use of a member of the

person's household, or for the use of an animal owned by the person or by a member of the person's household.

(11) The term "clinical workflow" means the integration of automated queries for prescription drug monitoring programs data and analytics into health information technologies such as electronic health record systems, health information exchanges, and/or pharmacy dispensing software systems, thus streamlining provider access through automated queries.

SEC. 399P. [280g–4] GRANTS TO STRENGTHEN THE HEALTHCARE SYSTEM'S RESPONSE TO DOMESTIC VIOLENCE, DATING VIOLENCE, SEXUAL ASSAULT, AND STALKING.

(a) IN GENERAL.—The Secretary shall award grants for—

(1) the development or enhancement and implementation of interdisciplinary training for health professionals, public health staff, community health workers, violence prevention advocates working with health providers, and allied health professionals;

(2) the development or enhancement and implementation of education programs for medical, psychology, dental, social work, nursing, and other health profession students, interns, residents, fellows, or current health care providers (including midwives and doulas);

(3) the development or enhancement and implementation of comprehensive statewide strategies to improve the capacity of clinics, public health facilities, hospitals, and other health settings (including behavioral and mental health programs) to prevent and respond to domestic violence, dating violence, sexual assault, and stalking;

(4) the development or enhancement and implementation of training programs to improve the capacity of early childhood programs to address domestic violence, dating violence, sexual assault, and stalking among families they serve; and

(5) the development or enhancement and implementation of comprehensive statewide strategies for health and violence prevention programs to work together to promote primary prevention of domestic violence, dating violence, sexual assault, and stalking.

(b) USE OF FUNDS.—

(1) REQUIRED USES.—Amounts provided under a grant under this section shall be used to—

(A) fund interdisciplinary training and education programs under paragraphs (1) and (2) of subsection (a) that—

(i) are designed to train medical, psychology, dental, social work, nursing, and other health profession students, interns, residents, fellows, or current health care providers to provide universal education on healthy relationships and provide trauma-informed health care services (including mental or behavioral health care services and referrals to appropriate community services) to individuals who are or who have been victims of domestic violence, dating violence, sexual assault, or stalking;

(ii) plan and develop training components that center the experiences of, and are developed in collaboration with, culturally specific individuals and American Indians and Alaska Natives, and include community-defined practices such as the use of doulas, midwives, and traditional healers, for integration into approved internship, residency, and fellowship training or continuing medical or other health education training that address physical, mental, and behavioral health issues, including protective factors, related to domestic violence, dating violence, sexual assault, stalking, and other forms of violence and abuse (including labor and sex trafficking), focus on reducing health inequities and preventing violence and abuse, and include the primacy of victim safety and confidentiality;

(iii) are designed to be inclusive of the experiences of all individuals, including LGBT individuals, and include training on improving equity and reducing disparities in access to health care services and prevention resources; and

(iv) include training on the use of a universal prevention education approach to both prevent and respond to domestic violence, dating violence, sexual assault, or stalking in health care settings;

(B) design and implement comprehensive strategies to improve the capacity of the health care system to prevent and respond to domestic or sexual violence in clinical and public health settings, hospitals, clinics, and other health settings (including behavioral and mental health), under subsection (a)(3) through—

(i) the implementation, dissemination, and evaluation of policies and procedures to guide health professionals and public health staff in identifying, responding to, and promoting prevention of domestic violence, dating violence, sexual assault, and stalking during in-person or virtual visits, including strategies to ensure that health information is maintained in a manner that protects the patient's privacy and safety, and safely uses health information technology to improve documentation, identification, assessment, treatment, and follow-up care and to maximize victim choice on the use and sharing of their health information;

(ii) the development of services to address the safety, medical, and mental health needs of patients by—

(I) increasing the capacity of existing health care professionals (including professionals who specialize in trauma or in substance use disorders) in behavioral and mental health care, community health workers, and public health staff to address domestic violence, dating violence, sexual assault, stalking, and children exposed to violence;

(II) contracting with or hiring advocates for victims of domestic violence or sexual assault to provide such services; or

(III) providing funding to State domestic and sexual violence coalitions to improve the capacity of such coalitions to coordinate and support health advocates and other health system partnerships;

(iii) the development of measures and methods for the evaluation of the practice of prevention, intervention, and documentation regarding victims of domestic violence, dating violence, sexual assault, and stalking during in-person or virtual visits, including the development and testing of quality improvement measurements, in accordance with the multi-stakeholder and quality measurement processes established under paragraphs (7) and (8) of section 1890(b) and section 1890A of the Social Security Act (42 U.S.C. 1395aaa(b)(7) and (8); 42 U.S.C. 1890A);

(iv) the provision of training and follow-up technical assistance to health care professionals, and public health staff, and allied health professionals to identify, assess, treat, and refer clients who are victims of domestic violence, dating violence, sexual assault, or stalking, and promote prevention during in-person or virtual visits, including using tools and training materials already developed;

(v) the development, implementation, dissemination, and evaluation of best practices, tools, and training materials, including culturally relevant tools, for mental health, behavioral health, and substance use disorder professionals to identify and respond to domestic violence, sexual violence, stalking, and dating violence; and

(vi) the development and provision of culturally relevant training and follow-up technical assistance to health care professionals, and public health staff, and allied health professionals to identify, assess, treat, and refer clients who are victims of domestic violence, dating violence, sexual assault, or stalking from culturally specific communities and promote prevention, using tools and training materials, developed by and for culturally specific communities, with priority given to trainings provided by culturally specific organizations; and

(C) design and implement comprehensive strategies to prevent domestic or sexual violence including through the use of universal education in clinical and public health settings, hospitals, clinics and other health settings.

(2) PERMISSIBLE USES.—

(A) CHILD ABUSE AND ABUSE IN LATER LIFE.—To the extent consistent with the purpose of this section, a grantee may use amounts received under this section to address, as part of a comprehensive programmatic approach

implemented under the grant, issues relating to child abuse or abuse in later life.

(B) RURAL AREAS.—Grants funded under paragraphs (1) and (2) of subsection (a) may be used to offer to rural areas community-based training opportunities, which may include the use of distance learning networks and other available technologies needed to reach isolated rural areas, for medical, nursing, and other health profession students and residents on domestic violence, dating violence, sexual assault, stalking, and, as appropriate, other forms of violence and abuse.

(C) OTHER USES.—Grants funded under subsection (a)(3) may be used for—

(i) the development of training modules and policies that address the overlap of child abuse, domestic violence, dating violence, sexual assault, and stalking and abuse in later life, as well as childhood exposure to domestic and sexual violence;

(ii) the development, expansion, and implementation of programs that promote the prevention of sexual assault as well as sexual assault forensic medical examination or sexual assault nurse examiner programs;

(iii) the inclusion of the health effects of lifetime exposure to violence and abuse and exposure to violence across generations as well as related protective factors and behavioral risk factors in health professional training schools including medical, dental, nursing, social work, and mental and behavioral health curricula, and allied health service training courses;

(iv) the integration of knowledge of domestic violence, dating violence, sexual assault, and stalking into health care accreditation and professional licensing examinations, such as medical, dental, mental health, social work, and nursing boards, and where appropriate, other allied health exams and certifications;

(v) providing funding to culturally specific organizations to improve the capacity of such organizations to engage and partner with health care providers to support victims and meet increased referrals from health systems;

(vi) developing a State-level pilot program to—

(I) improve the response of substance use disorder treatment programs, harm reduction programs for people who use substances, and systems to domestic violence, dating violence, sexual assault, and stalking;

(II) improve the capacity of substance use disorder treatment programs, harm reduction programs for people who use substances, and systems to serve survivors of domestic violence, dating violence, sexual assault, and stalking dealing with substance use disorder; and

(III) improve the capacity of domestic violence, dating violence, sexual assault, and stalking programs to serve survivors who have substance use history; or

(vii) developing and utilizing existing technical assistance and training resources to improve the capacity of substance use disorder treatment programs and harm reduction programs for people who use substances to address domestic violence, dating violence, sexual assault, and stalking among patients the programs serve.

(c) REQUIREMENTS FOR GRANTEES.—

(1) CONFIDENTIALITY AND SAFETY.—

(A) IN GENERAL.—Grantees under this section shall ensure that all programs developed with grant funds address issues of confidentiality and patient safety and comply with applicable confidentiality and nondisclosure requirements under section 40002(b)(2) of the Violence Against Women Act of 1994 and the Family Violence Prevention and Services Act, and that faculty and staff associated with delivering educational components are fully trained in procedures that will protect the immediate and ongoing security and confidentiality of the patients, patient records, and staff. Such grantees shall consult entities with demonstrated expertise in the confidentiality and safety needs of victims of domestic violence, dating violence, sexual assault, and stalking on the development and adequacy of confidentially and security procedures, and provide documentation of such consultation.

(B) ADVANCE NOTICE OF INFORMATION DISCLOSURE.—Grantees under this section shall provide to patients advance notice about any circumstances under which information may be disclosed, such as mandatory reporting laws, and shall give patients the option to receive information and referrals without affirmatively disclosing abuse.

(2) LIMITATION ON ADMINISTRATIVE EXPENSES.—A grantee shall use not more than 10 percent of the amounts received under a grant under this section for administrative expenses.

(3) APPLICATION.—

(A) PREFERENCE.—In selecting grant recipients under this section, the Secretary shall give preference to applicants based on the strength of their evaluation strategies, with priority given to—

(i) outcome based evaluations;

(ii) culturally specific and population specific organizations; and

(iii) programs developing and implementing community-driven solutions to address domestic violence, dating violence, sexual assault, or stalking.

(B) SUBSECTION (A)(1) AND (2) GRANTEES.—Applications for grants under paragraphs (1) and (2) of subsection (a) shall include—

(i) documentation that the applicant represents a team of entities working collaboratively to strengthen

the response of the health care system to domestic violence, dating violence, sexual assault, or stalking, and which includes at least one of each of—

(I) an accredited school of allopathic or osteopathic medicine, psychology, nursing, dentistry, social work, or other health field;

(II) a health care facility or system; or

(III) a government or nonprofit entity, including a culturally specific organization or community-based organization working to address the social determinants of health, with a history of effective work in the fields of domestic violence, dating violence, sexual assault, or stalking; and

(ii) strategies for the dissemination and sharing of curricula and other educational materials developed under the grant, if any, with other interested health professions schools and national resource repositories for materials on domestic violence, dating violence, sexual assault, and stalking.

(C) SUBSECTION (A)(3) GRANTEES.—An entity desiring a grant under subsection (a)(3) shall submit an application to the Secretary at such time, in such a manner, and containing such information and assurances as the Secretary may require, including—

(i) documentation that all training, education, screening, assessment, services, treatment, and any other approach to patient care will be informed by an understanding of violence and abuse victimization and trauma-specific approaches that will be integrated into prevention, intervention, and treatment activities;

(ii) strategies—

(I) for the development and implementation of policies to prevent and address domestic violence, dating violence, sexual assault, and stalking over the lifespan and generations in health care settings; and

(II) to address primary prevention of domestic violence, dating violence, sexual assault, and stalking over the lifespan and generations, including strategies that address related social determinants of health, economic justice, and equity issues, and that are inclusive of LGBT individuals;

(iii) a plan for consulting with State and tribal domestic violence or sexual assault coalitions, national nonprofit victim advocacy organizations, culturally specific organizations, and population specific organizations with demonstrated expertise in domestic violence, dating violence, sexual assault, or stalking;

(iv) with respect to an application for a grant under which the grantee will have contact with patients, a plan, developed in collaboration with local victim service providers (including culturally specific organizations), to respond appropriately to and make

correct referrals for individuals who disclose that they are victims of domestic violence, dating violence, sexual assault, stalking, or other types of violence, and documentation provided by the grantee of an ongoing collaborative relationship with a local victim service provider; and

(v) with respect to an application for a grant proposing to fund a program described in subsection (b)(2)(C)(ii), a certification that any sexual assault forensic medical examination and sexual assault nurse examiner programs supported with such grant funds will adhere to the guidelines set forth by the Attorney General.

(d) ELIGIBLE ENTITIES.—

(1) IN GENERAL.—To be eligible to receive funding under paragraph (1) or (2) of subsection (a), an entity shall be—

(A) a nonprofit organization with a history of effective work in the field of training health professionals with an understanding of, and clinical skills pertinent to, domestic violence, dating violence, sexual assault, or stalking, and lifetime exposure to violence and abuse;

(B) an accredited school of allopathic or osteopathic medicine, psychology, nursing, dentistry, social work, or allied health;

(C) a health care provider membership or professional organization, or a health care system; or

(D) a State, tribal, territorial, or local entity.

(2) SUBSECTION (A)(3) GRANTEES.—To be eligible to receive funding under subsection (a)(3), an entity shall be—

(A) a State department (or other division) of health (including mental health or substance abuse agencies), a State, tribal, or territorial domestic violence or sexual assault coalition or victim service provider, or any other nonprofit, nongovernmental organization with a history of effective work in the fields of domestic violence, dating violence, sexual assault, or stalking, and health care, including physical or behavioral health care and substance use disorder prevention and treatment; or

(B) a local victim service provider, a local department (or other division) of health, a local health clinic, hospital, behavioral health treatment system, or health system, a community-based organization with a history of effective work in the field of domestic violence, dating violence, sexual assault, or stalking and health care, including physical or mental health care or substance use disorder prevention and treatment, or a community-based organization with a history of partnership with programs in the field of domestic violence, dating violence, sexual assault, or stalking and health care, including physical or mental health care or substance use disorder prevention and treatment.

(e) TECHNICAL ASSISTANCE.—

(1) IN GENERAL.—Of the funds made available to carry out this section for any fiscal year, the Secretary may make grants or enter into contracts to provide technical assistance with re-

spect to the planning, development, and operation of any program, activity or service carried out pursuant to this section. Not more than 8 percent of the funds appropriated under this section in each fiscal year may be used to fund technical assistance under this subsection.

(2) AVAILABILITY OF MATERIALS.—The Secretary shall make publicly available materials developed by grantees under this section, including materials on training, best practices, and research and evaluation.

(3) REPORTING.—The Secretary shall publish a biennial report on—

(A) the distribution of funds under this section; and

(B) the programs and activities supported by such funds.

(f) RESEARCH AND EVALUATION.—

(1) IN GENERAL.—Of the funds made available to carry out this section for any fiscal year, the Secretary may use not more than 20 percent to make a grant or enter into a contract for research and evaluation of—

(A) grants awarded under this section; and

(B) other training for health professionals and effective interventions in the health care setting that prevent domestic violence, dating violence, and sexual assault across the lifespan, prevent the health effects of such violence, and improve the safety and health of individuals who are currently being victimized.

(2) RESEARCH.—Research authorized in paragraph (1) may include—

(A) research on the effects of domestic violence, dating violence, sexual assault, and childhood exposure to domestic, dating or sexual violence on health behaviors, health conditions, and health status of individuals, families, and populations, including underserved populations;

(B) research to determine effective health care interventions to respond to and prevent domestic violence, dating violence, sexual assault, and stalking;

(C) research on the impact of domestic, dating and sexual violence, childhood exposure to such violence, and stalking on the health care system, health care utilization, health care costs, and health status; and

(D) research on the impact of adverse childhood experiences on adult experience with domestic violence, dating violence, sexual assault, stalking, and adult health outcomes, including how to reduce or prevent the impact of adverse childhood experiences through the health care setting.

(g) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $20,000,000 for each of fiscal years 2023 through 2027.

(h) DEFINITIONS.—Except as otherwise provided, the definitions in section 40002 of the Violence Against Women Act of 1994 shall apply to this section.

SEC. 399Q. [280g–5] PUBLIC AND HEALTH CARE PROVIDER EDUCATION AND SUPPORT SERVICES.

(a) IN GENERAL.—The Secretary, directly or through the awarding of grants to public or private nonprofit entities, may conduct activities, which may include demonstration projects for the purpose of improving the provision of information on prematurity to health professionals and other health care providers and the public and improving the treatment and outcomes mothers of infants born preterm, and infants born preterm, as appropriate.

(b) ACTIVITIES.—Activities to be carried out under subsection (a) may include the establishment of—

(1) programs, including those to test and evaluate strategies, which, in collaboration with States, localities, tribes, and community organizations, support the provision of information and education to health professionals, other health care providers, and the public concerning—

(A) the core risk factors for preterm labor and delivery;

(B) evidence-based strategies to prevent preterm birth and associated outcomes;

(C) medically indicated deliveries before full term, and the risks of non-medically indicated deliveries before full term;

(D) the importance of preconception and prenatal care, including—

(i) smoking cessation;

(ii) weight maintenance and good nutrition, including folic acid intake;

(iii) the screening for and the treatment of infections;

(iv) screening for and treatment of substance use disorders;

(v) screening for and treatment of maternal depression;

(vi) maternal immunization; and

(vii) stress management;

(E) treatments and outcomes for premature infants, including late preterm infants; and

(F) the informational needs of families during the stay of an infant in a neonatal intensive care unit.

(2) programs to increase the availability, awareness, and use of pregnancy and post-term information services that provide evidence-based, clinical information through counselors, community outreach efforts, electronic or telephonic communication, or other appropriate means regarding causes associated with prematurity, birth defects, or health risks to a post-term infant, as well as prevention of a future preterm birth;

(3) programs to respond to the informational needs of families during the stay of an infant in a neonatal intensive care unit, during the transition of the infant to the home, and in the event of a newborn death; and

(4) such other programs as the Secretary determines appropriate to achieve the purpose specified in subsection (a).

(c) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $1,900,000 for each of fiscal years 2014 through 2018.

SEC. 399R. [280g–6] CHRONIC KIDNEY DISEASE INITIATIVES.

(a) IN GENERAL.—The Secretary shall establish pilot projects to—

(1) increase public and medical community awareness (particularly of those who treat patients with diabetes and hypertension) regarding chronic kidney disease, focusing on prevention;

(2) increase screening for chronic kidney disease, focusing on Medicare beneficiaries at risk of chronic kidney disease; and

(3) enhance surveillance systems to better assess the prevalence and incidence of chronic kidney disease.

(b) SCOPE AND DURATION.—

(1) SCOPE.—The Secretary shall select at least 3 States in which to conduct pilot projects under this section.

(2) DURATION.—The pilot projects under this section shall be conducted for a period that is not longer than 5 years and shall begin on January 1, 2009.

(c) EVALUATION AND REPORT.—The Comptroller General of the United States shall conduct an evaluation of the pilot projects conducted under this section. Not later than 12 months after the date on which the pilot projects are completed, the Comptroller General shall submit to Congress a report on the evaluation.

(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary for the purpose of carrying out this section.

SEC. 399S. [280g–7] AMYOTROPHIC LATERAL SCLEROSIS REGISTRY.

(a) ESTABLISHMENT.—

(1) IN GENERAL.—Not later than 1 year after the receipt of the report described in subsection (b)(2)(A), the Secretary, acting through the Director of the Centers for Disease Control and Prevention, may, if scientifically advisable—

(A) develop a system to collect data on amyotrophic lateral sclerosis (referred to in this section as "ALS") and other motor neuron disorders that can be confused with ALS, misdiagnosed as ALS, and in some cases progress to ALS, including information with respect to the incidence and prevalence of the disease in the United States; and

(B) establish a national registry for the collection and storage of such data to develop a population-based registry of cases in the United States of ALS and other motor neuron disorders that can be confused with ALS, misdiagnosed as ALS, and in some cases progress to ALS.

(2) PURPOSE.—It is the purpose of the registry established under paragraph (1)(B) to—

(A) better describe the incidence and prevalence of ALS in the United States;

(B) examine appropriate factors, such as environmental and occupational, that may be associated with the disease;

(C) better outline key demographic factors (such as age, race or ethnicity, gender, and family history of individuals who are diagnosed with the disease) associated with the disease;

(D) better examine the connection between ALS and other motor neuron disorders that can be confused with ALS, misdiagnosed as ALS, and in some cases progress to ALS; and

(E) other matters as recommended by the Advisory Committee established under subsection (b).

(b) ADVISORY COMMITTEE.—

(1) ESTABLISHMENT.—Not later than 180 days after the date of the enactment of this section, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, may establish a committee to be known as the Advisory Committee on the National ALS Registry (referred to in this section as the "Advisory Committee"). The Advisory Committee shall be composed of not more than 27 members to be appointed by the Secretary, acting through the Centers for Disease Control and Prevention, of which—

(A) two-thirds of such members shall represent governmental agencies—

(i) including at least one member representing—

(I) the National Institutes of Health, to include, upon the recommendation of the Director of the National Institutes of Health, representatives from the National Institute of Neurological Disorders and Stroke and the National Institute of Environmental Health Sciences;

(II) the Department of Veterans Affairs;

(III) the Agency for Toxic Substances and Disease Registry; and

(IV) the Centers for Disease Control and Prevention; and

(ii) of which at least one such member shall be a clinician with expertise on ALS and related diseases, an epidemiologist with experience in data registries, a statistician, an ethicist, and a privacy expert (relating to the privacy regulations under the Health Insurance Portability and Accountability Act of 1996); and

(B) one-third of such members shall be public members, including at least one member representing—

(i) national and voluntary health associations;

(ii) patients with ALS or their family members;

(iii) clinicians with expertise on ALS and related diseases;

(iv) epidemiologists with experience in data registries;

(v) geneticists or experts in genetics who have experience with the genetics of ALS or other neurological diseases and

(vi) other individuals with an interest in developing and maintaining the National ALS Registry.

(2) DUTIES.—The Advisory Committee may review information and make recommendations to the Secretary concerning—

(A) the development and maintenance of the National ALS Registry;

(B) the type of information to be collected and stored in the Registry;

(C) the manner in which such data is to be collected;

(D) the use and availability of such data including guidelines for such use; and

(E) the collection of information about diseases and disorders that primarily affect motor neurons that are considered essential to furthering the study and cure of ALS.

(3) REPORT.—Not later than 270 days after the date on which the Advisory Committee is established, the Advisory Committee may submit a report to the Secretary concerning the review conducted under paragraph (2) that contains the recommendations of the Advisory Committee with respect to the results of such review.

(c) GRANTS.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may award grants to, and enter into contracts and cooperative agreements with, public or private nonprofit entities for the collection, analysis, and reporting of data on ALS and other motor neuron disorders that can be confused with ALS, misdiagnosed as ALS, and in some cases progress to ALS after receiving the report under subsection (b)(3).

(d) COORDINATION WITH STATE, LOCAL, AND FEDERAL REGISTRIES.—

(1) [100] IN GENERAL.—In establishing the National ALS Registry under subsection (a), the Secretary, acting through the Director of the Centers for Disease Control and Prevention, may—

(A) identify, build upon, expand, and coordinate among existing data and surveillance systems, surveys, registries, and other Federal public health and environmental infrastructure wherever possible, which may include—

(i) any registry pilot projects previously supported by the Centers for Disease Control and Prevention;

(ii) the Department of Veterans Affairs ALS Registry;

(iii) the DNA and Cell Line Repository of the National Institute of Neurological Disorders and Stroke Human Genetics Resource Center at the National Institutes of Health;

(iv) Agency for Toxic Substances and Disease Registry studies, including studies conducted in Illinois, Missouri, El Paso and San Antonio, Texas, and Massachusetts;

(v) State-based ALS registries;

(vi) the National Vital Statistics System; and

[100] So in law. Subsection (d) (as added by section 2 of Public Law 110–373) does not include a paragraph (2).

(vii) any other existing or relevant databases that collect or maintain information on those motor neuron diseases recommended by the Advisory Committee established in subsection (b); and

(B) provide for research access to ALS data as recommended by the Advisory Committee established in subsection (b) to the extent permitted by applicable statutes and regulations and in a manner that protects personal privacy consistent with applicable privacy statutes and regulations.

(C) COORDINATION WITH NIH AND DEPARTMENT OF VETERANS AFFAIRS.—Consistent with applicable privacy statutes and regulations, the Secretary may ensure that epidemiological and other types of information obtained under subsection (a) is made available to the National Institutes of Health and the Department of Veterans Affairs.

(e) DEFINITION.—For the purposes of this section, the term "national voluntary health association" means a national non-profit organization with chapters or other affiliated organizations in States throughout the United States with experience serving the population of individuals with ALS and have demonstrated experience in ALS research, care, and patient services.

SEC. 399S–1. [280g–7a] SURVEILLANCE OF NEUROLOGICAL DISEASES.

(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention and in coordination with other agencies as the Secretary determines, shall, as appropriate—

(1) enhance and expand infrastructure and activities to track the epidemiology of neurological diseases; and

(2) incorporate information obtained through such activities into an integrated surveillance system, which may consist of or include a registry, to be known as the National Neurological Conditions Surveillance System.

(b) RESEARCH.—The Secretary shall ensure that the National Neurological Conditions Surveillance System is designed in a manner that facilitates further research on neurological diseases.

(c) CONTENT.—In carrying out subsection (a), the Secretary—

(1) shall provide for the collection and storage of information on the incidence and prevalence of neurological diseases in the United States;

(2) to the extent practicable, shall provide for the collection and storage of other available information on neurological diseases, including information related to persons living with neurological diseases who choose to participate, such as—

(A) demographics, such as age, race, ethnicity, sex, geographic location, family history, and other information, as appropriate;

(B) risk factors that may be associated with neurological diseases, such as genetic and environmental risk factors and other information, as appropriate; and

(C) diagnosis and progression markers;

(3) may provide for the collection and storage of information relevant to analysis on neurological diseases, such as information concerning—

(A) the natural history of the diseases;

(B) the prevention of the diseases;

(C) the detection, management, and treatment approaches for the diseases; and

(D) the development of outcomes measures;

(4) may address issues identified during the consultation process under subsection (d); and

(5) initially may address a limited number of neurological diseases.

(d) CONSULTATION.—In carrying out this section, the Secretary shall consult with individuals with appropriate expertise, which may include—

(1) epidemiologists with experience in disease surveillance or registries;

(2) representatives of national voluntary health associations that—

(A) focus on neurological diseases; and

(B) have demonstrated experience in research, care, or patient services;

(3) health information technology experts or other information management specialists;

(4) clinicians with expertise in neurological diseases; and

(5) research scientists with experience conducting translational research or utilizing surveillance systems for scientific research purposes.

(e) GRANTS.—The Secretary may award grants to, or enter into contracts or cooperative agreements with, public or private nonprofit entities to carry out activities under this section.

(f) COORDINATION WITH OTHER FEDERAL, STATE, AND LOCAL AGENCIES.—Subject to subsection (h), the Secretary shall—

(1) make information and analysis in the National Neurological Conditions Surveillance System available, as appropriate—

(A) to Federal departments and agencies, such as the National Institutes of Health and the Department of Veterans Affairs; and

(B) to State and local agencies; and

(2) identify, build upon, leverage, and coordinate among existing data and surveillance systems, surveys, registries, and other Federal public health infrastructure, wherever practicable.

(g) PUBLIC ACCESS.—Subject to subsection (h), the Secretary shall ensure that information and analysis in the National Neurological Conditions Surveillance System are available, as appropriate, to the public, including researchers.

(h) PRIVACY.—The Secretary shall ensure that information and analysis in the National Neurological Conditions Surveillance System are made available only to the extent permitted by applicable Federal and State law, and in a manner that protects personal privacy, to the extent required by applicable Federal and State privacy law, at a minimum.

(i) REPORTS.—

(1) REPORT ON INFORMATION AND ANALYSES.—Not later than 1 year after the date on which any system is established under this section, the Secretary shall submit an interim report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives regarding aggregate information collected pursuant to this section and epidemiological analyses, as appropriate. Such report shall be posted on the Internet website of the Department of Health and Human Services and shall be updated biennially.

(2) IMPLEMENTATION REPORT.—Not later than 4 years after the date of the enactment of this section, the Secretary shall submit a report to the Congress concerning the implementation of this section. Such report shall include information on—

(A) the development and maintenance of the National Neurological Conditions Surveillance System;

(B) the type of information collected and stored in the surveillance system;

(C) the use and availability of such information, including guidelines for such use; and

(D) the use and coordination of databases that collect or maintain information on neurological diseases.

(j) DEFINITION.—In this section, the term "national voluntary health association" means a national nonprofit organization with chapters, other affiliated organizations, or networks in States throughout the United States with experience serving the population of individuals with neurological disease and have demonstrated experience in neurological disease research, care, and patient services.

(k) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $5,000,000 for each of fiscal years 2018 through 2022.

SEC. 399T. [280g–8] SUPPORT FOR PATIENTS RECEIVING A POSITIVE DIAGNOSIS OF DOWN SYNDROME OR OTHER PRENATALLY OR POSTNATALLY DIAGNOSED CONDITIONS.

(a) DEFINITIONS.—In this section:

(1) DOWN SYNDROME.—The term "Down syndrome" refers to a chromosomal disorder caused by an error in cell division that results in the presence of an extra whole or partial copy of chromosome 21.

(2) HEALTH CARE PROVIDER.—The term "health care provider" means any person or entity required by State or Federal law or regulation to be licensed, registered, or certified to provide health care services, and who is so licensed, registered, or certified.

(3) POSTNATALLY DIAGNOSED CONDITION.—The term "postnatally diagnosed condition" means any health condition identified during the 12-month period beginning at birth.

(4) PRENATALLY DIAGNOSED CONDITION.—The term "prenatally diagnosed condition" means any fetal health condition identified by prenatal genetic testing or prenatal screening procedures.

(5) PRENATAL TEST.—The term "prenatal test" means diagnostic or screening tests offered to pregnant women seeking routine prenatal care that are administered on a required or recommended basis by a health care provider based on medical history, family background, ethnic background, previous test results, or other risk factors.

(b) INFORMATION AND SUPPORT SERVICES.—

(1) IN GENERAL.—The Secretary, acting through the Director of the National Institutes of Health, the Director of the Centers for Disease Control and Prevention, or the Administrator of the Health Resources and Services Administration, may authorize and oversee certain activities, including the awarding of grants, contracts or cooperative agreements to eligible entities, to—

(A) collect, synthesize, and disseminate current evidence-based information relating to Down syndrome or other prenatally or postnatally diagnosed conditions; and

(B) coordinate the provision of, and access to, new or existing supportive services for patients receiving a positive diagnosis for Down syndrome or other prenatally or postnatally diagnosed conditions, including—

(i) the establishment of a resource telephone hotline accessible to patients receiving a positive test result or to the parents of newly diagnosed infants with Down syndrome and other diagnosed conditions;

(ii) the expansion and further development of the National Dissemination Center for Children with Disabilities, so that such Center can more effectively conduct outreach to new and expecting parents and provide them with up-to-date information on the range of outcomes for individuals living with the diagnosed condition, including physical, developmental, educational, and psychosocial outcomes;

(iii) the expansion and further development of national and local peer-support programs, so that such programs can more effectively serve women who receive a positive diagnosis for Down syndrome or other prenatal conditions or parents of infants with a postnatally diagnosed condition;

(iv) the establishment of a national registry, or network of local registries, of families willing to adopt newborns with Down syndrome or other prenatally or postnatally diagnosed conditions, and links to adoption agencies willing to place babies with Down syndrome or other prenatally or postnatally diagnosed conditions, with families willing to adopt; and

(v) the establishment of awareness and education programs for health care providers who provide, interpret, or inform parents of the results of prenatal tests for Down syndrome or other prenatally or postnatally diagnosed conditions, to patients, consistent with the

purpose described in section 2(b)(1)[101] of the Prenatally and Postnatally Diagnosed Conditions Awareness Act.

(2) ELIGIBLE ENTITY.—In this subsection, the term "eligible entity" means—

(A) a State or a political subdivision of a State;

(B) a consortium of 2 or more States or political subdivisions of States;

(C) a territory;

(D) a health facility or program operated by or pursuant to a contract with or grant from the Indian Health Service; or

(E) any other entity with appropriate expertise in prenatally and postnatally diagnosed conditions (including nationally recognized disability groups), as determined by the Secretary.

(3) DISTRIBUTION.—In distributing funds under this subsection, the Secretary shall place an emphasis on funding partnerships between health care professional groups and disability advocacy organizations.

(c) PROVISION OF INFORMATION TO PROVIDERS.—

(1) IN GENERAL.—A grantee under this section shall make available to health care providers of parents who receive a prenatal or postnatal diagnosis the following:

(A) Up-to-date, evidence-based, written information concerning the range of outcomes for individuals living with the diagnosed condition, including physical, developmental, educational, and psychosocial outcomes.

(B) Contact information regarding support services, including information hotlines specific to Down syndrome or other prenatally or postnatally diagnosed conditions, resource centers or clearinghouses, national and local peer support groups, and other education and support programs as described in subsection (b)(2).

(2) INFORMATIONAL REQUIREMENTS.—Information provided under this subsection shall be—

(A) culturally and linguistically appropriate as needed by women receiving a positive prenatal diagnosis or the family of infants receiving a postnatal diagnosis; and

(B) approved by the Secretary.

(d) REPORT.—Not later than 2 years after the date of enactment of this section, the Government Accountability Office shall submit a report to Congress concerning the effectiveness of current healthcare and family support programs serving as resources for the families of children with disabilities.

SEC. 399U. [280g–10] COMMUNITY PREVENTIVE SERVICES TASK FORCE.

(a) ESTABLISHMENT AND PURPOSE.—The Director of the Centers for Disease Control and Prevention shall convene an independent Community Preventive Services Task Force (referred to in this subsection as the "Task Force") to be composed of individuals with appropriate expertise. Such Task Force shall review the sci-

[101] So in law. Probably should read "section 2(1)".

entific evidence related to the effectiveness, appropriateness, and cost-effectiveness of community preventive interventions for the purpose of developing recommendations, to be published in the Guide to Community Preventive Services (referred to in this section as the "Guide"), for individuals and organizations delivering population-based services, including primary care professionals, health care systems, professional societies, employers, community organizations, non-profit organizations, schools, governmental public health agencies, Indian tribes, tribal organizations and urban Indian organizations, medical groups, Congress and other policymakers. Community preventive services include any policies, programs, processes or activities designed to affect or otherwise affecting health at the population level.

(b) DUTIES.—The duties of the Task Force shall include—

(1) the development of additional topic areas for new recommendations and interventions related to those topic areas, including those related to specific populations and age groups, as well as the social, economic and physical environments that can have broad effects on the health and disease of populations and health disparities among sub-populations and age groups;

(2) at least once during every 5-year period, review interventions and update recommendations related to existing topic areas, including new or improved techniques to assess the health effects of interventions, including health impact assessment and population health modeling;

(3) improved integration with Federal Government health objectives and related target setting for health improvement;

(4) the enhanced dissemination of recommendations;

(5) the provision of technical assistance to those health care professionals, agencies, and organizations that request help in implementing the Guide recommendations; and

(6) providing yearly reports to Congress and related agencies identifying gaps in research and recommending priority areas that deserve further examination, including areas related to populations and age groups not adequately addressed by current recommendations.

(c) ROLE OF AGENCY.—The Director shall provide ongoing administrative, research, and technical support for the operations of the Task Force, including coordinating and supporting the dissemination of the recommendations of the Task Force, ensuring adequate staff resources, and assistance to those organizations requesting it for implementation of Guide recommendations.

(d) COORDINATION WITH PREVENTIVE SERVICES TASK FORCE.—The Task Force shall take appropriate steps to coordinate its work with the U.S. Preventive Services Task Force and the Advisory Committee on Immunization Practices, including the examination of how each task force's recommendations interact at the nexus of clinic and community.

(e) OPERATION.—In carrying out the duties under subsection (b), the Task Force shall not be subject to the provisions of chapter 10 of title 5, United States Code.

(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary for each fiscal year to carry out the activities of the Task Force.

SEC. 399V. [280g–11] AWARDS TO SUPPORT COMMUNITY HEALTH WORKERS AND COMMUNITY HEALTH.

(a) IN GENERAL.—The Secretary shall award grants, contracts, or cooperative agreements to eligible entities to promote positive health behaviors and outcomes for populations in medically underserved communities by leveraging community health workers, including by addressing ongoing and longer-term community health needs, and by building the capacity of the community health worker workforce. Such grants, contracts, and cooperative agreements shall be awarded in alignment and coordination with existing funding arrangements supporting community health workers.

(b) USE OF FUNDS.—Subject to any requirements for the scope of licensure, registration, or certification of a community health worker under applicable State law, grants, contracts, and cooperative agreements awarded under subsection (a) shall be used to —

(1) recruit, hire, train, and retain community health workers that reflect the needs of the community;

(2) support community health workers in providing education and outreach, in a community setting, regarding—

(A) health conditions prevalent in—

(i) medically underserved communities (as defined in section 799B), particularly racial and ethnic minority populations; and

(ii) other such at-risk populations or geographic areas that may require additional support during public health emergencies, which may include counties identified by the Secretary using applicable measures developed by the Centers for Disease Control and Prevention or other Federal agencies; and

(B) addressing health disparities, including by—

(i) promoting awareness of services and resources to increase access to health care, mental health and substance use disorder services, child services, technology, housing services, educational services, nutrition services, employment services, and other services; and

(ii) assisting in conducting individual and community needs assessments;

(3) educate community members, including regarding effective strategies to promote healthy behaviors;

(4) educate and provide outreach regarding enrollment in health insurance including the Children's Health Insurance Program under title XXI of the Social Security Act, Medicare under title XVIII of such Act and Medicaid under title XIX of such Act;

(5) identify and refer underserved populations to appropriate health care agencies and community-based programs and organizations in order to increase access to quality health care services and to streamline care, including serving as a liaison between communities and health care agencies; and

(6) support community health workers in educating, guiding, or providing home visitation services regarding chronic diseases, maternal health, prenatal, and postpartum care in order to improve maternal and infant health outcomes.

(c) APPLICATION.—To be eligible to receive an award under subsection (a), an 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.

(d) PRIORITY.—In making awards under subsection (a), the Secretary shall give priority to applicants that—

(1) propose to serve—

(A) areas with populations that have a high rate of chronic disease, infant mortality, or maternal morbidity and mortality;

(B) low-income populations, including medically underserved populations (as defined in section 330(b)(3));

(C) populations residing in health professional shortage areas (as defined in section 332(a));

(D) populations residing in maternity care health professional target areas identified under section 332(k); or

(E) rural or traditionally underserved populations, including racial and ethnic minority populations or low-income populations;

(2) have experience in providing health or health-related social services to individuals who are underserved with respect to such services, including rural populations and racial and ethnic minority populations;

(3) have documented community activity and experience and established relationships with community health workers in the communities expected to be served by the program;

(4) develop a plan for providing services to the extent practicable, in the language and cultural context most appropriate to individuals expected to be served by the program; and

(5) propose to use evidence-informed or evidence-based practices, as applicable and appropriate.

(e) COLLABORATION WITH ACADEMIC INSTITUTIONS AND THE ONE-STOP DELIVERY SYSTEM.—The Secretary shall encourage eligible entities receiving funds under this section to collaborate with academic institutions, health professions schools, minority-serving institutions (defined, for purposes of this subsection, as institutions and programs described in section 326(e)(1) of the Higher Education Act of 1965 and institutions described in section 371(a) of such Act), area health education centers under section 751 of this Act, and one-stop delivery systems under section 121 of the Workforce Innovation and Opportunity Act. Nothing in this section shall be construed to require such collaboration.

(f) TECHNICAL ASSISTANCE.—The Secretary may provide to eligible entities that receive awards under subsection (a) technical assistance with respect to planning, development, and operation of community health worker programs authorized or supported under this section.

(g) DISSEMINATION OF BEST PRACTICES.—Not later than 4 years after the date of enactment of the PREVENT Pandemics Act, the Secretary shall, based on activities carried out under this section and in consultation with relevant stakeholders, identify and disseminate evidence-based or evidence-informed practices regarding recruitment and retention of community health workers and paraprofessionals to address ongoing public health and community

health needs, and to prepare for, and respond to, future public health emergencies.

(h) REPORT TO CONGRESS.—Not later than 4 years after the date of enactment of the PREVENT Pandemics Act, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions 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 a report concerning the effectiveness of the program under this section in addressing ongoing public health and community health needs. Such report shall include recommendations regarding any improvements to such program, including recommendations for how to improve recruitment, training, and retention of the community health workforce.

(i) AUTHORIZATION OF APPROPRIATIONS.—For purposes of carrying out this section, there are authorized to be appropriated $50,000,000 for each of fiscal years 2023 through 2027.

(j) DEFINITIONS.—In this section:

(1) ELIGIBLE ENTITY.—The term "eligible entity" means a public or nonprofit private entity, including a State or political subdivision of a State, an Indian Tribe or Tribal organization, an urban Indian organization, a community-based organization, a public health department, a free health clinic, a hospital, or a Federally-qualified health center ([102](as defined in section 1861(aa)(4) of the Social Security Act), or a consortium of any such entities.

(2) INDIAN TRIBE; TRIBAL ORGANIZATION.—The terms "Indian Tribe" and "Tribal organization" have the meanings given the terms "Indian tribe" and "tribal organization", respectively, in section 4 of the Indian Self-Determination and Education Assistance Act.

(3) URBAN INDIAN ORGANIZATION.—The term "urban Indian organization" has the meaning given such term in section 4 of the Indian Health Care Improvement Act.

SEC. 399V–1. [280g–12] PRIMARY CARE EXTENSION PROGRAM.

(a) ESTABLISHMENT, PURPOSE AND DEFINITION.—

(1) IN GENERAL.—The Secretary, acting through the Director of the Agency for Healthcare Research and Quality, shall establish a Primary Care Extension Program.

(2) PURPOSE.—The Primary Care Extension Program shall provide support and assistance to primary care providers to educate providers about preventive medicine, health promotion, chronic disease management, mental and behavioral health services (including substance abuse prevention and treatment services), and evidence-based and evidence-informed therapies and techniques, in order to enable providers to incorporate such matters into their practice and to improve community health by working with community-based health connectors (referred to in this section as "Health Extension Agents").

(3) DEFINITIONS.—In this section:

[102] Double parenthesis so in law. See the amendment made by section 2222(a)(9)(C)(ii) of division FF of Public Law 117-328.

(A) HEALTH EXTENSION AGENT.—The term "Health Extension Agent" means any local, community-based health worker who facilitates and provides assistance to primary care practices by implementing quality improvement or system redesign, incorporating the principles of the patient-centered medical home to provide high-quality, effective, efficient, and safe primary care and to provide guidance to patients in culturally and linguistically appropriate ways, and linking practices to diverse health system resources.

(B) PRIMARY CARE PROVIDER.—The term "primary care provider" means a clinician who provides integrated, accessible health care services and who is accountable for addressing a large majority of personal health care needs, including providing preventive and health promotion services for men, women, and children of all ages, developing a sustained partnership with patients, and practicing in the context of family and community, as recognized by a State licensing or regulatory authority, unless otherwise specified in this section.

(b) GRANTS TO ESTABLISH STATE HUBS AND LOCAL PRIMARY CARE EXTENSION AGENCIES.—

(1) GRANTS.—The Secretary shall award competitive grants to States for the establishment of State- or multistate-level primary care Primary Care Extension Program State Hubs (referred to in this section as "Hubs").

(2) COMPOSITION OF HUBS.—A Hub established by a State pursuant to paragraph (1)—

(A) shall consist of, at a minimum, the State health department, the entity responsible for administering the State Medicaid program (if other than the State health department), the State-level entity administering the Medicare program, and the departments that train providers in primary care in 1 or more health professions schools in the State; and

(B) may include entities such as hospital associations, primary care practice-based research networks, health professional societies, State primary care associations, State licensing boards, organizations with a contract with the Secretary under section 1153 of the Social Security Act, consumer groups, and other appropriate entities.

(c) STATE AND LOCAL ACTIVITIES.—

(1) HUB ACTIVITIES.—Hubs established under a grant under subsection (b) shall—

(A) submit to the Secretary a plan to coordinate functions with quality improvement organizations and area health education centers if such entities are members of the Hub not described in subsection (b)(2)(A);

(B) contract with a county- or local-level entity that shall serve as the Primary Care Extension Agency to administer the services described in paragraph (2);

(C) organize and administer grant funds to county- or local-level Primary Care Extension Agencies that serve a catchment area, as determined by the State; and

(D) organize State-wide or multistate networks of local-level Primary Care Extension Agencies to share and disseminate information and practices.

(2) LOCAL PRIMARY CARE EXTENSION AGENCY ACTIVITIES.—

(A) REQUIRED ACTIVITIES.—Primary Care Extension Agencies established by a Hub under paragraph (1) shall—

(i) assist primary care providers to implement a patient-centered medical home to improve the accessibility, quality, and efficiency of primary care services, including health homes;

(ii) develop and support primary care learning communities to enhance the dissemination of research findings for evidence-based practice, assess implementation of practice improvement, share best practices, and involve community clinicians in the generation of new knowledge and identification of important questions for research;

(iii) participate in a national network of Primary Care Extension Hubs and propose how the Primary Care Extension Agency will share and disseminate lessons learned and best practices; and

(iv) develop a plan for financial sustainability involving State, local, and private contributions, to provide for the reduction in Federal funds that is expected after an initial 6-year period of program establishment, infrastructure development, and planning.

(B) DISCRETIONARY ACTIVITIES.—Primary Care Extension Agencies established by a Hub under paragraph (1) may—

(i) provide technical assistance, training, and organizational support for community health teams established under section 3602 of the Patient Protection and Affordable Care Act;

(ii) collect data and provision of primary care provider feedback from standardized measurements of processes and outcomes to aid in continuous performance improvement;

(iii) collaborate with local health departments, community health centers, tribes and tribal entities, and other community agencies to identify community health priorities and local health workforce needs, and participate in community-based efforts to address the social and primary determinants of health, strengthen the local primary care workforce, and eliminate health disparities;

(iv) develop measures to monitor the impact of the proposed program on the health of practice enrollees and of the wider community served; and

(v) participate in other activities, as determined appropriate by the Secretary.

(d) FEDERAL PROGRAM ADMINISTRATION.—

(1) GRANTS; TYPES.—Grants awarded under subsection (b) shall be—

(A) program grants, that are awarded to State or multistate entities that submit fully-developed plans for the implementation of a Hub, for a period of 6 years; or

(B) planning grants, that are awarded to State or multistate entities with the goal of developing a plan for a Hub, for a period of 2 years.

(2) APPLICATIONS.—To be eligible for a grant under subsection (b), a State or multistate entity shall submit to the Secretary an application, at such time, in such manner, and containing such information as the Secretary may require.

(3) EVALUATION.—A State that receives a grant under subsection (b) shall be evaluated at the end of the grant period by an evaluation panel appointed by the Secretary.

(4) CONTINUING SUPPORT.—After the sixth year in which assistance is provided to a State under a grant awarded under subsection (b), the State may receive additional support under this section if the State program has received satisfactory evaluations with respect to program performance and the merits of the State sustainability plan, as determined by the Secretary.

(5) LIMITATION.—A State shall not use in excess of 10 percent of the amount received under a grant to carry out administrative activities under this section. Funds awarded pursuant to this section shall not be used for funding direct patient care.

(e) REQUIREMENTS ON THE SECRETARY.—In carrying out this section, the Secretary shall consult with the heads of other Federal agencies with demonstrated experience and expertise in health care and preventive medicine, such as the Centers for Disease Control and Prevention, the Substance Abuse and Mental Health Administration, the Health Resources and Services Administration, the National Institutes of Health, the Office of the National Coordinator for Health Information Technology, the Indian Health Service, the Agricultural Cooperative Extension Service of the Department of Agriculture, and other entities, as the Secretary determines appropriate.

(f) AUTHORIZATION OF APPROPRIATIONS.—To awards grants as provided in subsection (d), there are authorized to be appropriated $120,000,000 for each of fiscal years 2011 and 2012, and such sums as may be necessary to carry out this section for each of fiscal years 2013 through 2014.

SEC. 399V–2. [280g–13] NATIONAL CONGENITAL HEART DISEASE RESEARCH, SURVEILLANCE, AND AWARENESS.

(a) IN GENERAL.—The Secretary shall, as appropriate—

(1) enhance and expand research and data collection efforts related to congenital heart disease, including to study and track the epidemiology of congenital heart disease to understand health outcomes for individuals with congenital heart disease across all ages;

(2) conduct activities to improve public awareness of, and education related to, congenital heart disease, including care of individuals with such disease; and

(3) award grants to entities to undertake the activities described in this section.

(b) ACTIVITIES.—

(1) IN GENERAL.—The Secretary shall carry out activities, including, as appropriate, through a national cohort study and a nationally-representative, population-based surveillance system, to improve the understanding of the epidemiology of congenital heart disease in all age groups, with particular attention to—

(A) the incidence and prevalence of congenital heart disease in the United States;

(B) causation and risk factors associated with, and natural history of, congenital heart disease;

(C) health care utilization by individuals with congenital heart disease;

(D) demographic factors associated with congenital heart disease, such as age, race, ethnicity, sex, and family history of individuals who are diagnosed with the disease; and

(E) evidence-based practices related to care and treatment for individuals with congenital heart disease.

(2) PERMISSIBLE CONSIDERATIONS.—In carrying out the activities under this section, the Secretary may, as appropriate—

(A) collect data on the health outcomes, including behavioral and mental health outcomes, of a diverse population of individuals of all ages with congenital heart disease, such that analysis of the outcomes will inform evidence-based practices for individuals with congenital heart disease; and

(B) consider health disparities among individuals with congenital heart disease, which may include the consideration of prenatal exposures.

(c) AWARENESS CAMPAIGN.—The Secretary may carry out awareness and educational activities related to congenital heart disease in individuals of all ages, which may include information for patients, family members, and health care providers, on topics such as the prevalence of such disease, the effect of such disease on individuals of all ages, and the importance of long-term, specialized care for individuals with such disease.

(d) PUBLIC ACCESS.—The Secretary shall ensure that, subject to subsection (e), information collected under this section is made available, as appropriate, to the public, including researchers.

(e) PATIENT PRIVACY.—The Secretary shall ensure that the data and information collected under this section are made available in a manner that, at a minimum, protects personal privacy to the extent required by applicable Federal and State law.

(f) REPORT AND STRATEGY.—

(1) REPORT.—Not later than 2 years after the date of enactment of the Congenital Heart Futures Reauthorization Act of 2024, the Secretary shall issue a report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate including the following:

(A) A description of past and present activities of the Department of Health and Human Services to increase awareness and knowledge of the public with respect to

congenital heart disease, including efforts to address the lifelong needs of congenital heart disease patients.

(B) An assessment of past and present activities of the Department of Health and Human Services to increase education and training of health care providers with respect to congenital heart disease, including efforts to address the lifelong needs of congenital heart disease patients.

(C) A description of the current workforce capacity in the United States of health care providers who treat adult patients living with congenital heart disease.

(2) STRATEGY.—

(A) DEVELOPMENT; SUBMISSION TO CONGRESS.—Not later than 1 year after submitting the report required by paragraph (1), the Secretary shall develop and submit to Congress a strategy for improving efforts to increase awareness and knowledge of the public and education and training of health care providers with respect to congenital heart disease. Such strategy shall include findings and recommendations to—

(i) address any public awareness and research gaps and opportunities related to the lifelong needs of congenital heart disease patients, including long-term health outcomes, quality of life, mental health, and health care utilization;

(ii) address any shortages in the current workforce of health care providers who treat adult patients living with congenital heart disease, which may include strategies to enhance fellowship training programs or other continuing education programs; and

(iii) foster collaboration and dissemination of information across Federal agencies, health care providers, researchers, and patient organizations.

(B) CONSULTATION.—In developing the strategy under subparagraph (A), the Secretary shall, as appropriate, consult with qualified stakeholder groups, including patient organizations, health care professionals, research entities, health insurance providers, accrediting organizations, and relevant Federal agencies, including the Centers for Disease Control and Prevention, the National Institutes of Health, and the Health Resources and Services Administration.

(g) ELIGIBILITY FOR GRANTS.—To be eligible to receive a grant under subsection (a)(3), an entity shall—

(1) be a public or private nonprofit entity with specialized experience in congenital heart disease; and

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

(h) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $10,000,000 for each of fiscal years 2025 through 2029.

SEC. 399V–3. [280g–14] NATIONAL DIABETES PREVENTION PROGRAM.

(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish a national diabetes prevention program (referred to in this section as the "program") targeted at adults at high risk for diabetes in order to eliminate the preventable burden of diabetes.

(b) PROGRAM ACTIVITIES.—The program described in subsection (a) shall include—

(1) a grant program for community-based diabetes prevention program model sites;

(2) a program within the Centers for Disease Control and Prevention to determine eligibility of entities to deliver community-based diabetes prevention services;

(3) a training and outreach program for lifestyle intervention instructors; and

(4) evaluation, monitoring and technical assistance, and applied research carried out by the Centers for Disease Control and Prevention.

(c) ELIGIBLE ENTITIES.—To be eligible for a grant under subsection (b)(1), an entity shall be a State or local health department, a tribal organization, a national network of community-based nonprofits focused on health and wellbeing, an academic institution, or other entity, as the Secretary determines.

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

SEC. 399V–4. [280g–15] STATE DEMONSTRATION PROGRAMS TO EVALUATE ALTERNATIVES TO CURRENT MEDICAL TORT LITIGATION.

(a) IN GENERAL.—The Secretary is authorized to award demonstration grants to States for the development, implementation, and evaluation of alternatives to current tort litigation for resolving disputes over injuries allegedly caused by health care providers or health care organizations. In awarding such grants, the Secretary shall ensure the diversity of the alternatives so funded.

(b) DURATION.—The Secretary may award grants under subsection (a) for a period not to exceed 5 years.

(c) CONDITIONS FOR DEMONSTRATION GRANTS.—

(1) REQUIREMENTS.—Each State desiring a grant under subsection (a) shall develop an alternative to current tort litigation that—

(A) allows for the resolution of disputes over injuries allegedly caused by health care providers or health care organizations; and

(B) promotes a reduction of health care errors by encouraging the collection and analysis of patient safety data related to disputes resolved under subparagraph (A) by organizations that engage in efforts to improve patient safety and the quality of health care.

(2) ALTERNATIVE TO CURRENT TORT LITIGATION.—Each State desiring a grant under subsection (a) shall demonstrate how the proposed alternative described in paragraph (1)(A)—

(A) makes the medical liability system more reliable by increasing the availability of prompt and fair resolution of disputes;

(B) encourages the efficient resolution of disputes;

(C) encourages the disclosure of health care errors;

(D) enhances patient safety by detecting, analyzing, and helping to reduce medical errors and adverse events;

(E) improves access to liability insurance;

(F) fully informs patients about the differences in the alternative and current tort litigation;

(G) provides patients the ability to opt out of or voluntarily withdraw from participating in the alternative at any time and to pursue other options, including litigation, outside the alternative;

(H) would not conflict with State law at the time of the application in a way that would prohibit the adoption of an alternative to current tort litigation; and

(I) would not limit or curtail a patient's existing legal rights, ability to file a claim in or access a State's legal system, or otherwise abrogate a patient's ability to file a medical malpractice claim.

(3) SOURCES OF COMPENSATION.—Each State desiring a grant under subsection (a) shall identify the sources from and methods by which compensation would be paid for claims resolved under the proposed alternative to current tort litigation, which may include public or private funding sources, or a combination of such sources. Funding methods shall to the extent practicable provide financial incentives for activities that improve patient safety.

(4) SCOPE.—

(A) IN GENERAL.—Each State desiring a grant under subsection (a) shall establish a scope of jurisdiction (such as Statewide, designated geographic region, a designated area of health care practice, or a designated group of health care providers or health care organizations) for the proposed alternative to current tort litigation that is sufficient to evaluate the effects of the alternative. No scope of jurisdiction shall be established under this paragraph that is based on a health care payer or patient population.

(B) NOTIFICATION OF PATIENTS.—A State shall demonstrate how patients would be notified that they are receiving health care services that fall within such scope, and the process by which they may opt out of or voluntarily withdraw from participating in the alternative. The decision of the patient whether to participate or continue participating in the alternative process shall be made at any time and shall not be limited in any way.

(5) PREFERENCE IN AWARDING DEMONSTRATION GRANTS.—In awarding grants under subsection (a), the Secretary shall give preference to States—

(A) that have developed the proposed alternative through substantive consultation with relevant stakeholders, including patient advocates, health care providers and health care organizations, attorneys with expertise in

representing patients and health care providers, medical malpractice insurers, and patient safety experts;

(B) that make proposals that are likely to enhance patient safety by detecting, analyzing, and helping to reduce medical errors and adverse events; and

(C) that make proposals that are likely to improve access to liability insurance.

(d) APPLICATION.—

(1) IN GENERAL.—Each State desiring a grant under subsection (a) shall submit to the Secretary an application, at such time, in such manner, and containing such information as the Secretary may require.

(2) REVIEW PANEL.—

(A) IN GENERAL.—In reviewing applications under paragraph (1), the Secretary shall consult with a review panel composed of relevant experts appointed by the Comptroller General.

(B) COMPOSITION.—

(i) NOMINATIONS.—The Comptroller General shall solicit nominations from the public for individuals to serve on the review panel.

(ii) APPOINTMENT.—The Comptroller General shall appoint, at least 9 but not more than 13, highly qualified and knowledgeable individuals to serve on the review panel and shall ensure that the following entities receive fair representation on such panel:

(I) Patient advocates.

(II) Health care providers and health care organizations.

(III) Attorneys with expertise in representing patients and health care providers.

(IV) Medical malpractice insurers.

(V) State officials.

(VI) Patient safety experts.

(C) CHAIRPERSON.—The Comptroller General shall designate a member of the review panel to be the chairperson of the review panel.

(D) AVAILABILITY OF INFORMATION.—The Secretary shall make available to the review panel such information, personnel, and administrative services and assistance as the review panel may reasonably require to carry out its duties.

(E) INFORMATION FROM AGENCIES.—The review panel may request directly from any department or agency of the United States any information that such panel considers necessary to carry out its duties. To the extent consistent with applicable laws and regulations, the head of such department or agency shall furnish the requested information to the review panel.

(e) REPORTS.—

(1) BY STATE.—Each State receiving a grant under subsection (a) shall submit to the Secretary an annual report evaluating the effectiveness of activities funded with grants awarded under such subsection. Such report shall, at a minimum, in-

clude the impact of the activities funded on patient safety and on the availability and price of medical liability insurance.

(2) BY SECRETARY.—The Secretary shall submit to Congress an annual compendium of the reports submitted under paragraph (1) and an analysis of the activities funded under subsection (a) that examines any differences that result from such activities in terms of the quality of care, number and nature of medical errors, medical resources used, length of time for dispute resolution, and the availability and price of liability insurance.

(f) TECHNICAL ASSISTANCE.—

(1) IN GENERAL.—The Secretary shall provide technical assistance to the States applying for or awarded grants under subsection (a).

(2) REQUIREMENTS.—Technical assistance under paragraph (1) shall include—

(A) guidance on non-economic damages, including the consideration of individual facts and circumstances in determining appropriate payment, guidance on identifying avoidable injuries, and guidance on disclosure to patients of health care errors and adverse events; and

(B) the development, in consultation with States, of common definitions, formats, and data collection infrastructure for States receiving grants under this section to use in reporting to facilitate aggregation and analysis of data both within and between States.

(3) USE OF COMMON DEFINITIONS, FORMATS, AND DATA COLLECTION INFRASTRUCTURE.—States not receiving grants under this section may also use the common definitions, formats, and data collection infrastructure developed under paragraph (2)(B).

(g) EVALUATION.—

(1) IN GENERAL.—The Secretary, in consultation with the review panel established under subsection (d)(2), shall enter into a contract with an appropriate research organization to conduct an overall evaluation of the effectiveness of grants awarded under subsection (a) and to annually prepare and submit a report to Congress. Such an evaluation shall begin not later than 18 months following the date of implementation of the first program funded by a grant under subsection (a).

(2) CONTENTS.—The evaluation under paragraph (1) shall include—

(A) an analysis of the effects of the grants awarded under subsection (a) with regard to the measures described in paragraph (3);

(B) for each State, an analysis of the extent to which the alternative developed under subsection (c)(1) is effective in meeting the elements described in subsection (c)(2);

(C) a comparison among the States receiving grants under subsection (a) of the effectiveness of the various alternatives developed by such States under subsection (c)(1);

(D) a comparison, considering the measures described in paragraph (3), of States receiving grants approved

under subsection (a) and similar States not receiving such grants; and

(E) a comparison, with regard to the measures described in paragraph (3), of—

(i) States receiving grants under subsection (a);

(ii) States that enacted, prior to the date of enactment of the Patient Protection and Affordable Care Act, any cap on non-economic damages; and

(iii) States that have enacted, prior to the date of enactment of the Patient Protection and Affordable Care Act, a requirement that the complainant obtain an opinion regarding the merit of the claim, although the substance of such opinion may have no bearing on whether the complainant may proceed with a case.

(3) MEASURES.—The evaluations under paragraph (2) shall analyze and make comparisons on the basis of—

(A) the nature and number of disputes over injuries allegedly caused by health care providers or health care organizations;

(B) the nature and number of claims in which tort litigation was pursued despite the existence of an alternative under subsection (a);

(C) the disposition of disputes and claims, including the length of time and estimated costs to all parties;

(D) the medical liability environment;

(E) health care quality;

(F) patient safety in terms of detecting, analyzing, and helping to reduce medical errors and adverse events;

(G) patient and health care provider and organization satisfaction with the alternative under subsection (a) and with the medical liability environment; and

(H) impact on utilization of medical services, appropriately adjusted for risk.

(4) FUNDING.—The Secretary shall reserve 5 percent of the amount appropriated in each fiscal year under subsection (k) to carry out this subsection.

(h) MEDPAC AND MACPAC REPORTS.—

(1) MEDPAC.—The Medicare Payment Advisory Commission shall conduct an independent review of the alternatives to current tort litigation that are implemented under grants under subsection (a) to determine the impact of such alternatives on the Medicare program under title XVIII of the Social Security Act, and its beneficiaries.

(2) MACPAC.—The Medicaid and CHIP Payment and Access Commission shall conduct an independent review of the alternatives to current tort litigation that are implemented under grants under subsection (a) to determine the impact of such alternatives on the Medicaid or CHIP programs under titles XIX and XXI of the Social Security Act, and their beneficiaries.

(3) REPORTS.—Not later than December 31, 2016, the Medicare Payment Advisory Commission and the Medicaid and CHIP Payment and Access Commission shall each submit to Congress a report that includes the findings and recommenda-

tions of each respective Commission based on independent reviews conducted under paragraphs (1) and (2), including an analysis of the impact of the alternatives reviewed on the efficiency and effectiveness of the respective programs.

(i) OPTION TO PROVIDE FOR INITIAL PLANNING GRANTS.—Of the funds appropriated pursuant to subsection (k), the Secretary may use a portion not to exceed $500,000 per State to provide planning grants to such States for the development of demonstration project applications meeting the criteria described in subsection (c). In selecting States to receive such planning grants, the Secretary shall give preference to those States in which State law at the time of the application would not prohibit the adoption of an alternative to current tort litigation.

(j) DEFINITIONS.—In this section:

(1) HEALTH CARE SERVICES.—The term "health care services" means any services provided by a health care provider, or by any individual working under the supervision of a health care provider, that relate to—

(A) the diagnosis, prevention, or treatment of any human disease or impairment; or

(B) the assessment of the health of human beings.

(2) HEALTH CARE ORGANIZATION.—The term "health care organization" means any individual or entity which is obligated to provide, pay for, or administer health benefits under any health plan.

(3) HEALTH CARE PROVIDER.—The term "health care provider" means any individual or entity—

(A) licensed, registered, or certified under Federal or State laws or regulations to provide health care services; or

(B) required to be so licensed, registered, or certified but that is exempted by other statute or regulation.

(k) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, $50,000,000 for the 5-fiscal year period beginning with fiscal year 2011.

(l) CURRENT STATE EFFORTS TO ESTABLISH ALTERNATIVE TO TORT LITIGATION.—Nothing in this section shall be construed to limit any prior, current, or future efforts of any State to establish any alternative to tort litigation.

(m) RULE OF CONSTRUCTION.—Nothing in this section shall be construed as limiting states' authority over or responsibility for their state justice systems.

SEC. 399V–5. [280g–16] FOOD SAFETY INTEGRATED CENTERS OF EXCELLENCE.

(a) IN GENERAL.—Not later than 1 year after the date of enactment of the FDA Food Safety Modernization Act, the Secretary, acting through the Director of the Centers for Disease Control and Prevention and in consultation with the working group described in subsection (b)(2), shall designate 5 Integrated Food Safety Centers of Excellence (referred to in this section as the "Centers of Excellence") to serve as resources for Federal, State, and local public health professionals to respond to foodborne illness outbreaks. The Centers of Excellence shall be headquartered at selected State health departments.

(b) SELECTION OF CENTERS OF EXCELLENCE.—

(1) ELIGIBLE ENTITIES.—To be eligible to be designated as a Center of Excellence under subsection (a), an entity shall—

(A) be a State health department;

(B) partner with 1 or more institutions of higher education that have demonstrated knowledge, expertise, and meaningful experience with regional or national food production, processing, and distribution, as well as leadership in the laboratory, epidemiological, and environmental detection and investigation of foodborne illness; and

(C) provide to the Secretary such information, at such time, and in such manner, as the Secretary may require.

(2) WORKING GROUP.—Not later than 180 days after the date of enactment of the FDA Food Safety Modernization Act, the Secretary shall establish a diverse working group of experts and stakeholders from Federal, State, and local food safety and health agencies, the food industry, including food retailers and food manufacturers, consumer organizations, and academia to make recommendations to the Secretary regarding designations of the Centers of Excellence.

(3) ADDITIONAL CENTERS OF EXCELLENCE.—The Secretary may designate eligible entities to be regional Food Safety Centers of Excellence, in addition to the 5 Centers designated under subsection (a).

(c) ACTIVITIES.—Under the leadership of the Director of the Centers for Disease Control and Prevention, each Center of Excellence shall be based out of a selected State health department, which shall provide assistance to other regional, State, and local departments of health through activities that include—

(1) providing resources, including timely information concerning symptoms and tests, for frontline health professionals interviewing individuals as part of routine surveillance and outbreak investigations;

(2) providing analysis of the timeliness and effectiveness of foodborne disease surveillance and outbreak response activities;

(3) providing training for epidemiological and environmental investigation of foodborne illness, including suggestions for streamlining and standardizing the investigation process;

(4) establishing fellowships, stipends, and scholarships to train future epidemiological and food-safety leaders and to address critical workforce shortages;

(5) training and coordinating State and local personnel;

(6) strengthening capacity to participate in existing or new foodborne illness surveillance and environmental assessment information systems; and

(7) conducting research and outreach activities focused on increasing prevention, communication, and education regarding food safety.

(d) REPORT TO CONGRESS.—Not later than 2 years after the date of enactment of the FDA Food Safety Modernization Act, the Secretary shall submit to Congress a report that—

(1) describes the effectiveness of the Centers of Excellence; and

(2) provides legislative recommendations or describes additional resources required by the Centers of Excellence.

(e) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated such sums as may be necessary to carry out this section.

(f) NO DUPLICATION OF EFFORT.—In carrying out activities of the Centers of Excellence or other programs under this section, the Secretary shall not duplicate other Federal foodborne illness response efforts.

SEC. 399V–6. [280g–17] DESIGNATION AND INVESTIGATION OF POTENTIAL CANCER CLUSTERS.

(a) DEFINITIONS.—In this section:

(1) CANCER CLUSTER.—The term "cancer cluster" means the incidence of a particular cancer within a population group, a geographical area, and a period of time that is greater than expected for such group, area, and period.

(2) PARTICULAR CANCER.—The term "particular cancer" means one specific type of cancer or a type of cancers scientifically proven to have the same cause.

(3) POPULATION GROUP.—The term "population group" means a group, for purposes of calculating cancer rates, defined by factors such as race, ethnicity, age, or gender.

(b) CRITERIA FOR DESIGNATION OF POTENTIAL CANCER CLUSTERS.—

(1) DEVELOPMENT OF CRITERIA.—The Secretary shall develop criteria for the designation of potential cancer clusters.

(2) REQUIREMENTS.—The criteria developed under paragraph (1) shall consider, as appropriate—

(A) a standard for cancer cluster identification and reporting protocols used to determine when cancer incidence is greater than would be typically observed;

(B) scientific screening standards that ensure that a cluster of a particular cancer involves the same type of cancer, or types of cancers;

(C) the population in which the cluster of a particular cancer occurs by factors such as race, ethnicity, age, and gender, for purposes of calculating cancer rates;

(D) the boundaries of a geographic area in which a cluster of a particular cancer occurs so as not to create or obscure a potential cluster by selection of a specific area; and

(E) the time period over which the number of cases of a particular cancer, or the calculation of an expected number of cases, occurs.

(c) GUIDELINES FOR INVESTIGATION OF POTENTIAL CANCER CLUSTERS.—The Secretary, in consultation with the Council of State and Territorial Epidemiologists and representatives of State and local health departments, shall develop, publish, and periodically update guidelines for investigating potential cancer clusters. The guidelines shall—

(1) recommend that investigations of cancer clusters—

(A) use the criteria developed under subsection (b);

(B) use the best available science; and

(C) rely on a weight of the scientific evidence;

(2) provide standardized methods of reviewing and categorizing data, including from health surveillance systems and reports of potential cancer clusters; and

(3) provide guidance for using appropriate epidemiological and other approaches for investigations.

(d) INVESTIGATION OF CANCER CLUSTERS.—

(1) SECRETARY DISCRETION.—The Secretary—

(A) in consultation with representatives of the relevant State and local health departments, shall consider whether it is appropriate to conduct an investigation of a potential cancer cluster; and

(B) in conducting investigations shall have the discretion to prioritize certain potential cancer clusters, based on the availability of resources.

(2) COORDINATION.—In investigating potential cancer clusters, the Secretary shall coordinate with agencies within the Department of Health and Human Services and other Federal agencies, such as the Environmental Protection Agency.

(3) BIOMONITORING.—In investigating potential cancer clusters, the Secretary shall rely on all appropriate biomonitoring information collected under other Federal programs, such as the National Health and Nutrition Examination Survey. The Secretary may provide technical assistance for relevant biomonitoring studies of other Federal agencies.

(e) DUTIES.—The Secretary shall—

(1) ensure that appropriate staff of agencies within the Department of Health and Human Services are prepared to provide timely assistance, to the extent practicable, upon receiving a request to investigate a potential cancer cluster from a State or local health authority;

(2) maintain staff expertise in epidemiology, toxicology, data analysis, environmental health and cancer surveillance, exposure assessment, pediatric health, pollution control, community outreach, health education, laboratory sampling and analysis, spatial mapping, and informatics;

(3) consult with community members as investigations into potential cancer clusters are conducted, as the Secretary determines appropriate;

(4) collect, store, and disseminate reports on investigations of potential cancer clusters, the possible causes of such clusters, and the actions taken to address such clusters; and

(5) provide technical assistance for investigating cancer clusters to State and local health departments through existing programs, such as the Epi-Aids program of the Centers for Disease Control and Prevention and the Assessments of Chemical Exposures Program of the Agency for Toxic Substances and Disease Registry.

SEC. 399V–7. [280g-18] MATERNAL MENTAL HEALTH HOTLINE.

(a) IN GENERAL.—The Secretary shall maintain, by grant or contract, a national maternal mental health hotline to provide emotional support, information, brief intervention, and mental health and substance use disorder resources to pregnant and postpartum

women at risk of, or affected by, maternal mental health and substance use disorders, and to their families or household members.

(b) REQUIREMENTS FOR HOTLINE.—The hotline under subsection (a) shall—

(1) be a 24/7 real-time hotline;

(2) provide voice and text support;

(3) be staffed by certified peer specialists, licensed health care professionals, or licensed mental health professionals who are trained on—

(A) maternal mental health and substance use disorder prevention, identification, and intervention; and

(B) providing culturally and linguistically appropriate support; and

(4) provide maternal mental health and substance use disorder assistance and referral services to meet the needs of underserved populations, individuals with disabilities, and family and household members of pregnant or postpartum women at risk of experiencing maternal mental health and substance use disorders.

(c) ADDITIONAL REQUIREMENTS.—In maintaining the hotline under subsection (a), the Secretary shall—

(1) consult with the Domestic Violence Hotline, National Suicide Prevention Lifeline, and Veterans Crisis Line to ensure that pregnant and postpartum women are connected in real-time to the appropriate specialized hotline service, when applicable;

(2) conduct a public awareness campaign for the hotline;

(3) consult with Federal departments and agencies, including the Substance Abuse and Mental Health Services Administration and the Department of Veterans Affairs, to increase awareness regarding the hotline; and

(4) consult with appropriate State, local, and Tribal public health officials, including officials who administer programs that serve low-income pregnant and postpartum individuals.

(d) ANNUAL REPORT.—The Secretary shall submit an annual report to the Congress on the hotline under subsection (a) and implementation of this section, including—

(1) an evaluation of the effectiveness of activities conducted or supported under subsection (a);

(2) a directory of entities or organizations to which staff maintaining the hotline funded under this section may make referrals; and

(3) such additional information as the Secretary determines appropriate.

(e) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $10,000,000 for each of fiscal years 2023 through 2027.

PART Q—PROGRAMS TO IMPROVE THE HEALTH OF CHILDREN

SEC. 399W. [280h] GRANTS TO PROMOTE CHILDHOOD NUTRITION AND PHYSICAL ACTIVITY.

(a) IN GENERAL.—The Secretary, acting though the Director of the Centers for Disease Control and Prevention, shall award competitive grants to States and political subdivisions of States for the development and implementation of State and community-based intervention programs to promote good nutrition and physical activity in children and adolescents.

(b) ELIGIBILITY.—To be eligible to receive a grant under this section a State or political subdivision of a State shall prepare and submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require, including a plan that describes—

(1) how the applicant proposes to develop a comprehensive program of school- and community-based approaches to encourage and promote good nutrition and appropriate levels of physical activity with respect to children or adolescents in local communities;

(2) the manner in which the applicant shall coordinate with appropriate State and local authorities, such as State and local school departments, State departments of health, chronic disease directors, State directors of programs under section 17 of the Child Nutrition Act of 1966, 5-a-day coordinators, governors councils for physical activity and good nutrition, and State and local parks and recreation departments; and

(3) the manner in which the applicant will evaluate the effectiveness of the program carried out under this section.

(c) USE OF FUNDS.—A State or political subdivision of a State shall use amount received under a grant under this section to—

(1) develop, implement, disseminate, and evaluate school- and community-based strategies in States to reduce inactivity and improve dietary choices among children and adolescents;

(2) expand opportunities for physical activity programs in school- and community-based settings; and

(3) develop, implement, and evaluate programs that promote good eating habits and physical activity including opportunities for children with cognitive and physical disabilities.

(d) TECHNICAL ASSISTANCE.—The Secretary may set-aside an amount not to exceed 10 percent of the amount appropriated for a fiscal year under subsection (h) to permit the Director of the Centers for Disease Control and Prevention to—

(1) provide States and political subdivisions of States with technical support in the development and implementation of programs under this section; and

(2) disseminate information about effective strategies and interventions in preventing and treating obesity through the promotion of good nutrition and physical activity.

(e) LIMITATION ON ADMINISTRATIVE COSTS.—Not to exceed 10 percent of the amount of a grant awarded to the State or political subdivision under subsection (a) for a fiscal year may be used by the State or political subdivision for administrative expenses.

(f) TERM.—A grant awarded under subsection (a) shall be for a term of 3 years.

(g) DEFINITION.—In this section, the term "children and adolescents" means individuals who do not exceed 18 years of age.

(h) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section such sums as may be necessary for each of the fiscal years 2001 through 2005.

SEC. 399X. [280h–1] APPLIED RESEARCH PROGRAM.

(a) IN GENERAL.—The Secretary, acting through the Centers for Disease Control and Prevention and in consultation with the Director of the National Institutes of Health, shall—

(1) conduct research to better understand the relationship between physical activity, diet, and health and factors that influence health-related behaviors;

(2) develop and evaluate strategies for the prevention and treatment of obesity to be used in community-based interventions and by health professionals;

(3) develop and evaluate strategies for the prevention and treatment of eating disorders, such as anorexia and bulimia;

(4) conduct research to establish the prevalence, consequences, and costs of childhood obesity and its effects in adulthood;

(5) identify behaviors and risk factors that contribute to obesity;

(6) evaluate materials and programs to provide nutrition education to parents and teachers of children in child care or pre-school and the food service staff of such child care and preschool entities; and

(7) evaluate materials and programs that are designed to educate and encourage physical activity in child care and preschool facilities.

(b) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section such sums as may be necessary for each of the fiscal years 2001 through 2005.

SEC. 399Y. [280h–2] EDUCATION CAMPAIGN.

(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, and in collaboration with national, State, and local partners, physical activity organizations, nutrition experts, and health professional organizations, shall develop a national public campaign to promote and educate children and their parents concerning—

(1) the health risks associated with obesity, inactivity, and poor nutrition;

(2) ways in which to incorporate physical activity into daily living; and

(3) the benefits of good nutrition and strategies to improve eating habits.

(b) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section such sums as may be necessary for each of the fiscal years 2001 through 2005.

SEC. 399Z. [280h–3] HEALTH PROFESSIONAL EDUCATION AND TRAINING.

(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, in collaboration with the Administrator of the Health Resources and Services Administration and the heads of other agencies, and in consultation with appropriate health professional associations, shall develop and carry out a program to educate and train health professionals in effective strategies to—

(1) better identify and assess patients with obesity or an eating disorder or patients at-risk of becoming obese or developing an eating disorder;

(2) counsel, refer, or treat patients with obesity or an eating disorder; and

(3) educate patients and their families about effective strategies to improve dietary habits and establish appropriate levels of physical activity.

(b) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section such sums as may be necessary for each of the fiscal years 2001 through 2005.

SEC. 399Z–1. [280h–5] SCHOOL-BASED HEALTH CENTERS.

(a) DEFINITIONS; ESTABLISHMENT OF CRITERIA.—In this section:

(1) COMPREHENSIVE PRIMARY HEALTH SERVICES.—The term "comprehensive primary health services" means the core services offered by school-based health centers, which shall include the following:

(A) PHYSICAL.—Comprehensive health assessments, diagnosis, and treatment of minor, acute, and chronic medical conditions, and referrals to, and follow-up for, specialty care and oral and vision health services.

(B) MENTAL HEALTH.—Mental health and substance use disorder assessments, crisis intervention, counseling, treatment, and referral to a continuum of services including emergency psychiatric care, community support programs, inpatient care, and outpatient programs.

(2) MEDICALLY UNDERSERVED CHILDREN AND ADOLESCENTS.—

(A) IN GENERAL.—The term "medically underserved children and adolescents" means a population of children and adolescents who are residents of an area designated as a medically underserved area or a health professional shortage area by the Secretary.

(B) CRITERIA.—The Secretary shall prescribe criteria for determining the specific shortages of personal health services for medically underserved children and adolescents under subparagraph (A) that shall—

(i) take into account any comments received by the Secretary from the chief executive officer of a State and local officials in a State; and

(ii) include factors indicative of the health status of such children and adolescents of an area, including the ability of the residents of such area to pay for health services, the accessibility of such services, the availability of health professionals to such children

and adolescents, and other factors as determined appropriate by the Secretary.

(3) SCHOOL-BASED HEALTH CENTER.—The term "school-based health center" means a health clinic that—

(A) meets the definition of a school-based health center under section 2110(c)(9)(A) of the Social Security Act and is administered by a sponsoring facility (as defined in section 2110(c)(9)(B) of the Social Security Act);

(B) provides, at a minimum, comprehensive primary health services during school hours to children and adolescents by health professionals in accordance with established standards, community practice, reporting laws, and other State laws, including parental consent and notification laws that are not inconsistent with Federal law; and

(C) does not perform abortion services.

(b) AUTHORITY TO AWARD GRANTS.—The Secretary shall award grants for the costs of the operation of school-based health centers (referred to in this section as "SBHCs") that meet the requirements of this section.

(c) APPLICATIONS.—To be eligible to receive a grant under this section, an entity shall—

(1) be an SBHC (as defined in subsection (a)(3)); and

(2) submit to the Secretary an application at such time, in such manner, and containing—

(A) evidence that the applicant meets all criteria necessary to be designated an SBHC;

(B) evidence of local need for the services to be provided by the SBHC;

(C) an assurance that—

(i) SBHC services will be provided to those children and adolescents for whom parental or guardian consent has been obtained in cooperation with Federal, State, and local laws governing health care service provision to children and adolescents;

(ii) the SBHC has made and will continue to make every reasonable effort to establish and maintain collaborative relationships with other health care providers in the catchment area of the SBHC;

(iii) the SBHC will provide on-site access during the academic day when school is in session and 24-hour coverage through an on-call system and through its backup health providers to ensure access to services on a year-round basis when the school or the SBHC is closed;

(iv) the SBHC will be integrated into the school environment and will coordinate health services with school personnel, such as administrators, teachers, nurses, counselors, and support personnel, as well as with other community providers co-located at the school;

(v) the SBHC sponsoring facility assumes all responsibility for the SBHC administration, operations, and oversight; and

(vi) the SBHC will comply with Federal, State, and local laws concerning patient privacy and student records, including regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 and section 444 of the General Education Provisions Act; and

(D) such other information as the Secretary may require.

(d) PREFERENCES AND CONSIDERATION.—In reviewing applications:

(1) The Secretary may give preference to applicants who demonstrate an ability to serve the following:

(A) Communities that have evidenced barriers to primary health care and mental health and substance use disorder prevention services for children and adolescents.

(B) Communities with high per capita numbers of children and adolescents who are uninsured, underinsured, or enrolled in public health insurance programs.

(C) Populations of children and adolescents that have historically demonstrated difficulty in accessing health and mental health and substance use disorder prevention services.

(2) The Secretary may give consideration to whether an applicant has received a grant under subsection (a) of section 4101 of the Patient Protection and Affordable Care Act.

(e) WAIVER OF REQUIREMENTS.—The Secretary may—

(1) under appropriate circumstances, waive the application of all or part of the requirements of this subsection with respect to an SBHC for not to exceed 2 years; and

(2) upon a showing of good cause, waive the requirement that the SBHC provide all required comprehensive primary health services for a designated period of time to be determined by the Secretary.

(f) USE OF FUNDS.—

(1) FUNDS.—Funds awarded under a grant under this section—

(A) may be used for—

(i) acquiring and leasing equipment (including the costs of amortizing the principle of, and paying interest on, loans for such equipment);

(ii) providing training related to the provision of required comprehensive primary health services and additional health services;

(iii) the management and operation of health center programs;

(iv) the payment of salaries for physicians, nurses, and other personnel of the SBHC; and

(B) may not be used to provide abortions.

(2) CONSTRUCTION.—The Secretary may award grants which may be used to pay the costs associated with expanding and modernizing existing buildings for use as an SBHC, including the purchase of trailers or manufactured buildings to install on the school property.

(3) LIMITATIONS.—

(A) IN GENERAL.—Any provider of services that is determined by a State to be in violation of a State law described in subsection (a)(3)(B) with respect to activities carried out at a SBHC shall not be eligible to receive additional funding under this section.

(B) NO OVERLAPPING GRANT PERIOD.—No entity that has received funding under section 330 for a grant period shall be eligible for a grant under this section for with respect to the same grant period.

(g) MATCHING REQUIREMENT.—

(1) IN GENERAL.—Each eligible entity that receives a grant under this section shall provide, from non-Federal sources, an amount equal to 20 percent of the amount of the grant (which may be provided in cash or in-kind) to carry out the activities supported by the grant.

(2) WAIVER.—The Secretary may waive all or part of the matching requirement described in paragraph (1) for any fiscal year for the SBHC if the Secretary determines that applying the matching requirement to the SBHC would result in serious hardship or an inability to carry out the purposes of this section.

(h) SUPPLEMENT, NOT SUPPLANT.—Grant funds provided under this section shall be used to supplement, not supplant, other Federal or State funds.

(i) EVALUATION.—The Secretary shall develop and implement a plan for evaluating SBHCs and monitoring quality performance under the awards made under this section.

(j) AGE APPROPRIATE SERVICES.—An eligible entity receiving funds under this section shall only provide age appropriate services through a SBHC funded under this section to an individual.

(k) PARENTAL CONSENT.—An eligible entity receiving funds under this section shall not provide services through a SBHC funded under this section to an individual without the consent of the parent or guardian of such individual if such individual is considered a minor under applicable State law.

(l) TECHNICAL ASSISTANCE.—The Secretary shall provide technical assistance by grants or contracts awarded to private, nonprofit entities with demonstrated expertise related to school-based health centers. Such technical assistance, taking into account local and regional differences among school based health centers, shall support such entities in providing services described in subsection (a)(1) pursuant to this section, including mental health and substance use disorder services, and may include technical assistance relating to program operations and support for the implementation of evidence-based or evidence-informed best practices related to the provision of high quality health care services to children and adolescents.

(m) AUTHORIZATION OF APPROPRIATIONS.—For purposes of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2022 through 2026.

SEC. 399Z–2. [280h–6] INFANT AND EARLY CHILDHOOD MENTAL HEALTH PROMOTION, INTERVENTION, AND TREATMENT.

(a) GRANTS.—The Secretary shall—

(1) award grants to eligible entities to develop, maintain, or enhance infant and early childhood mental health promotion, intervention, and treatment programs, including—

(A) programs for infants and children at significant risk of developing, showing early signs of, or having been diagnosed with mental illness, including a serious emotional disturbance; and

(B) multigenerational therapy and other services that support the caregiving relationship; and

(2) ensure that programs funded through grants under this section are evidence-informed or evidence-based models, practices, and methods that are, as appropriate, culturally and linguistically appropriate, and can be replicated in other appropriate settings.

(b) ELIGIBLE CHILDREN AND ENTITIES.—In this section:

(1) ELIGIBLE CHILD.—The term "eligible child" means a child from birth to not more than 12 years of age who—

(A) is at risk for, shows early signs of, or has been diagnosed with a mental illness, including a serious emotional disturbance; and

(B) may benefit from infant and early childhood intervention or treatment programs or specialized preschool or elementary school programs that are evidence-based or that have been scientifically demonstrated to show promise but would benefit from further applied development.

(2) ELIGIBLE ENTITY.—The term "eligible entity" means a human services agency or nonprofit institution that—

(A) employs licensed mental health professionals who have specialized training and experience in infant and early childhood mental health assessment, diagnosis, and treatment, or is accredited or approved by the appropriate State agency, as applicable, to provide for children from infancy to 12 years of age mental health promotion, intervention, or treatment services; and

(B) provides services or programs described in subsection (a) that are evidence-based or that have been scientifically demonstrated to show promise but would benefit from further applied development.

(c) APPLICATION.—An eligible entity seeking a grant under subsection (a) shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

(d) USE OF FUNDS FOR EARLY INTERVENTION AND TREATMENT PROGRAMS.—An eligible entity may use amounts awarded under a grant under subsection (a)(1) to carry out the following:

(1) Provide age-appropriate mental health promotion and early intervention services or mental illness treatment services, which may include specialized programs, for eligible children at significant risk of developing, showing early signs of, or having been diagnosed with a mental illness, including a serious emotional disturbance. Such services may include social and behavioral services as well as multigenerational therapy and other services that support the caregiving relationship.

(2) Provide training for health care professionals with expertise in infant and early childhood mental health care with respect to appropriate and relevant integration with other disciplines such as primary care clinicians, early intervention specialists, child welfare staff, home visitors, early care and education providers, and others who work with young children and families.

(3) Provide mental health consultation to personnel of early care and education programs (including licensed or regulated center-based and home-based child care, home visiting, preschool special education, and early intervention programs) who work with children and families.

(4) Provide training for mental health clinicians in infant and early childhood in promising and evidence-based practices and models for infant and early childhood mental health treatment and early intervention, including with regard to practices for identifying and treating mental illness and behavioral disorders of infants and children resulting from exposure or repeated exposure to adverse childhood experiences or childhood trauma.

(5) Provide age-appropriate assessment, diagnostic, and intervention services for eligible children, including early mental health promotion, intervention, and treatment services.

(e) MATCHING FUNDS.—The Secretary may not award a grant under this section to an eligible entity unless the eligible entity agrees, with respect to the costs to be incurred by the eligible entity in carrying out the activities described in subsection (d), to make available non-Federal contributions (in cash or in kind) toward such costs in an amount that is not less than 10 percent of the total amount of Federal funds provided in the grant.

(f) TECHNICAL ASSISTANCE.—The Secretary may, directly or by awarding grants or contracts to public and private nonprofit entities, provide training and technical assistance to eligible entities to carry out activities described in subsection (d).

(g) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $50,000,000 for the period of fiscal years 2023 through 2027.

PART R—PROGRAMS RELATING TO AUTISM

SEC. 399AA. [280i] DEVELOPMENTAL DISABILITIES SURVEILLANCE AND RESEARCH PROGRAM.

(a) AUTISM SPECTRUM DISORDER AND OTHER DEVELOPMENTAL DISABILITIES.—

(1) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may award grants or cooperative agreements to eligible entities for the collection, analysis, and reporting of State epidemiological data for children and adults with autism spectrum disorder and other developmental disabilities. An eligible entity shall assist with the development and coordination of State autism spectrum disorder and other developmental disability surveillance efforts within a region. In making such awards, the Secretary may provide direct technical assistance in lieu of cash.

(2) DATA STANDARDS.—In submitting epidemiological data to the Secretary pursuant to paragraph (1), an eligible entity shall report data according to guidelines prescribed by the Director of the Centers for Disease Control and Prevention, after consultation with relevant State, local, and Tribal public health officials, private sector developmental disability researchers, and advocates for individuals with autism spectrum disorder and other developmental disabilities.

(3) ELIGIBILITY.—To be eligible to receive an award under paragraph (1), an entity shall be a public or nonprofit private entity (including a health department of a State or a political subdivision of a State, a university, any other educational institution, an Indian Tribe, or a Tribal organization), and submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

(b) CENTERS OF EXCELLENCE IN AUTISM SPECTRUM DISORDER EPIDEMIOLOGY.—

(1) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall, subject to the availability of appropriations, award grants or cooperative agreements for the establishment or support of regional centers of excellence in autism spectrum disorder and other developmental disabilities epidemiology for the purpose of collecting and analyzing information on the number, incidence, correlates, and causes of autism spectrum disorder and other developmental disabilities for children and adults across the lifespan.

(2) REQUIREMENTS.—To be eligible to receive a grant or cooperative agreement under paragraph (1), an entity shall submit to the Secretary an application containing such agreements and information as the Secretary may require, including an agreement that the center to be established or supported under the grant or cooperative agreement shall operate in accordance with the following:

(A) The center will collect, analyze, and report autism spectrum disorder and other developmental disability data according to guidelines prescribed by the Director of the Centers for Disease Control and Prevention, after consultation with State, local, and Tribal public health officials, private sector developmental disability researchers, advocates for individuals with autism spectrum disorder, and advocates for individuals with other developmental disabilities.

(B) The center will develop or extend an area of special research expertise (including genetics, epigenetics, and epidemiological research related to environmental exposures), immunology, and other relevant research specialty areas.

(C) The center will identify eligible cases and controls through its surveillance system and conduct research into factors which may cause or increase the risk of autism spectrum disorder and other developmental disabilities.

(c) FEDERAL RESPONSE.—The Secretary shall coordinate the Federal response to requests for assistance from State health, mental health, and education department officials regarding potential or alleged autism spectrum disorder or developmental disability clusters.

(d) DEFINITIONS.—In this part:

(1) INDIAN TRIBE;[103] TRIBAL ORGANIZATION.—The terms "Indian Tribe" and "Tribal organization" have the meanings given such terms in section 4 of the Indian Health Care Improvement Act.

(2) OTHER DEVELOPMENTAL DISABILITIES.—The term "other developmental disabilities" has the meaning given the term "developmental disability" in section 102(8) of the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (42 U.S.C. 15002(8)).

(3) STATE.—The term "State" means each of the several States, the District of Columbia, the Commonwealth of Puerto Rico, American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, the Virgin Islands, and the Trust Territory of the Pacific Islands.

(e) SUNSET.—This section shall not apply after September 30, 2029.

SEC. 399BB. [280i–1] AUTISM EDUCATION, EARLY DETECTION, AND INTERVENTION.

(a) PURPOSE.—It is the purpose of this section—

(1) to increase awareness, reduce barriers to screening and diagnosis, promote evidence-based interventions for individuals with autism spectrum disorder and other developmental disabilities, and train professionals to utilize valid and reliable screening tools to diagnose or rule out and provide evidence-based interventions for individuals with autism spectrum disorder and other developmental disabilities across their lifespan; and

(2) to conduct activities under this section with a focus on an interdisciplinary approach (as defined in programs developed under section 501(a)(2) of the Social Security Act) that will also focus on specific issues for children who are not receiving an early diagnosis and subsequent interventions.

(b) IN GENERAL.—The Secretary shall, subject to the availability of appropriations, establish and evaluate activities to—

(1) provide culturally and linguistically appropriate information and education on autism spectrum disorder and other developmental disabilities to increase public awareness of developmental milestones;

(2) promote research, which may include research that takes a community-based approach, into the development and validation of reliable screening and diagnostic tools for individuals with autism spectrum disorder and other developmental disabilities and disseminate information regarding those screening and diagnostic tools;

[103] The casing of the word "Tribe" in the paragraph heading is so in law. See the amendment made by section 3(a)(3)(A) of Public Law 118-180.

(3) promote early screening of individuals at increased likelihood for autism spectrum disorder and other developmental disabilities as early as practicable, given evidence-based screening techniques and interventions;

(4) promote evidence-based screening techniques and interventions for individuals with autism spectrum disorder and other developmental disabilities across their lifespan, which may give consideration to the perspectives of parents and guardians;

(5) increase the number of individuals who are able to confirm or rule out a diagnosis of autism spectrum disorder and other developmental disabilities;

(6) increase the number of individuals able to provide evidence-based interventions for individuals diagnosed with autism spectrum disorder or other developmental disabilities; and

(7) promote the use of evidence-based interventions for individuals at increased likelihood for autism spectrum disorder and other developmental disabilities as early as practicable.

(c) INFORMATION AND EDUCATION.—

(1) IN GENERAL.—In carrying out subsection (b)(1), the Secretary, in collaboration with the Secretary of Education and the Secretary of Agriculture, shall, subject to the availability of appropriations, provide culturally and linguistically appropriate information regarding autism spectrum disorder and other developmental disabilities, risk factors, characteristics, identification, diagnosis or rule out, and evidence-based interventions to meet the needs of individuals with autism spectrum disorder and other developmental disabilities across their lifespan and the needs of their families through—

(A) Federal programs, including—

(i) the Head Start program;

(ii) the Early Start program;

(iii) the Healthy Start program;

(iv) programs under the Child Care and Development Block Grant Act of 1990;

(v) programs under title XIX of the Social Security Act (particularly the Medicaid Early and Periodic Screening, Diagnosis and Treatment Program);

(vi) the program under title XXI of the Social Security Act (the State Children's Health Insurance Program);

(vii) the program under title V of the Social Security Act (the Maternal and Child Health Block Grant Program);

(viii) the program under parts B and C of the Individuals with Disabilities Education Act;

(ix) the special supplemental nutrition program for women, infants, and children established under section 17 of the Child Nutrition Act of 1966 (42 U.S.C. 1786); and

(x) the State grant program under the Rehabilitation Act of 1973.

(B) State licensed child care facilities; and

(C) other community-based organizations or points of entry for individuals with autism spectrum disorder and other developmental disabilities to receive services.

(2) LEAD AGENCY.—

(A) DESIGNATION.—As a condition on the provision of assistance or the conduct of activities under this section with respect to a State, the Secretary may require the Governor of the State—

(i) to designate a public agency as a lead agency to coordinate the activities provided for under paragraph (1) in the State at the State level; and

(ii) acting through such lead agency, to make available to individuals and their family members, guardians, advocates, or authorized representatives; providers; and other appropriate individuals in the State, comprehensive culturally and linguistically appropriate information about State and local resources regarding autism spectrum disorder and other developmental disabilities, risk factors, characteristics, identification, diagnosis or rule out, available services and supports (which may include respite care for caregivers of individuals with autism spectrum disorder or other developmental disabilities), and evidence-based interventions.

(B) REQUIREMENTS OF AGENCY.—In designating the lead agency under subparagraph (A)(i), the Governor shall—

(i) select an agency that has demonstrated experience and expertise in—

(I) autism spectrum disorder and other developmental disability issues; and

(II) developing, implementing, conducting, and administering programs and delivering education, information, and referral services (including technology-based curriculum-development services) to individuals with autism spectrum disorder and developmental disabilities and their family members, guardians, advocates or authorized representatives, providers, and other appropriate individuals locally and across the State; and

(ii) consider input from individuals with autism spectrum disorder and developmental disabilities and their family members, guardians, advocates or authorized representatives, providers, and other appropriate individuals.

(C) INFORMATION.—Information under subparagraph (A)(ii) shall be provided through—

(i) toll-free telephone numbers;

(ii) Internet websites;

(iii) mailings; or

(iv) such other means as the Governor may require.

(d) TOOLS.—

(1) IN GENERAL.—To promote the use of valid and reliable screening tools for autism spectrum disorder and other developmental disabilities, the Secretary shall develop a curriculum for continuing education to assist individuals in recognizing the need for valid and reliable screening tools and the use of such tools.

(2) COLLECTION, STORAGE, COORDINATION, AND AVAILABILITY.—The Secretary, in collaboration with the Secretary of Education, shall provide for the collection, storage, coordination, and public availability of tools described in paragraph (1), educational materials and other products that are used by the Federal programs referred to in subsection (c)(1)(A), as well as—

(A) programs authorized under the Developmental Disabilities Assistance and Bill of Rights Act of 2000;

(B) early intervention programs or interagency coordinating councils authorized under part C of the Individuals with Disabilities Education Act; and

(C) children with special health care needs programs authorized under title V of the Social Security Act.

(3) REQUIRED SHARING.—In establishing mechanisms and entities under this subsection, the Secretary, and the Secretary of Education, shall ensure the sharing of tools, materials, and products developed under this subsection among entities receiving funding under this section.

(e) DIAGNOSIS.—

(1) TRAINING.—The Secretary, in coordination with activities conducted under title V of the Social Security Act, shall, subject to the availability of appropriations, expand, and strengthen the capacity of, existing interdisciplinary training opportunities or opportunities to increase the number of sites able to diagnose or rule out individuals with autism spectrum disorder or other developmental disabilities across their lifespan and ensure that—

(A) competitive grants or cooperative agreements are awarded to public or nonprofit agencies, including institutions of higher education, to expand and strengthen the capacity of existing, or, in States that do not have such a program, develop new, maternal and child health interdisciplinary leadership education in neurodevelopmental and related disabilities programs (similar to the programs developed under section 501(a)(2) of the Social Security Act);

(B) trainees under such training programs—

(i) receive an appropriate balance of academic, clinical, and community opportunities;

(ii) are culturally competent;

(iii) are ethnically diverse;

(iv) demonstrate a capacity to evaluate, diagnose or rule out, develop, and provide evidence-based interventions to individuals with autism spectrum disorder and other developmental disabilities across their lifespan; and

(v) demonstrate an ability to use a family-centered approach, which may include collaborating with research centers or networks to provide training for providers of respite care (as defined in section 2901) or other providers, as applicable; and

(C) program sites—

(i) provide culturally and linguistically appropriate services;

(ii) take a multidisciplinary approach and have experience working with underserved populations; and

(iii) identify opportunities to partner with community-based organizations to expand the capacity of communities to serve individuals with autism spectrum disorder or other developmental disabilities.

(2) DEVELOPMENTAL-BEHAVIORAL PEDIATRICIAN TRAINING PROGRAMS.—

(A) IN GENERAL.—In making awards under this subsection, the Secretary may prioritize awards to applicants that are developmental-behavioral pediatrician training programs located in rural or underserved areas.

(B) DEFINITION OF UNDERSERVED AREA.—In this paragraph, the term "underserved area" means—

(i) a health professional shortage area (as defined in section 332(a)(1)(A)); and

(ii) an urban or rural area designated by the Secretary as an area with a shortage of personal health services (as described in section 330(b)(3)(A)).

(C) REPORT.—Not later than 2 years after the date of the enactment of the Autism CARES Act of 2024, 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 that examines the need for, and feasibility of, expanding the developmental-behavioral pediatrician training programs described in subparagraph (A).

(3) TECHNICAL ASSISTANCE.—The Secretary may award one or more grants under this section to provide technical assistance to the network of interdisciplinary training programs.

(4) BEST PRACTICES.—The Secretary shall promote research into additional valid and reliable tools for shortening the time required to confirm or rule out a diagnosis of autism spectrum disorder or other developmental disabilities and detecting individuals with autism spectrum disorder or other developmental disabilities at an earlier age.

(f) INTERVENTION.—The Secretary shall promote research through grants or contracts, which may include grants or contracts to research centers or networks, to—

(1) develop and evaluate evidence-based practices and interventions to improve outcomes for individuals with autism spectrum disorder or other developmental disabilities by addressing physical and behavioral health and communication needs of such individuals across the lifespan;

(2) develop guidelines for such evidence-based practices and interventions; and

(3) disseminate information related to such evidence-based practices and interventions and guidelines.

(g) SUNSET.—This section shall not apply after September 30, 2029.

SEC. 399CC. [280i–2] INTERAGENCY AUTISM COORDINATING COMMITTEE.

(a) ESTABLISHMENT.—The Secretary shall establish a committee, to be known as the "Interagency Autism Coordinating Committee" (in this section referred to as the "Committee"), to coordinate all efforts within the Department of Health and Human Services concerning autism spectrum disorder.

(b) RESPONSIBILITIES.—In carrying out its duties under this section, the Committee shall, on a regular basis—

(1) monitor autism spectrum disorder research, and to the extent practicable services and support activities, across all relevant Federal departments and agencies, including coordination of Federal activities with respect to autism spectrum disorder;

(2) summarize of advances in autism spectrum disorder research related to causes, prevention, treatment, early screening, diagnosis or rule out, interventions, including school and community-based interventions, and access to services and supports for individuals with autism spectrum disorder across the lifespan of such individuals;

(3) make recommendations to the Secretary regarding any appropriate changes to such activities, including with respect to the strategic plan developed under paragraph (5);

(4) make recommendations to the Secretary regarding public participation in decisions relating to autism spectrum disorder, and the process by which public feedback can be better integrated into such decisions;

(5) develop a strategic plan for the conduct of, and support for, autism spectrum disorder research, as described in section 409C(a)(1), which shall include—

(A) proposed budgetary requirements; and

(B) recommendations to ensure that autism spectrum disorder research, and services and support activities to the extent practicable, of the Department of Health and Human Services and of other Federal departments and agencies are not unnecessarily duplicative; and

(6) submit to the Congress and the President—

(A) an annual update on the summary of advances described in paragraph (2); and

(B) a biennial update on the strategic plan described in paragraph (5), including progress made in achieving the goals outlined in such strategic plan and any specific measures taken pursuant to such strategic plan.

(c) MEMBERSHIP.—

(1) FEDERAL MEMBERSHIP.—The Committee shall be composed of the following Federal members—

(A) the Director of the Centers for Disease Control and Prevention;

(B) the Director of the National Institutes of Health, and the Directors of such national research institutes of

the National Institutes of Health as the Secretary determines appropriate;

(C) the heads of such other agencies as the Secretary determines appropriate, such as the Administration for Community Living, Administration for Children and Families, the Centers for Medicare & Medicaid Services, the Food and Drug Administration, and the Health Resources and Services Administration; and

(D) representatives of other Federal Governmental agencies that serve individuals with autism spectrum disorder such as the Department of Education, the Department of Labor, the Department of Justice, the Department of Veterans Affairs, the Department of Housing and Urban Development, and the Department of Defense.

(2) NON-FEDERAL MEMBERS.—Not more than ½, but not fewer than ⅓, of the total membership of the Committee, shall be composed of non-Federal public members to be appointed by the Secretary, of which—

(A) at least three such members shall be individuals with a diagnosis of autism spectrum disorder;

(B) at least three such members shall be parents or legal guardians of an individual with an autism spectrum disorder; and

(C) at least three such members shall be representatives of leading research, advocacy, and service organizations for individuals with autism spectrum disorder.

(3) PERIOD OF APPOINTMENT; VACANCIES.—

(A) PERIOD OF APPOINTMENT FOR NON-FEDERAL MEMBERS.—Non-Federal members shall serve for a term of 4 years, and may be reappointed for one additional 4-year term.

(B) VACANCIES.—A vacancy on the Committee shall be filled in the manner in which the original appointment was made and shall not affect the powers or duties of the Committee. 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 been appointed.

(d) ADMINISTRATIVE SUPPORT; TERMS OF SERVICE; OTHER PROVISIONS.—The following provisions shall apply with respect to the Committee:

(1) The Committee shall receive necessary and appropriate administrative support from the Secretary.

(2) The Committee shall meet at the call of the chairperson or upon the request of the Secretary. The Committee shall meet not fewer than 2 times each year.

(3) All meetings of the Committee shall be public and shall include appropriate time periods for questions and presentations by the public.

(e) SUBCOMMITTEES; ESTABLISHMENT AND MEMBERSHIP.—In carrying out its functions, the Committee may establish subcommittees and convene workshops and conferences. Such subcommittees shall be composed of Committee members and may

hold such meetings as are necessary to enable the subcommittees to carry out their duties.

(f) SUNSET.—This section shall not apply after September 30, 2029, and the Committee shall be terminated on such date.

SEC. 399DD. [280i–3] REPORTS TO CONGRESS.

(a) PROGRESS REPORT.—

(1) IN GENERAL.—Not later than 4 years after September 30, 2024, the Secretary, in consultation with other relevant Federal departments and agencies, shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, and make publicly available, including through posting on the website of the Department of Health and Human Services, a progress report on activities related to autism spectrum disorder and other developmental disabilities. Such report shall include activities and research related to the entire population of individuals with autism spectrum disorder, including those individuals with co-occurring conditions and the full range of needs for supports and services, including such supports and services to ensure the safety, and promote the well-being, of such individuals.

(2) CONTENTS.—The report submitted under subsection (a) shall contain—

(A) a description of the progress made in implementing the provisions of the Autism CARES Act of 2024;

(B) a description of the amounts expended on the implementation of the amendments made by the Autism CARES Act of 2024;

(C) information on the incidence and prevalence of autism spectrum disorder, including available information on the prevalence of autism spectrum disorder among children and adults, and identification of any changes over time with respect to the incidence and prevalence of autism spectrum disorder;

(D) information on the average age of diagnosis for children with autism spectrum disorder and other disabilities, including how that age may have changed over the 4-year period beginning on the date of enactment of the Autism CARES Act of 2024 and, as appropriate, how this age varies across population subgroups;

(E) information on the average age for intervention for individuals diagnosed with autism spectrum disorder and other developmental disabilities, including how that age may have changed over the 4-year period beginning on the date of enactment of the Autism CARES Act of 2024 and, as appropriate, how this age varies across population subgroups;

(F) information on the average time between initial screening and then diagnosis or rule out for individuals with autism spectrum disorder or other developmental disabilities, as well as information on the average time between diagnosis and evidence-based intervention for individuals with autism spectrum disorder or other develop-

mental disabilities and, as appropriate, on how such average time varies across population subgroups;

(G) information on the effectiveness and outcomes of interventions for individuals diagnosed with autism spectrum disorder, including by severity level as practicable, and other developmental disabilities and how the age of the individual or other factors, such as demographic characteristics, may affect such effectiveness;

(H) information on the effectiveness and outcomes of innovative and newly developed intervention strategies for individuals with autism spectrum disorder or other developmental disabilities;

(I) a description of the actions taken to implement and the progress made on implementation of the strategic plan developed by the Interagency Autism Coordinating Committee under section 399CC(b); and

(J) information on how States use home- and community-based services and other supports to ensure that individuals with autism spectrum disorder and other developmental disabilities are living, working, and participating in their community.

(b) REPORT ON THE MENTAL HEALTH NEEDS OF INDIVIDUALS WITH AUTISM SPECTRUM DISORDER ACROSS THEIR LIFESPAN.—

(1) IN GENERAL.—Not later than 2 years after the date of enactment of the Autism CARES Act of 2024, the Secretary shall prepare and submit, to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report concerning the mental health needs of individuals with autism spectrum disorder.

(2) CONTENTS.—The report submitted under paragraph (1) shall contain—

(A) an overview of policies and programs relevant to the mental health of individuals with autism spectrum disorder across their lifespan, including an identification of existing Federal laws, regulations, policies, research, and programs; and

(B) recommendations to improve mental health outcomes and address related disparities in mental health care for individuals with autism spectrum disorder, including prevention, care coordination, and community-based services.

(c) UPDATE ON YOUNG ADULTS AND YOUTH TRANSITIONING TO ADULTHOOD.—Not later than 2 years after the date of enactment of the Autism CARES Act of 2024, the Secretary, in coordination with other relevant Federal departments and agencies, as appropriate, 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 an update to the report required pursuant to subsection (b) of this section, as added by section 6 of the Autism Cares Act of 2014 (Public Law 113–157), and in effect before the date of enactment of the Autism CARES Act of 2019 (Public Law 116–60), concerning young adults with autism spectrum disorder and the challenges related to the

transition from existing school-based services to those services available during adulthood.

SEC. 399EE. [280i–4] AUTHORIZATION OF APPROPRIATIONS.

(a) DEVELOPMENTAL DISABILITIES SURVEILLANCE AND RESEARCH PROGRAM.—To carry out section 399AA, there is authorized to be appropriated $28,100,000 for each of fiscal years 2025 through 2029.

(b) AUTISM EDUCATION, EARLY DETECTION, AND INTERVENTION.—To carry out section 399BB, there is authorized to be appropriated $56,344,000 for each of fiscal years 2025 through 2029.

(c) INTERAGENCY AUTISM COORDINATING COMMITTEE; CERTAIN OTHER PROGRAMS.—To carry out sections 399CC and 409C, there is authorized to be appropriated $306,000,000 for each of fiscal years 2025 through 2029.

PART S—HEALTH CARE QUALITY PROGRAMS

Subpart I—National Strategy for Quality Improvement in Health Care

SEC. 399HH. [280j] NATIONAL STRATEGY FOR QUALITY IMPROVEMENT IN HEALTH CARE.

(a) ESTABLISHMENT OF NATIONAL STRATEGY AND PRIORITIES.—

(1) NATIONAL STRATEGY.—The Secretary, through a transparent collaborative process, shall establish a national strategy to improve the delivery of health care services, patient health outcomes, and population health.

(2) IDENTIFICATION OF PRIORITIES.—

(A) IN GENERAL.—The Secretary shall identify national priorities for improvement in developing the strategy under paragraph (1).

(B) REQUIREMENTS.—The Secretary shall ensure that priorities identified under subparagraph (A) will—

(i) have the greatest potential for improving the health outcomes, efficiency, and patient-centeredness of health care for all populations, including children and vulnerable populations;

(ii) identify areas in the delivery of health care services that have the potential for rapid improvement in the quality and efficiency of patient care;

(iii) address gaps in quality, efficiency, comparative effectiveness information (taking into consideration the limitations set forth in subsections (c) and (d) of section 1182 of the Social Security Act), and health outcomes measures and data aggregation techniques;

(iv) improve Federal payment policy to emphasize quality and efficiency;

(v) enhance the use of health care data to improve quality, efficiency, transparency, and outcomes;

(vi) address the health care provided to patients with high-cost chronic diseases;

(vii) improve research and dissemination of strategies and best practices to improve patient safety and reduce medical errors, preventable admissions and readmissions, and health care-associated infections;

(viii) reduce health disparities across health disparity populations (as defined in section 485E) and geographic areas; and

(ix) address other areas as determined appropriate by the Secretary.

(C) CONSIDERATIONS.—In identifying priorities under subparagraph (A), the Secretary shall take into consideration the recommendations submitted by the entity with a contract under section 1890(a) of the Social Security Act and other stakeholders.

(D) COORDINATION WITH STATE AGENCIES.—The Secretary shall collaborate, coordinate, and consult with State agencies responsible for administering the Medicaid program under title XIX of the Social Security Act and the Children's Health Insurance Program under title XXI of such Act with respect to developing and disseminating strategies, goals, models, and timetables that are consistent with the national priorities identified under subparagraph (A).

(b) STRATEGIC PLAN.—

(1) IN GENERAL.—The national strategy shall include a comprehensive strategic plan to achieve the priorities described in subsection (a).

(2) REQUIREMENTS.—The strategic plan shall include provisions for addressing, at a minimum, the following:

(A) Coordination among agencies within the Department, which shall include steps to minimize duplication of efforts and utilization of common quality measures, where available. Such common quality measures shall be measures identified by the Secretary under section 1139A or 1139B of the Social Security Act or endorsed under section 1890 of such Act.

(B) Agency-specific strategic plans to achieve national priorities.

(C) Establishment of annual benchmarks for each relevant agency to achieve national priorities.

(D) A process for regular reporting by the agencies to the Secretary on the implementation of the strategic plan.

(E) Strategies to align public and private payers with regard to quality and patient safety efforts.

(F) Incorporating quality improvement and measurement in the strategic plan for health information technology required by the American Recovery and Reinvestment Act of 2009 (Public Law 111–5).

(c) PERIODIC UPDATE OF NATIONAL STRATEGY.—The Secretary shall update the national strategy not less than annually. Any such update shall include a review of short- and long-term goals.

(d) SUBMISSION AND AVAILABILITY OF NATIONAL STRATEGY AND UPDATES.—

(1) DEADLINE FOR INITIAL SUBMISSION OF NATIONAL STRATEGY.—Not later than January 1, 2011, the Secretary shall submit to the relevant committees of Congress the national strategy described in subsection (a).

(2) UPDATES.—

(A) IN GENERAL.—The Secretary shall submit to the relevant committees of Congress an annual update to the strategy described in paragraph (1).

(B) INFORMATION SUBMITTED.—Each update submitted under subparagraph (A) shall include—

(i) a review of the short- and long-term goals of the national strategy and any gaps in such strategy;

(ii) an analysis of the progress, or lack of progress, in meeting such goals and any barriers to such progress;

(iii) the information reported under section 1139A of the Social Security Act, consistent with the reporting requirements of such section; and

(iv) in the case of an update required to be submitted on or after January 1, 2014, the information reported under section 1139B(b)(4) of the Social Security Act, consistent with the reporting requirements of such section.

(C) SATISFACTION OF OTHER REPORTING REQUIREMENTS.—Compliance with the requirements of clauses (iii) and (iv) of subparagraph (B) shall satisfy the reporting requirements under sections 1139A(a)(6) and 1139B(b)(4), respectively, of the Social Security Act.

(e) HEALTH CARE QUALITY INTERNET WEBSITE.—Not later than January 1, 2011, the Secretary shall create an Internet website to make public information regarding—

(1) the national priorities for health care quality improvement established under subsection (a)(2);

(2) the agency-specific strategic plans for health care quality described in subsection (b)(2)(B); and

(3) other information, as the Secretary determines to be appropriate.

SEC. 399II. [280j–1] COLLECTION AND ANALYSIS OF DATA FOR QUALITY AND RESOURCE USE MEASURES.

(a) IN GENERAL.—

(1) ESTABLISHMENT OF STRATEGIC FRAMEWORK.—The Secretary shall establish and implement an overall strategic framework to carry out the public reporting of performance information, as described in section 399JJ. Such strategic framework may include methods and related timelines for implementing nationally consistent data collection, data aggregation, and analysis methods.

(2) COLLECTION AND AGGREGATION OF DATA.—The Secretary shall collect and aggregate consistent data on quality and resource use measures from information systems used to support health care delivery, and may award grants or contracts for this purpose. The Secretary shall align such collection and aggregation efforts with the requirements and assistance regarding the expansion of health information technology

systems, the interoperability of such technology systems, and related standards that are in effect on the date of enactment of the Patient Protection and Affordable Care Act.

(3) SCOPE.—The Secretary shall ensure that the data collection, data aggregation, and analysis systems described in paragraph (1) involve an increasingly broad range of patient populations, providers, and geographic areas over time.

(b) GRANTS OR CONTRACTS FOR DATA COLLECTION.—

(1) IN GENERAL.—The Secretary may award grants or contracts to eligible entities to support new, or improve existing, efforts to collect and aggregate quality and resource use measures described under subsection (c).

(2) ELIGIBLE ENTITIES.—To be eligible for a grant or contract under this subsection, an entity shall—

(A) be—

(i) a multi-stakeholder entity that coordinates the development of methods and implementation plans for the consistent reporting of summary quality and cost information;

(ii) an entity capable of submitting such summary data for a particular population and providers, such as a disease registry, regional collaboration, health plan collaboration, or other population-wide source; or

(iii) a Federal Indian Health Service program or a health program operated by an Indian tribe (as defined in section 4 of the Indian Health Care Improvement Act);

(B) promote the use of the systems that provide data to improve and coordinate patient care;

(C) support the provision of timely, consistent quality and resource use information to health care providers, and other groups and organizations as appropriate, with an opportunity for providers to correct inaccurate measures; and

(D) agree to report, as determined by the Secretary, measures on quality and resource use to the public in accordance with the public reporting process established under section 399JJ.

(c) CONSISTENT DATA AGGREGATION.—The Secretary may award grants or contracts under this section only to entities that enable summary data that can be integrated and compared across multiple sources. The Secretary shall provide standards for the protection of the security and privacy of patient data.

(d) MATCHING FUNDS.—The Secretary may not award a grant or contract under this section to an entity unless the entity agrees that it will make available (directly or through contributions from other public or private entities) non-Federal contributions toward the activities to be carried out under the grant or contract in an amount equal to $1 for each $5 of Federal funds provided under the grant or contract. Such non-Federal matching funds may be provided directly or through donations from public or private entities and may be in cash or in-kind, fairly evaluated, including plant, equipment, or services.

(e) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated such sums as may be necessary for fiscal years 2010 through 2014.

SEC. 399JJ. [280j–2] PUBLIC REPORTING OF PERFORMANCE INFORMATION.

(a) DEVELOPMENT OF PERFORMANCE WEBSITES.—The Secretary shall make available to the public, through standardized Internet websites, performance information summarizing data on quality measures. Such information shall be tailored to respond to the differing needs of hospitals and other institutional health care providers, physicians and other clinicians, patients, consumers, researchers, policymakers, States, and other stakeholders, as the Secretary may specify.

(b) INFORMATION ON CONDITIONS.—The performance information made publicly available on an Internet website, as described in subsection (a), shall include information regarding clinical conditions to the extent such information is available, and the information shall, where appropriate, be provider-specific and sufficiently disaggregated and specific to meet the needs of patients with different clinical conditions.

(c) CONSULTATION.—

(1) IN GENERAL.—In carrying out this section, the Secretary shall consult with the entity with a contract under section 1890(a) of the Social Security Act, and other entities, as appropriate, to determine the type of information that is useful to stakeholders and the format that best facilitates use of the reports and of performance reporting Internet websites.

(2) CONSULTATION WITH STAKEHOLDERS.—The entity with a contract under section 1890(a) of the Social Security Act shall convene multi-stakeholder groups, as described in such section, to review the design and format of each Internet website made available under subsection (a) and shall transmit to the Secretary the views of such multi-stakeholder groups with respect to each such design and format.

(d) COORDINATION.—Where appropriate, the Secretary shall coordinate the manner in which data are presented through Internet websites described in subsection (a) and for public reporting of other quality measures by the Secretary, including such quality measures under title XVIII of the Social Security Act.

(e) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated such sums as may be necessary for fiscal years 2010 through 2014.

SEC. 399KK. [280j–3] QUALITY IMPROVEMENT PROGRAM FOR HOSPITALS WITH A HIGH SEVERITY ADJUSTED READMISSION RATE.

(a) ESTABLISHMENT.—

(1) IN GENERAL.—Not later than 2 years after the date of enactment of this section, the Secretary shall make available a program for eligible hospitals to improve their readmission rates through the use of patient safety organizations (as defined in section 921(4)).

(2) ELIGIBLE HOSPITAL DEFINED.—In this subsection, the term "eligible hospital" means a hospital that the Secretary determines has a high rate of risk adjusted readmissions for the

conditions described in section 1886(q)(8)(A) of the Social Security Act and has not taken appropriate steps to reduce such readmissions and improve patient safety as evidenced through historically high rates of readmissions, as determined by the Secretary.

(3) RISK ADJUSTMENT.—The Secretary shall utilize appropriate risk adjustment measures to determine eligible hospitals.

(b) REPORT TO THE SECRETARY.—As determined appropriate by the Secretary, eligible hospitals and patient safety organizations working with those hospitals shall report to the Secretary on the processes employed by the hospital to improve readmission rates and the impact of such processes on readmission rates.

PART T—ORAL HEALTHCARE PREVENTION ACTIVITIES

SEC. 399LL. [280k] ORAL HEALTHCARE PREVENTION EDUCATION CAMPAIGN.

(a) ESTABLISHMENT OF ORAL HEALTH EDUCATION CAMPAIGN.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention and in consultation with professional oral health organizations, shall, subject to the availability of appropriations, establish a 5-year national, public education campaign (referred to in this section as the "campaign") that is focused on oral health education, including prevention of oral disease such as early childhood and other caries, periodontal disease, and oral cancer.

(b) REQUIREMENTS.—In establishing the campaign under subsection (a), the Secretary shall—

(1) ensure that activities are targeted towards specific populations such as children, pregnant women, parents, the elderly, individuals with disabilities, and ethnic and racial minority populations, including Indians, Alaska Natives and Native Hawaiians (as defined in section 4(c) of the Indian Health Care Improvement Act) in a culturally and linguistically appropriate manner; and

(2) utilize science-based strategies to convey oral health prevention messages that include, but are not limited to, community water fluoridation and dental sealants.

(c) ACTION FOR DENTAL HEALTH PROGRAM.—

(1) IN GENERAL.—The Secretary, in consultation with the Director of the Centers for Disease Control and Prevention and the Administrator of the Health Resources and Services Administration, may award grants, contracts, or cooperative agreements to eligible entities to collaborate with State or local public health officials, tribal health officials, oral health professional organizations, and others, as appropriate, to develop and implement initiatives to improve oral health, including activities to prevent dental disease and reduce barriers to the provision of dental services, including—

(A) through community-wide dental disease prevention programs; and

(B) by increasing public awareness and education related to oral health and dental disease prevention.

(2) ELIGIBLE ENTITIES.—To be eligible to receive a grant, contract, or cooperative agreement under this subsection, an entity shall be—

(A) a dental association;

(B) a State or tribal health department or State or tribal oral health program;

(C) an accredited dental education, dental hygiene, or postdoctoral dental education program; or

(D) a non-profit community-based organization that partners with public and private non-profit entities, such as an academic institution, to facilitate the provision of dental services to underserved populations.

SEC. 399LL–1. [280k–1] RESEARCH-BASED DENTAL CARIES DISEASE MANAGEMENT.

(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall award demonstration grants to eligible entities to demonstrate the effectiveness of research-based dental caries disease management activities.

(b) ELIGIBILITY.—To be eligible for a grant under this section, an entity shall—

(1) be a community-based provider of dental services (as defined by the Secretary), including a Federally-qualified health center, a clinic of a hospital owned or operated by a State (or by an instrumentality or a unit of government within a State), a State or local department of health, a dental program of the Indian Health Service, an Indian tribe or tribal organization, or an urban Indian organization (as such terms are defined in section 4 of the Indian Health Care Improvement Act), a health system provider, a private provider of dental services, medical, dental, public health, nursing, nutrition educational institutions, or national organizations involved in improving children's oral health; and

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

(c) USE OF FUNDS.—A grantee shall use amounts received under a grant under this section to demonstrate the effectiveness of research-based dental caries disease management activities.

(d) USE OF INFORMATION.—The Secretary shall, as practicable and appropriate, utilize information generated from grantees under this section in planning and implementing the oral health education campaign and action for dental health program under section 399LL.

SEC. 399LL–2. [280k–2] AUTHORIZATION OF APPROPRIATIONS.

There is authorized to be appropriated to carry out this part, such sums as may be necessary.

PART U—EMPLOYER-BASED WELLNESS PROGRAM

SEC. 399MM. [280l] TECHNICAL ASSISTANCE FOR EMPLOYER-BASED WELLNESS PROGRAMS.

In order to expand the utilization of evidence-based prevention and health promotion approaches in the workplace, the Director shall—

(1) provide employers (including small, medium, and large employers, as determined by the Director) with technical assistance, consultation, tools, and other resources in evaluating such employers' employer-based wellness programs, including—

(A) measuring the participation and methods to increase participation of employees in such programs;

(B) developing standardized measures that assess policy, environmental and systems changes necessary to have a positive health impact on employees' health behaviors, health outcomes, and health care expenditures; and

(C) evaluating such programs as they relate to changes in the health status of employees, the absenteeism of employees, the productivity of employees, the rate of workplace injury, and the medical costs incurred by employees; and

(2) build evaluation capacity among workplace staff by training employers on how to evaluate employer-based wellness programs and ensuring evaluation resources, technical assistance, and consultation are available to workplace staff as needed through such mechanisms as web portals, call centers, or other means.

SEC. 399MM–1. [280l–1] NATIONAL WORKSITE HEALTH POLICIES AND PROGRAMS STUDY.

(a) IN GENERAL.—In order to assess, analyze, and monitor over time data about workplace policies and programs, and to develop instruments to assess and evaluate comprehensive workplace chronic disease prevention and health promotion programs, policies and practices, not later than 2 years after the date of enactment of this part, and at regular intervals (to be determined by the Director) thereafter, the Director shall conduct a national worksite health policies and programs survey to assess employer-based health policies and programs.

(b) REPORT.—Upon the completion of each study under subsection (a), the Director shall submit to Congress a report that includes the recommendations of the Director for the implementation of effective employer-based health policies and programs.

SEC. 399MM–2. [280l–2] PRIORITIZATION OF EVALUATION BY SECRETARY.

The Secretary shall evaluate, in accordance with this part, all programs funded through the Centers for Disease Control and Prevention before conducting such an evaluation of privately funded programs unless an entity with a privately funded wellness program requests such an evaluation.

SEC. 399MM–3. [280l–3] PROHIBITION OF FEDERAL WORKPLACE WELLNESS REQUIREMENTS.

Notwithstanding any other provision of this part, any recommendations, data, or assessments carried out under this part shall not be used to mandate requirements for workplace wellness programs.

PART V—PROGRAMS RELATING TO BREAST HEALTH AND CANCER

SEC. 399NN. [280m] YOUNG WOMEN'S BREAST HEALTH AWARENESS AND SUPPORT OF YOUNG WOMEN DIAGNOSED WITH BREAST CANCER.

(a) PUBLIC EDUCATION CAMPAIGN.—

(1) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall conduct a national evidence-based education campaign to increase awareness of young women's knowledge regarding—

(A) breast health in young women of all racial, ethnic, and cultural backgrounds;

(B) breast awareness and good breast health habits;

(C) the occurrence of breast cancer and the general and specific risk factors in women who may be at high risk for breast cancer based on familial, racial, ethnic, and cultural backgrounds such as Ashkenazi Jewish populations;

(D) evidence-based information that would encourage young women and their health care professional to increase early detection of breast cancers; and

(E) the availability of health information and other resources for young women diagnosed with breast cancer.

(2) EVIDENCE-BASED, AGE APPROPRIATE MESSAGES.—The campaign shall provide evidence-based, age-appropriate messages and materials as developed by the Centers for Disease Control and Prevention and the Advisory Committee established under paragraph (4).

(3) MEDIA CAMPAIGN.—In conducting the education campaign under paragraph (1), the Secretary shall award grants to entities to establish national multimedia campaigns oriented to young women that may include advertising through television, radio, print media, billboards, posters, all forms of existing and especially emerging social networking media, other Internet media, and any other medium determined appropriate by the Secretary.

(4) ADVISORY COMMITTEE.—

(A) ESTABLISHMENT.—Not later than 60 days after the date of the enactment of this section, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish an advisory committee to assist in creating and conducting the education campaigns under paragraph (1) and subsection (b)(1).

(B) MEMBERSHIP.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall appoint to the advisory committee under subparagraph (A) such members as deemed necessary to prop-

erly advise the Secretary, and shall include organizations and individuals with expertise in breast cancer, disease prevention, early detection, diagnosis, public health, social marketing, genetic screening and counseling, treatment, rehabilitation, palliative care, and survivorship in young women.

(b) HEALTH CARE PROFESSIONAL EDUCATION CAMPAIGN.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, and in consultation with the Administrator of the Health Resources and Services Administration, shall conduct an education campaign among physicians and other health care professionals to increase awareness—

(1) of breast health, symptoms, and early diagnosis and treatment of breast cancer in young women, including specific risk factors such as family history of cancer and women that may be at high risk for breast cancer, such as Ashkenazi Jewish population;

(2) on how to provide counseling to young women about their breast health, including knowledge of their family cancer history and importance of providing regular clinical breast examinations;

(3) concerning the importance of discussing healthy behaviors, and increasing awareness of services and programs available to address overall health and wellness, and making patient referrals to address tobacco cessation, good nutrition, and physical activity;

(4) on when to refer patients to a health care provider with genetics expertise;

(5) on how to provide counseling that addresses long-term survivorship and health concerns of young women diagnosed with breast cancer; and

(6) on when to provide referrals to organizations and institutions that provide credible health information and substantive assistance and support to young women diagnosed with breast cancer.

(c) PREVENTION RESEARCH ACTIVITIES.—The Secretary, acting through—

(1) the Director of the Centers for Disease Control and Prevention, shall conduct prevention research on breast cancer in younger women, including—

(A) behavioral, survivorship studies, and other research on the impact of breast cancer diagnosis on young women;

(B) formative research to assist with the development of educational messages and information for the public, targeted populations, and their families about breast health, breast cancer, and healthy lifestyles;

(C) testing and evaluating existing and new social marketing strategies targeted at young women; and

(D) surveys of health care providers and the public regarding knowledge, attitudes, and practices related to breast health and breast cancer prevention and control in high-risk populations; and

(2) the Director of the National Institutes of Health, shall conduct research to develop and validate new screening tests and methods for prevention and early detection of breast cancer in young women.

(d) SUPPORT FOR YOUNG WOMEN DIAGNOSED WITH BREAST CANCER.—

(1) IN GENERAL.—The Secretary shall award grants to organizations and institutions to provide health information from credible sources and substantive assistance directed to young women diagnosed with breast cancer and pre-neoplastic breast diseases.

(2) PRIORITY.—In making grants under paragraph (1), the Secretary shall give priority to applicants that deal specifically with young women diagnosed with breast cancer and pre-neoplastic breast disease.

(e) NO DUPLICATION OF EFFORT.—In conducting an education campaign or other program under subsections (a), (b), (c), or (d), the Secretary shall avoid duplicating other existing Federal breast cancer education efforts.

(f) MEASUREMENT; REPORTING.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall—

(1) measure—

(A) young women's awareness regarding breast health, including knowledge of family cancer history, specific risk factors and early warning signs, and young women's proactive efforts at early detection;

(B) the number or percentage of young women utilizing information regarding lifestyle interventions that foster healthy behaviors;

(C) the number or percentage of young women receiving regular clinical breast exams; and

(D) the number or percentage of young women who perform breast self exams, and the frequency of such exams, before the implementation of this section;

(2) not less than every 3 years, measure the impact of such activities; and

(3) submit reports to the Congress on the results of such measurements.

(g) DEFINITION.—In this section, the term "young women" means women 15 to 44 years of age.

(h) AUTHORIZATION OF APPROPRIATIONS.—To carry out subsections (a), (b), (c)(1), and (d), there are authorized to be appropriated $9,000,000 for each of fiscal years 2022 through 2026.

PART W—PARKINSON'S AND RELATED DISORDERS

SEC. 399OO. [42 U.S.C. 280n] NATIONAL PARKINSON'S PROJECT.

(a) DEFINITION OF PARKINSON'S.—In this section, the term "Parkinson's" means—

(1) Parkinson's disease; and

(2) all other neurodegenerative Parkinsonisms, including multiple system atrophy, corticobasal degeneration, progressive supranuclear palsy, and Parkinson's-related dementia.

(b) ESTABLISHMENT.—The Secretary shall carry out a national project, to be known as the National Parkinson's Project (referred to in this section as the "Project"), to prevent, diagnose, treat, and cure Parkinson's.

(c) ACTIVITIES CARRIED OUT THROUGH PROJECT.—In carrying out the Project, the Secretary shall—

(1) create, maintain, and periodically update an integrated national plan to prevent, diagnose, treat, and cure Parkinson's, ameliorate symptoms, and slow or stop progression;

(2) carry out the annual assessment under subsection (d);

(3) provide information, including—

(A) an estimate of the level of current Federal investment in preventing, diagnosing, treating, and curing Parkinson's, ameliorating symptoms, and slowing or stopping progression; and

(B) if applicable, an estimate of the investment necessary to prevent, diagnose, treat, and cure Parkinson's, ameliorate symptoms, and slow or stop progression;

(4) coordinate research and services across all Federal agencies related to Parkinson's;

(5) encourage the development of safe and effective treatments, strategies, and other approaches to prevent, diagnose, treat, and cure Parkinson's, ameliorate symptoms, and slow or stop progression;

(6) improve the—

(A) early diagnosis of Parkinson's; and

(B) coordination of the care and treatment of individuals with Parkinson's;

(7) review the impact of Parkinson's on the physical, mental, and social health of individuals living with Parkinson's and their caregivers and families;

(8) coordinate with international bodies, to the extent possible, to integrate and inform the mission to prevent, diagnose, treat, and cure Parkinson's, ameliorate symptoms, and slow or stop progression globally; and

(9) to the extent practicable, collaborate with other entities to prevent duplication of existing research activities for related disorders.

(d) ANNUAL ASSESSMENT.—Not later than 24 months after the date of enactment of this section, and annually thereafter, the Secretary shall carry out an assessment of the Nation's progress in preparing for, and responding to, the escalating burden of Parkinson's, including—

(1) recommendations for priority actions based on the assessment;

(2) a description of any steps that are planned or have already been taken to implement such recommendations, including whether such recommendations can be implemented under existing law; and

(3) such other items as the Secretary determines appropriate.

(e) ADVISORY COUNCIL.—

(1) IN GENERAL.—The Secretary shall establish and maintain an Advisory Council on Parkinson's Research, Care, and Services (referred to in this section as the "Advisory Council") to advise the Secretary on Parkinson's-related issues.

(2) MEMBERSHIP.—

(A) FEDERAL MEMBERS.—The Advisory Council shall be comprised of experts, to be appointed by the Secretary, who collectively are from various backgrounds and perspectives, including at least one member from each of—

(i) the Centers for Disease Control and Prevention;

(ii) the Administration on Community Living;

(iii) the Centers for Medicare & Medicaid Services;

(iv) the National Institutes of Health;

(v) the Agency for Healthcare Research and Quality;

(vi) the Department of Veterans Affairs;

(vii) the Food and Drug Administration;

(viii) the National Science Foundation;

(ix) the Department of Defense;

(x) the Environmental Protection Agency;

(xi) the Office of Minority Health;

(xii) the Indian Health Service;

(xiii) the Office of the Surgeon General of the Public Health Service; and

(xiv) other relevant Federal departments and agencies as determined by the Secretary.

(B) NON-FEDERAL MEMBERS.—In addition to the members listed in subparagraph (A), the Advisory Council shall include 10 expert members, to be appointed by the Secretary, who shall include representatives of minority communities, communities disproportionately affected by Parkinson's, and communities underrepresented in Parkinson's research, who shall each be from outside the Federal Government, and who shall include—

(i) 2 Parkinson's patient advocates, at least 1 of whom is living with young-onset Parkinson's;

(ii) 1 Parkinson's family caregiver;

(iii) 1 health care provider;

(iv) 2 biomedical researchers with Parkinson's-related expertise in basic, translational, clinical, or drug development science;

(v) 1 movement disorder specialist who treats Parkinson's patients;

(vi) 1 dementia specialist who treats Parkinson's patients; and

(vii) 2 representatives from nonprofit organizations that have demonstrated experience in Parkinson's-related research or Parkinson's-related patient care and other services.

(C) REPRESENTATION.—The Secretary shall ensure that the members of the Advisory Council are collectively representative of agencies, professions, individuals, and

entities concerned with, or affected by, activities under this section.

(3) MEETINGS.—

(A) FREQUENCY.—The Advisory Council shall meet—

(i) at least once each quarter during the 2-year period beginning on the date on which the Advisory Council is established; and

(ii) at the Secretary's discretion after such period.

(B) ANNUAL RESEARCH MEETING.—Not later than 24 months after the date of enactment of this section, and every year thereafter, the Advisory Council shall convene a meeting of Federal and non-Federal organizations to discuss Parkinson's research.

(C) OPEN MEETINGS.—The meetings under subparagraphs (A) and (B) shall be open to the public.

(4) ANNUAL REPORT.—Not later than 18 months after the date of enactment of this section, and every year thereafter, the Advisory Council shall provide to the Secretary and Congress a report containing—

(A) a list of all federally-funded efforts in Parkinson's research, prevention, diagnosis, treatment, clinical care, and institutional-, home-, and community-based programs and the outcomes of such efforts;

(B) recommendations for priority actions to expand, eliminate, coordinate, refocus, streamline, or condense Federal programs based on each program's performance, mission, scope, and purpose;

(C) recommendations to—

(i) reduce the financial impact of Parkinson's on families living with Parkinson's;

(ii) improve health outcomes for, and the quality of life of, individuals living with Parkinson's;

(iii) prevent Parkinson's, ameliorate symptoms, and slow or stop progression;

(iv) improve the quality of care provided to beneficiaries with Parkinson's who receive coverage through a federally-funded health care program, such as the Medicare program under title XVIII of the Social Security Act or the Medicaid program under title XIX of such Act;

(v) research the association between environmental triggers and Parkinson's to help reduce exposure to potential triggers; and

(vi) research and better understand the underlying factors contributing to Parkinson's;

(D) priority actions to improve all federally-funded efforts in Parkinson's research, prevention, diagnosis, treatment, clinical care, and institutional-, home-, and community-based programs;

(E) an evaluation of the implementation, including outcomes, of the national plan under subsection (c)(1); and

(F) implementation steps to address the recommendations and priority actions under subparagraphs (B), (C),

and (D), based in part on the evaluation under subparagraph (E).

(5) TERMINATION.—The Advisory Council shall terminate at the end of calendar year 2035.

(f) INFORMATION SHARING.—Each Federal department and agency that has information relating to Parkinson's shall share such information with the Secretary consistent with the statutory obligations of such department or agency regarding disclosure of information, as necessary to enable the Secretary to complete a report under subsection (e)(4).

(g) SUNSET.—The section shall cease to be effective at the end of calendar year 2035.