§ 242q–3. Repealed. Pub. L. 109–482, title I, § 104(b)(3)(B), Jan. 15, 2007, 120 Stat. 3694

Section, Pub. L. 101–557, title III, § 304, Nov. 15, 1990, 104 Stat. 2770, related to reports that provided recommendations required in section 242q(b) of this title.

EFFECTIVE DATE OF REPEAL

Repeal applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as an Effective Date of 2007 Amendment note under section 281 of this title.

§ 242q–4. Definitions

For purposes of sections 242q to 242q–5 of this title:

(1) Aging research

(A) The term ''aging research'' means research on the aging process and on the diagnosis and treatment of diseases, disorders, and complications related to aging, including menopause. Such research includes research on such treatments, and on medical devices and other medical interventions regarding such diseases, disorders, and complications, that can assist individuals in avoiding institutionalization and prolonged hospitalization and in otherwise increasing the independence of the individuals.

(B) For purposes of subparagraph (A), the term ''independence'', with respect to diseases, disorders, and complications of aging, means the functional ability of individuals to perform activities of daily living or instrumental activities of daily living without assistance or supervision.

(2) Secretary

The term ''Secretary'' means the Secretary of Health and Human Services.

(3) Task Force

The term ''Task Force'' means the Task Force on Aging Research established under section 242q(a) of this title.

(Pub. L. 101–557, title III, § 304, formerly § 305, Nov. 15, 1990, 104 Stat. 2770; renumbered § 304, Pub. L. 109–482, title I, § 104(b)(3)(B), Jan. 15, 2007, 120 Stat. 3694.)

CODIFICATION

Section was enacted as part of the Home Health Care and Alzheimer's Disease Amendments of 1990, and not as part of the Public Health Service Act which comprises this chapter.

PRIOR PROVISIONS

A prior section 304 of Pub. L. 101–557 was classified to section 242q–3 of this title, prior to repeal by Pub. L. 109–482.

§ 242q–5. Authorization of appropriations

For the purpose of carrying out sections 242q to 242q–5 of this title, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1991 through 1993.

(Pub. L. 101–557, title III, § 305, formerly § 306, Nov. 15, 1990, 104 Stat. 2770; renumbered § 305, Pub. L. 109–482, title I, § 104(b)(3)(B), Jan. 15, 2007, 120 Stat. 3694.)

CODIFICATION

Section was enacted as part of the Home Health Care and Alzheimer's Disease Amendments of 1990, and not as part of the Public Health Service Act which comprises this chapter.

PRIOR PROVISIONS

A prior section 305 of Pub. L. 101–557 was renumbered section 304 and is classified to section 242q–4 of this title.

§ 242r. Improvement and publication of data on food-related allergic responses

(a) In general

The Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control and Prevention and in consultation with the Commissioner of Food and Drugs, shall improve (including by educating physicians and other health care providers) the collection of, and publish as it becomes available, national data on—

(1) the prevalence of food allergies;

(2) the incidence of clinically significant or serious adverse events related to food allergies; and

(3) the use of different modes of treatment for and prevention of allergic responses to foods.

(b) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary.

(Pub. L. 108–282, title II, § 207, Aug. 2, 2004, 118 Stat. 910.)

CODIFICATION

Section was enacted as part of the Food Allergen Labeling and Consumer Protection Act of 2004, and not as part of the Public Health Service Act which comprises this chapter.

PART B—FEDERAL-STATE COOPERATION

§ 243. General grant of authority for cooperation

(a) Enforcement of quarantine regulations; prevention of communicable diseases

The Secretary is authorized to accept from State and local authorities any assistance in the enforcement of quarantine regulations made pursuant to this chapter 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) Comprehensive and continuing planning; training of personnel for State and local health work; fees

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 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) Development of plan to control epidemics and meet emergencies or problems resulting from disasters; cooperative planning; temporary assistance; reimbursement of United States

(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.

(July 1, 1944, ch. 373, title III, § 311, 58 Stat. 693; Pub. L. 89–749, § 5, Nov. 3, 1966, 80 Stat. 1190; Pub. L. 90–174, § 4, Dec. 5, 1967, 81 Stat. 536; Pub. L. 91–515, title II, § 282, Oct. 30, 1970, 84 Stat. 1308; Pub. L. 94–317, title II, § 202(b), (c), June 23, 1976, 90 Stat. 703; Pub. L. 97–35, title IX, § 902(c), Aug. 13, 1981, 95 Stat. 559; Pub. L. 97–414, § 8(d), Jan. 4, 1983, 96 Stat. 2060; Pub. L. 99–117, § 11(a), Oct. 7, 1985, 99 Stat. 494.)

AMENDMENTS

1985—Subsec. (c)(1). Pub. L. 99–117 struck out ''referred to in section 247b(f) of this title'' after ''epidemics of any disease or condition'', ''involving or resulting from disasters or any such disease'' after ''health emergencies or problems'' in first sentence, and struck out ''resulting from disasters or any disease or condition referred to in section 247b(f) of this title'' after ''(including epidemics and health emergencies)'' in second sentence.

1983—Subsec. (c)(2). Pub. L. 97–414 substituted ''six months'' for ''forty-five days'' after ''not in excess of''.

1981—Subsec. (a). Pub. L. 97–35, § 902(c)(1), inserted applicability to other public health matters, and struck out reference to section 246 of this title.

Subsec. (b). Pub. L. 97–35, § 902(c)(2), substituted ''public health activities'' for ''the purposes of section 246 of this title''.

1976—Subsec. (b). Pub. L. 94–317, § 202(c), inserted provision authorizing Secretary to charge only private entities reasonable fees for training of their personnel.

Subsec. (c). Pub. L. 94–317, § 202(b), made changes in phraseology and restructured provisions into pars. (1) and (2) and, in par. (1), as so restructured, inserted provisions authorizing Secretary to develop a plan utilizing Public Health Service personnel, equipment, medical supplies and other resources to control epidemics of any disease referred to in section 247b of this title.

1970—Subsecs. (a), (b). Pub. L. 91–515 substituted ''Secretary'' for ''Surgeon General'' wherever appearing.

1967—Subsec. (c). Pub. L. 90–174 added subsec. (c).

1966—Pub. L. 89–749 designated existing provisions as subsec. (a), added subsec. (b), and amended subsec. (b) to permit Surgeon General to train personnel for State and local health work.

EFFECTIVE DATE OF 1981 AMENDMENT

Amendment by Pub. L. 97–35 effective Oct. 1, 1981, see section 902(h) of Pub. L. 97–35, set out as a note under section 238*l* of this title.

EFFECTIVE DATE OF 1966 AMENDMENT

Section 5(a) of Pub. L. 89–749 provided that subsec. (b) of this section is effective July 1, 1966.

Section 5(b) of Pub. L. 89–749 provided that the amendment of subsec. (b) of this section, permitting the Surgeon General to train personnel for State and local health work, is effective July 1, 1967.

FOOD ALLERGENS IN THE FOOD CODE

Pub. L. 108–282, title II, § 209, Aug. 2, 2004, 118 Stat. 910, provided that: ''The Secretary of Health and Human Services shall, in the Conference for Food Protection, as part of its efforts to encourage cooperative activities between the States under section 311 of the Public Health Service Act (42 U.S.C. 243), pursue revision of the Food Code to provide guidelines for preparing allergen-free foods in food establishments, including in restaurants, grocery store delicatessens and bakeries, and elementary and secondary school cafeterias. The Secretary shall consider guidelines and recommendations developed by public and private entities for public and private food establishments for preparing allergen-free foods in pursuing this revision.''

TRAINING OF PRIVATE PERSONS SUBJECT TO REIMBURSEMENT OR ADVANCES TO APPROPRIATIONS

Pub. L. 103–333, title II, Sept. 30, 1994, 108 Stat. 2550, provided in part: ''That for fiscal year 1995 and subsequent fiscal years training of private persons shall be made subject to reimbursement or advances to this appropriation for not in excess of the full cost of such training''.

§ 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) of this section, 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) of this section may use funds received through such grant to—

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

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

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

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

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

(6) establish an information clearinghouse that provides information to increase public access to defibrillation in schools; and

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

(d) Application

(1) In general

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

(2) Contents

An application submitted under paragraph (1) shall—

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

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

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

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

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

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

(e) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated $25,000,000 for fiscal year 2003, and such sums as may be necessary for each of the fiscal years 2004 through 2006. Not more than 10 percent of amounts received under a grant awarded under this section may be used for administrative expenses.

(July 1, 1944, ch. 373, title III, §312, as added Pub. L. 107–188, title I, §159(c), June 12, 2002, 116 Stat. 634; amended Pub. L. 108–41, §2, July 1, 2003, 117 Stat. 839.)

PRIOR PROVISIONS

A prior section 244, acts July 1, 1944, ch. 373, title III, §312, 58 Stat. 693; July 3, 1946, ch. 538, §8, 60 Stat. 424; Dec. 5, 1967, Pub. L. 90–174, §12(b), 81 Stat. 541; Oct. 30, 1970, Pub. L. 91–515, title II, §282, 84 Stat. 1308, provided for health conferences, prior to repeal by Pub. L. 93–353, title I, §102(a), July 23, 1974, 88 Stat. 362. See section 242*o*(a) of this title.

A prior section 312 of act July 1, 1944, was classified to section 244–1 of this title prior to repeal by Pub. L. 94–484.

AMENDMENTS

2003—Subsec. (c)(6), (7). Pub. L. 108–41 added par. (6) and redesignated former par. (6) as (7).

FINDINGS

Pub. L. 107–188, title I, §159(b), June 12, 2002, 116 Stat. 634, provided that: ''Congress makes the following findings:

''(1) Over 220,000 Americans die each year from cardiac arrest. Every 2 minutes, an individual goes into cardiac arrest in the United States.

''(2) The chance of successfully returning to a normal heart rhythm diminishes by 10 percent each minute following sudden cardiac arrest.

''(3) Eighty percent of cardiac arrests are caused by ventricular fibrillation, for which defibrillation is the only effective treatment.

''(4) Sixty percent of all cardiac arrests occur outside the hospital. The average national survival rate for out-of-hospital cardiac arrest is only 5 percent.

''(5) Communities that have established and implemented public access defibrillation programs have achieved average survival rates for out-of-hospital cardiac arrest as high as 50 percent.

''(6) According to the American Heart Association, wide use of defibrillators could save as many as 50,000 lives nationally each year.

''(7) Successful public access defibrillation programs ensure that cardiac arrest victims have access to early 911 notification, early cardiopulmonary resuscitation, early defibrillation, and early advanced care.''

§ 244–1. Repealed. Pub. L. 94–484, title V, § 503(b), Oct. 12, 1976, 90 Stat. 2300

Section, act July 1, 1944, ch. 373, title III, § 312, formerly § 306, as added Aug. 2, 1956, ch. 871, title I, § 101, 70 Stat. 923; amended July 23, 1959, Pub. L. 86–105, § 1, 73 Stat. 239; Sept 8, 1960, Pub. L. 86–720, § 1(b), 74 Stat. 820; Aug. 27, 1964, Pub. L. 88–497, § 2, 78 Stat. 613; Aug. 16, 1968, Pub. L. 90–490, title III, § 302(b), 82 Stat. 789; Mar. 12, 1970, Pub. L. 91–208, § 3, 84 Stat. 52; Oct. 30, 1970, Pub. L. 91–515, title VI, § 601(b)(2), 84 Stat. 1311; June 18, 1973, Pub. L. 93–45, title I, § 104(a), 87 Stat. 91; renumbered § 312 and amended July 23, 1974, Pub. L. 93–353, title I, § 102(b), 88 Stat. 362; Oct. 12, 1976, Pub. L. 94–484, title I, § 101(a)(1), 90 Stat. 2244, related to graduate or specialized training for physicians, engineers, nurses, and other professional personnel.

EFFECTIVE DATE OF REPEAL

Section 503(c) of Pub. L. 94–484 provided that: ''The amendments made by this section [amending former section 295f–2 of this title and repealing this section and section 245a of this title] shall take effect October 1, 1977.''

§ 244a. Repealed. Pub. L. 93–353, title I, § 102(a), July 23, 1974, 88 Stat. 362

Section, act July 1, 1944, ch. 373, title III, § 312a, as added Aug. 31, 1954, ch. 1158, § 2, 68 Stat. 1025, related to birth and death statistics, annual collection, and compensation for transcription. See section 242k(h) of this title.

§ 245. Public access defibrillation demonstration projects

(a) In general

The Secretary shall award grants to political subdivisions of States, Indian tribes, and tribal organizations to develop and implement innovative, comprehensive, community-based public access defibrillation demonstration projects that—

(1) provide cardiopulmonary resuscitation and automated external defibrillation to cardiac arrest victims in unique settings;

(2) provide training to community members in cardiopulmonary resuscitation and automated external defibrillation; and

(3) maximize community access to automated external defibrillators.

(b) Use of funds

A recipient of a grant under subsection (a) of this section shall use the funds provided through the grant to—

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

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

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

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

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

(c) Application

(1) In general

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

(2) Contents

An application submitted under paragraph (1) may—

(A) describe the innovative, comprehensive, community-based public access defibrillation demonstration project to be funded with the grant;

(B) explain how such public access defibrillation demonstration project represents innovation in providing public access to automated external defibrillation; and

(C) provide for the collection of data regarding the effectiveness of the demonstration project to be funded with the grant in—

(i) providing emergency cardiopulmonary resuscitation and automated external defibrillation to cardiac arrest victims in the setting served by the demonstration project; and

(ii) affecting the cardiac arrest survival rate in the setting served by the demonstration project.

(d) Authorization of appropriations

There is authorized to be appropriated to carry out this section $5,000,000 for each of fiscal years 2002 through 2006. Not more than 10 percent of amounts received under a grant awarded under this section may be used for administrative expenses.

(July 1, 1944, ch. 373, title III, § 313, as added Pub. L. 107–188, title I, § 159(c), June 12, 2002, 116 Stat. 636.)

PRIOR PROVISIONS

A prior section 245, acts July 1, 1944, ch. 373, title III, § 313, 58 Stat. 693; Oct. 30, 1970, Pub. L. 91–515, title II, § 282, 84 Stat. 1308, provided for collection of vital statistics, prior to repeal by Pub. L. 93–353, title I, § 102(a), July 23, 1974, 88 Stat. 362. See section 242k(g) of this title.

A prior section 313 of act July 1, 1944, was classified to section 245a of this title prior to repeal by Pub. L. 94–484.

§ 245a. Repealed. Pub. L. 94–484, title V, § 503(b), Oct. 12, 1976, 90 Stat. 2300

Section, act July 1, 1944, ch. 373, title III, § 313, formerly § 309, as added Sept. 8, 1960, Pub. L. 86–720, § 1(a),

74 Stat. 819; amended Aug. 27, 1964, Pub. L. 88–497, § 3, 78 Stat. 613; Nov. 3, 1966, Pub. L. 89–749, § 4, 80 Stat. 1190; Dec. 5, 1967, Pub. L. 90–174, §§ 2(g), 8(c), 81 Stat. 534, 540; Aug. 16, 1968, Pub. L. 90–490, title III, § 302(a), 82 Stat. 788; Mar. 12, 1970, Pub. L. 91–208, §§ 1, 2, 84 Stat. 52; June 30, 1970, Pub. L. 91–296, title IV, § 401(b)(1)(B), 84 Stat. 352; June 18, 1973, Pub. L. 93–45, title I, § 104(b), (c), 87 Stat. 91; renumbered § 313 and amended July 23, 1974, Pub. L. 93–353, title I, § 102(c), 88 Stat. 362; Oct. 12, 1976, Pub. L. 94–484, title I, § 101(a)(2), (3), 90 Stat. 2244, related to graduate public health training grants.

EFFECTIVE DATE OF REPEAL

Repeal effective Oct. 1, 1977, see section 503(c) of Pub. L. 94–484, set out as a note under section 244–1 of this title.

§ 246. Grants and services to States

(a) Comprehensive health planning and services

(1) 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) 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) 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 recommend 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 nec-

essary to carry out the purposes of this subsection.

(3)(A) From the sums appropriated for such purpose for each fiscal year, the several States shall be entitled to allotments determined, in accordance with regulations, on the basis of the population and the per capita income of the respective States; except that no such allotment to any State for any fiscal year shall be less than 1 per centum of the sum appropriated for such fiscal year pursuant to paragraph (1). Any such allotment to a State for a fiscal year shall remain available for obligation by the State, in accordance with the provisions of this subsection and the State's plan approved thereunder, until the close of the succeeding fiscal year.

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

(4) 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.

(b) Project grants for areawide health planning; authorization of appropriations; prerequisites for grants; application; contents

(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) of this section, project grants to any other public or nonprofit private agency or organization (but with appropriate representation of the interests of local government where the recipient of the grant is not a local government or combination thereof or an agency of such government or combination) to cover not to exceed 75 per centum of the costs of projects for developing (and from time to time revising) comprehensive regional, metropolitan area, or other local area plans for coordination of existing and planned health services, including the facilities and persons required for provision of such services; and including the provision of such services through home health care; except that in the case of project grants made in any State prior to July 1, 1968, approval of such State agency shall be required only if such State has such a State plan in effect at the time of such grants. No grant may be made under this subsection after June 30, 1970, to any agency or organization to develop or revise health plans for an area unless the Secretary determines that such agency or organization provides means for appropriate representation of the interests of the hospitals, other health care facilities, and practicing physicians serving such area, and the general public. For the purposes of carrying out this subsection, there are hereby authorized to be appropriated $5,000,000 for the fiscal year ending June 30, 1967, $7,500,000 for the fiscal year ending June 30, 1968, $10,000,000 for the fiscal year ending June 30, 1969, $15,000,000 for the fiscal year ending June 30, 1970, $20,000,000 for the fiscal year ending June 30, 1971, $30,000,000 for the fiscal year ending June 30, 1972, $40,000,000 for the fiscal year ending June 30, 1973, and $25,100,000 for the fiscal year ending June 30, 1974.

(B) Project grants may be made by the Secretary under subparagraph (A) to the State agency administering or supervising the administration of the State plan approved under subsection (a) of this section 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 foreseeable 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 nonprofit 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 area-

wide 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.

(c) Project grants for training, studies, and demonstrations; authorization of appropriations

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.

(July 1, 1944, ch. 373, title III, §314, 58 Stat. 693; July 3, 1946, ch. 538, §9, 60 Stat. 424; June 16, 1948, ch. 481, §5, 62 Stat. 468; 1953 Reorg. Plan No. 1, §§5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Aug. 1, 1956, ch. 852, §18, 70 Stat. 910; Pub. L. 85–544, §1, July 22, 1958, 72 Stat. 400; Pub. L. 87–395, §2(a)–(d), Oct. 5, 1961, 75 Stat. 824; Pub. L. 87–688, §4(a)(1), Sept. 25, 1962, 76 Stat. 587; Pub. L. 89–109, §4, Aug. 5, 1965, 79 Stat. 436; Pub. L. 89–749, §3, Nov. 3, 1966, 80 Stat. 1181; Pub. L. 90–174, §§2(a)–(f), 3(b)(2), 8(a), (b), 12(d), Dec. 5, 1967, 81 Stat. 533–535, 540, 541; Pub. L. 91–296, title I, §111(b), title IV, §401(b)(1)(C), (D), June 30, 1970, 84 Stat. 340, 352; Pub. L. 91–513, title I, §3(b), Oct. 27, 1970, 84 Stat. 1241; Pub. L. 91–515, title II, §§220, 230, 240, 250, 260(a)–(c)(1), 282, Oct. 30, 1970, 84 Stat. 1304–1306, 1308; Pub. L. 91–616, title III, §331, Dec. 31, 1970, 84 Stat. 1853; Pub. L. 91–648, title IV, §403, Jan. 5, 1971, 84 Stat. 1925, as amended Pub. L. 95–454, title VI, §602(c), Oct. 13, 1978, 92 Stat. 1189; Pub. L. 92–255, title IV, §403(a), Mar. 21, 1972, 86 Stat. 77; Pub. L. 93–45, title I, §106, June 18, 1973, 87 Stat. 92; Pub. L. 93–151, §8, Nov. 9, 1973, 87 Stat. 568; Pub. L. 94–63, title I, §102, title V, §501(b), title VII, §701(a), (b), July 29, 1975, 89 Stat. 304, 346, 352; Pub. L. 94–484, title IX, §905(b)(1), Oct. 12, 1976, 90 Stat. 2325; Pub. L. 95–83, title III, §302, Aug. 1, 1977, 91 Stat. 387; Pub. L. 95–454, title VI, §602(c), Oct. 13, 1978, 92 Stat. 1189; Pub. L. 95–622, title I, §109, Nov. 9, 1978, 92 Stat. 3417; Pub. L. 95–626, title II, §201(a), (b)(2), Nov. 10, 1978, 92 Stat. 3570; Pub. L. 96–32, §6(e), (f), July 10, 1979, 93 Stat. 83; Pub. L. 96–79, title I, §115(k)(2), Oct. 4, 1979, 93 Stat. 610; Pub. L. 96–398, title I, §107(d), Oct. 7, 1980, 94 Stat. 1571; Pub. L. 97–35, title IX, §902(b), Aug. 13, 1981, 95 Stat. 559; Pub. L. 99–117, §12(a), Oct. 7, 1985, 99 Stat. 495; Pub. L. 102–54, §13(q)(1)(D), June 13, 1991, 105 Stat. 279.)

AMENDMENTS

1991—Subsec. (a)(2)(B). Pub. L. 102–54 substituted ''Department of Veterans Affairs'' for ''Veterans' Administration'', ''Secretary of Veterans Affairs'' for ''Administrator of Veterans' Affairs'' and ''such Department'' for ''such Administration''.

1985—Subsec. (g). Pub. L. 99–117 directed that subsec. (g) be repealed. Previously, subsec. (g) was repealed by Pub. L. 96–398. See 1980 Amendment note below.

1981—Subsec. (d). Pub. L. 97–35 struck out subsec. (d) which related to grants for services, form, manner, etc., of application, review of activities undertaken, allotments, and authorization of appropriations.

1980—Subsec. (g). Pub. L. 96–398 struck out subsec. (g) which related to application, procedures applicable, amount, etc., for State mental health program grants.

1979—Subsec. (d)(2)(C)(ii). Pub. L. 96–32, §6(e), substituted ''uniform national health program reporting system'' for ''uniform national reporting system''.

Subsec. (d)(4)(A). Pub. L. 96–32, §6(f), in provision following subd. (II) of cl. (ii), substituted ''the preceding provisions of this subparagraph'' for ''clauses (i) and (ii)'' and ''amount'' for ''amounts'' and inserted provision that if the amount appropriated for a fiscal year is equal to or less than the amount appropriated for fiscal year ending Sept. 30, 1979, the total amount of grants for a State health authority shall be an amount which bears the same ratio to the amount appropriated as the total amount of grants received by such authority from appropriations for fiscal year ending Sept. 30, 1979, bears to the amount appropriated for that fiscal year.

Subsec. (g)(2)(D)(iv). Pub. L. 96–79 substituted ''a plan which is consistent with the State health plan in effect for the State under section 300m–3(c) of this title and'' for ''a plan''.

1978—Subsec. (d). Pub. L. 95–626, §201(b)(2), completely revised subsec. (d) under which the Secretary is authorized to make grants to State health authorities to assist in meeting the costs of providing comprehensive public health services by including requirements that the States submit an application outlining how funds will be used to supplement non-Federal support for the provision of public health services in the State, by setting out formulae under which funds will be made available to States including definitions of ''applicable grant computation percentage'' and ''State and local expenditures for comprehensive public health services'', by requiring implementation of a national health program reporting system to assure accountability for expenditure of funds, and by authorizing appropriations of $150,000,000 for fiscal year ending Sept. 30, 1980, and $170,000,000 for fiscal year ending Sept. 30, 1981.

Subsec. (d)(7)(A). Pub. L. 95–626, §201(a)(1), inserted provision authorizing an appropriation of $103,000,000 for fiscal year ending Sept. 30, 1979.

Subsec. (d)(7)(B). Pub. L. 95–626, §201(a)(2), inserted provision authorizing an appropriation of $20,000,000 for fiscal year ending Sept. 30, 1979.

Subsec. (f). Pub. L. 95–454 designated existing provisions of section 403 of Pub. L. 91–648 (see 1971 Amendment note below) as subsec. (a) thereof and added subsec. (b) thereto repealing subsec. (f) of this section as subsec. (f) of this section had applied to commissioned officers of the Public Health Service.

Subsec. (g). Pub. L. 95–622 substituted provisions relating to grants for State mental health programs for provisions relating to regulations and amendments with respect to grants to States under subsecs. (a) and (d) and reduction and suspension of subsec. (a) and (d) grant payments.

1977—Subsec. (d)(7)(A). Pub. L. 95–83, §302(a), substituted provision for an appropriation authorization for fiscal year ending Sept. 30, 1977, for prior such authorization for fiscal year 1977, and authorized appropriation of $106,750,000 for fiscal year ending Sept. 30, 1978.

Subsec. (d)(7)(B). Pub. L. 95–83, §302(b), substituted provision for an appropriation authorization for fiscal

year ending Sept. 30, 1977, for prior such authorization for fiscal year 1977, and authorized appropriation of $12,680,000 for fiscal year ending Sept. 30, 1978.

1976—Subsec. (g)(4)(B). Pub. L. 94–484 defined ''State'' to include the Northern Mariana Islands.

1975—Subsec. (d). Pub. L. 94–63, §§102, 701(a), substituted provisions relating to grants made pursuant to allotments to State health and mental health authorities for meeting the costs of providing comprehensive public health services, for provisions relating to grants made pursuant to appropriations for fiscal year ending June 30, 1968 to fiscal year ending June 30, 1975, to State health or mental health authorities to aid in the establishment and maintenance of adequate public health services, including the training of personnel for State and local health work.

Subsec. (e). Pub. L. 94–63, §§501(b), 701(b), struck out subsec. (e) which authorized appropriations from fiscal year ending June 30, 1968 through fiscal year ending June 30, 1975 for project grants for health services and related training, set forth procedures for making such grants, and prohibited grants after the fiscal year ending June 30, 1975, for provisions of this chapter amended by title VII of the Health Revenue Sharing and Health Services Act of 1975.

1973—Subsec. (a)(1). Pub. L. 93–45, §106(a)(1), authorized appropriations of $10,000,000 for fiscal year ending June 30, 1974.

Subsec. (b)(1)(A). Pub. L. 93–45, §106(a)(2), (b), authorized appropriations of $25,100,000 for fiscal year ending June 30, 1974, and extended period for making project grants from June 30, 1973, to June 30, 1974.

Subsec. (c). Pub. L. 93–45, §106(a)(3), (b), authorized appropriations of $4,700,000 for fiscal year ending June 30, 1974, and extended period for grants from June 30, 1973, to June 30, 1974.

Subsec. (d)(1). Pub. L. 93–45, §106(a)(4), authorized appropriations of $90,000,000 for fiscal year ending June 30, 1974.

Subsec. (e). Pub. L. 93–151 prohibited use of appropriated funds for lead based paint poisoning control.

Pub. L. 93–45, §106(a)(5), authorized appropriations of $230,700,000 for fiscal year ending June 30, 1974, and prohibited any grant for such fiscal year to cover cost of services described in cl. (1) or (2) of the first sentence if a grant or contract to cover cost of such services may be made or entered into from funds authorized to be appropriated for such fiscal year under an appropriations authorization in any provision of this chapter (other than this subsection) amended by title I of the Health Programs Extension Act of 1973.

1972—Subsec. (d)(2)(K). Pub. L. 92–255 required State plans to provide for licensing of facilities for treatment and rehabilitation of persons with drug abuse and other drug dependence problems and for expansion of State mental health programs and other prevention and treatment programs in the field of drug abuse and drug dependence.

1971—Subsec. (f). Pub. L. 91–648, §403(a), as amended by Pub. L. 94–454, §602(c), repealed subsec. (f) which authorized the Secretary to arrange the interchange of personnel with States to aid in discharge of responsibilities in field of health care, except as subsec. (b) applied to commissioned officers of the Public Health Service. See 1978 Amendment note above.

1970—Pub. L. 91–515, §282, substituted ''Secretary'' for ''Surgeon General'' in subsecs. (a)(1), (a)(2)(C), (E) to (H), (K), (a)(3)(B), (a)(4), (b)(1)(A), (c), (d)(1), (d)(2)(C), (F) to (H), (J), (d)(4)(A), (d)(6), and (g)(1) to (3).

Subsec. (a)(1). Pub. L. 91–515, §220(a), extended period for making grants to States from June 30, 1970 to June 30, 1973, and authorized appropriations for the fiscal years ending June 30, 1971, June 30, 1972, and June 30, 1973.

Subsec. (a)(2)(B). Pub. L. 91–515, §220(b), (c), inserted provisions authorizing appointment of an exofficio member from representatives of Federal, State, and local agencies involved, and requiring representation of the regional medical program or programs included in whole or in part within the State.

Subsec. (a)(2)(C). Pub. L. 91–515, §220(d), inserted ''and including home health care'' after ''private'' and ''and including environmental considerations as they relate to public health'' after ''people of the State''.

Subsec. (b). Pub. L. 91–515, §230, redesignated existing provisions as subsec. (b)(1)(A), and, as so redesignated, extended period for making project grants from June 30, 1970 to June 30, 1973, inserted ''and including the provision of such services through home health care'' after ''such services'', and authorized appropriations for the fiscal years ending June 30, 1971, June 30, 1972, and June 30, 1973, and added subsec. (b)(1)(B) and (b)(2).

Pub. L. 91–296, §111(b), inserted provisions requiring that before grants be made to agencies or organizations to develop or revise health plans for an area the Secretary determine that the agency or organization provides means for appropriate representation of the interests of the hospitals, practicing physicians, and the general public.

Subsec. (c). Pub. L. 91–515, §240, extended period for making grants from June 30, 1970, to June 30, 1973, and authorized appropriations for the fiscal years ending June 30, 1971, June 30, 1972, and June 30, 1973.

Subsec. (d)(1). Pub. L. 91–515, §250(a), authorized appropriations for fiscal years ending June 30, 1971, June 30, 1972, and June 30, 1973.

Pub. L. 91–296, §401(b)(1)(C), struck out except which provided for use of up to 1 per centum by Secretary for evaluation.

Subsec. (d)(2)(C). Pub. L. 91–515, §250(b), inserted provisions requiring State plan to contain assurances that the plan is compatible with total health program of the State.

Subsec. (d)(2)(K). Pub. L. 91–513 added subpar. (K).

Subsec. (d)(2)(L). Pub. L. 91–616 added subpar. (L).

Subsec. (e). Pub. L. 91–515, §260(a), (b), (c)(1), inserted provisions authorizing appropriations for fiscal years ending June 30, 1971, June 30, 1972, and June 30, 1973, provisions authorizing grants to cover part of cost of equity requirements and amortization of loans on facilities acquired from the Office of Economic Opportunity or construction in connection with any program or project transferred from the Office of Economic Opportunity, and provisions requiring the application for any grant made under this subsection to be referred for review and comment to the appropriate areawide health planning agency, or, if no such agency is in the area, then to such other public or nonprofit private agency or organization (if any) which performs similar functions.

Pub. L. 91–296, §401(b)(1)(D), struck out provision for use of up to 1 per centum of appropriation for grants under subsec. (e) by the Secretary for evaluation.

1967—Subsec. (a)(1). Pub. L. 90–174, §2(a)(1), extended period for making grants to States from June 30, 1968, to June 30, 1970, increased appropriations authorization for fiscal year ending June 30, 1968, from $5,000,000 to $7,000,000, and authorized appropriations of $10,000,000 and $15,000,000 for fiscal years ending June 30, 1969, and 1970, respectively.

Subsec. (a)(2)(I) to (K). Pub. L. 90–174, §2(a)(2), added subpar. (I) and redesignated former subpars. (I) and (J) as (J) and (K), respectively.

Subsec. (a)(4). Pub. L. 90–174, §2(a)(3), limited Federal share of expenditures, in case of allotments for fiscal year ending June 30, 1968, to 75 per centum of cost of planning.

Subsec. (b). Pub. L. 90–174, §2(b)(1), (2), extended period for making grants to public or nonprofit private organizations from June 30, 1968, to June 30, 1970, and authorized appropriations of $10,000,000 and $15,000,000 for fiscal years ending June 30, 1969, and 1970, respectively, and provided for appropriate representation of interests of local government where recipient of grant is not a local government or combination thereof or an agency of such government or combination, respectively.

Subsec. (c). Pub. L. 90–174, §2(c), extended period for making grants to public or nonprofit private organizations from June 30, 1968, to June 30, 1970, and author-

ized appropriations of $5,000,000 and $7,500,000 for fiscal years ending June 30, 1969, and 1970, respectively.

Subsec. (d)(1). Pub. L. 90–174, §§2(d)(1), 8(a), increased appropriations authorization for fiscal year ending June 30, 1968, from $62,500,000 to $70,000,000, and authorized appropriations of $90,000,000 and $100,000,000 for fiscal years ending June 30, 1969, and 1970, respectively, and made program evaluation funds available for any fiscal year ending after June 30, 1968, respectively.

Subsec. (d)(5). Pub. L. 90–174, §2(d)(2), made Federal share of 66⅔ per centum applicable to the Trust Territory of the Pacific Islands.

Subsec. (d)(7). Pub. L. 90–174, §2(d)(3), provided for an allocation of 70 per centum of funds for provision under the State plan of services in communities of the State.

Subsec. (e). Pub. L. 90–174, §§2(e), 3(b)(2), 8(b), increased appropriations authorization for fiscal year ending June 30, 1968, from $62,500,000 to $90,000,000, authorized appropriations of $95,000,000 and $80,000,000 for fiscal years ending June 30, 1969, and 1970, respectively, inserted ''(including related training)'' after ''providing services'' in cl. (1), substituted ''developing'' for ''stimulating'' and inserted ''(including related training)'' after ''health services'' in cl. (2), struck out cl. (3) which authorized grants to cover part of cost of undertaking studies, demonstrations, or training designed to develop new methods or improve existing methods of providing health services, and made program evaluation funds available for any fiscal year ending after June 30, 1968.

Subsec. (f)(5). Pub. L. 90–174, §12(d)(1), inserted ''for'' before ''the expenses of travel''.

Subsec. (f)(6), (8). Pub. L. 90–174, §12(d)(2), substituted ''Department'' for ''Service''.

Subsec. (g)(4)(B). Pub. L. 90–174, §2(f), defined ''State'' to include the Trust Territory of the Pacific Islands.

1966—Subsec. (a). Pub. L. 89–749 substituted provisions authorizing the Surgeon General to make grants to States to assist in comprehensive and continuing planning for their current and future health needs, authorizing appropriations therefor, setting out the requirements for an acceptable State plan for comprehensive State health planning, covering the allotting of the appropriated sums to the States, and the payment of the allotted funds, for provisions authorizing the Surgeon General, through the use of grants and other assistance, to help local programs of prevention, treatment, and control of venereal diseases, covering the payment of the costs of assistance by personnel of the Public Health Service to assist in carrying out the purposes of the section with respect to venereal disease, and authorizing the appropriation of funds.

Subsec. (b). Pub. L. 89–749 substituted provisions for project grants by the Surgeon General covering the development of comprehensive regional, metropolitan, or local coordination of existing and planned health facilities and persons required for providing services and the authorization of appropriations of $5,000,000 for fiscal 1967 and $7,500,000 for fiscal 1968 for provisions authorizing the appropriation of funds to enable the Surgeon General to aid in the development of measures for the local prevention, treatment, and control of tuberculosis.

Subsec. (c). Pub. L. 89–749 substituted provisions for project grants for the development of improved or more effective comprehensive health planning throughout the United States and the authorization of appropriations of $1,500,000 for fiscal 1967 and $2,500,000 for fiscal 1968 for provisions authorizing the Surgeon General to assist, through grants and otherwise, in the establishment and maintenance of adequate public health services by States, counties, health districts, and other political subdivisions, authorizing appropriations therefor, and covering the allotment, payment, and allocation of appropriated funds.

Subsec. (d). Pub. L. 89–749 substituted provisions authorizing grants by the Surgeon General to State health or mental health authorities to assist in establishing and maintaining adequate public health services, setting out the requirements for an acceptable State plan for the supplying of public health services, authorizing an appropriation of $62,500,000 for fiscal 1968, the allotment of appropriated funds, payments to States, and the determination of the Federal share for provisions covering the allotment of appropriated funds among the several States on the basis of population, incidence of venereal disease, tuberculosis, mental health problems, and the financial needs of the various States.

Subsec. (e). Pub. L. 89–749 substituted provisions for project grants for health services development to public or private nonprofit agencies and for the authorization of an appropriation of $62,500,000 for fiscal 1968 for provisions covering the establishment and maintenance of community programs of heart disease control and the allotments and appropriations therefor.

Subsec. (f). Pub. L. 89–749 substituted provisions covering the interchange of personnel with States, the application of statutes covering Federal employees to interchanged personnel, and the coverage of State officers and employees, for provisions for the determination and certification of amounts paid to each State from allotments thereto.

Subsec. (g). Pub. L. 89–749 substituted provisions for consultation with State health planning agencies concerning regulations and amendments with respect to grants to States, the reduction of payments, cessation of payments for non-compliance, and definitions, for provisions limiting the expending of grant funds for purposes specified by statute and by the agency, organization, or institution to which payment was made.

Subsecs. (h) to (m). Pub. L. 89–749 struck out subsecs. (h) to (m) which dealt, respectively, with requirement that State funds be provided for same purpose as that for which allotted funds are spent, cessation of Federal aid and procedures in connection therewith, promulgation of rules and regulations and consultation with State health authorities precedent thereto, availability of appropriated funds for administrative expenses including printing and travel expenses, applicability of section to Guam and Samoa, and reduction of payments commensurate to expense of detailing of Public Health Service personnel to States.

1965—Subsec. (c). Pub. L. 89–109 substituted ''first six fiscal years ending after June 30, 1961'' for ''first five fiscal years ending after June 30, 1961'' and ''$5,000,000'' for ''$2,500,000''.

1962—Subsec. (*l*). Pub. L. 87–688 inserted ''and American Samoa'', ''or American Samoa'', and ''or American Samoa, respectively'' after ''Guam''.

1961—Subsec. (c). Pub. L. 87–395, §2(a)–(c), substituted ''of the first five fiscal years ending after June 30, 1961, the sum of $50,000,000'' for ''fiscal year a sum not to exceed $30,000,000'', ''such amount as may be necessary'' for ''an amount, not to exceed $3,000,000'', ''$2,500,000'' for ''$1,000,000'', and provided that when an appropriating act provides that the amounts it specifies are available only for allotments and payments for such services and activities under this subsection as specified in such act, the requirements of subsec. (h) shall apply to such allotments and payments.

Subsec. (m). Pub. L. 87–395, §2(d), added subsec. (m).

1958—Subsec. (c). Pub. L. 85–544 designated existing provisions of second sentence as cl. (1) and added cl. (2).

1956—Subsec. (*l*). Act Aug. 1, 1956, added subsec. (*l*).

1948—Subsec. (e). Act June 16, 1948, §5(a), added subsec. (e) to provide for community programs of heart disease control. Former subsec. (e) redesignated (f).

Subsec. (f). Act June 16, 1948, §5(a), (b), redesignated former subsec. (e) as (f) and inserted proviso relating to determination and certification of amounts to be paid under subsec. (e). Former subsec. (f) redesignated (g).

Subsec. (g). Act June 16, 1948, §5(a), (c), redesignated former subsec. (f) as (g) and brought subsecs. (e) and (f)(1) within the provisions of this subsection. Former subsec. (g) redesignated (h).

Subsec. (h). Act June 16, 1948, §5(a), (d), redesignated former subsec. (g) as (h) and made subsection applicable to agencies, institutions or other organizations specified in subsec. (f)(1). Former subsec. (h) redesignated (i).

Subsec. (i). Act June 16, 1948, § 5(a), (e), redesignated former subsec. (h) as (i), made subsection applicable to subsec. (e), and made technical changes as a result of the renumbering of subsections. Former subsec. (i) redesignated (j).

Subsecs. (j), (k). Act June 16, 1948, § 5(a), redesignated former subsecs. (i) and (j) as (j) and (k), respectively.

1946—Subsec. (c). Act July 3, 1946, increased annual appropriation from $20,000,000 to $30,000,000, and increased annual amount available to provide demonstrations and to train personnel for State and local health work from $2,000,000 to $3,000,000.

Subsec. (d). Act July 3, 1946, provided that Surgeon General shall give special consideration to the extent of the mental health problem as well as other special problems.

Subsecs. (f), (h), (i). Act July 3, 1946, provided that in matters relating to work in field of mental health Surgeon General shall deal with State mental health authorities where they differ from general health authorities.

EFFECTIVE DATE OF 1981 AMENDMENT

Amendment by Pub. L. 97–35 effective Oct. 1, 1981, see section 902(h) of Pub. L. 97–35, set out as a note under section 238*l* of this title.

EFFECTIVE DATE OF 1980 AMENDMENT

Section 107(d) of Pub. L. 96–398 provided that the amendment made by that section is effective Sept. 30, 1981. See Repeals note below.

EFFECTIVE DATE OF 1979 AMENDMENT

Amendment by Pub. L. 96–79 effective one year after Oct. 4, 1979, see section 129(a) of Pub. L. 96–79.

EFFECTIVE DATE OF 1978 AMENDMENTS

Section 201(b)(2) of Pub. L. 95–626 provided that the amendment made by section is effective Oct. 1, 1979.

Section 403(b) of Pub. L. 91–648, as added by section 602(c) of Pub. L. 95–454, provided that the repeal of subsec. (f) of this section (as applicable to commissioned officers of the Public Health Service) is effective beginning on the effective date of the Civil Service Reform Act of 1978, i.e., 90 days after Oct. 13, 1978.

EFFECTIVE DATE OF 1975 AMENDMENT

Section 102 of Pub. L. 94–63 provided that the amendment made by that section is effective with respect to grants made under subsec. (d) of this section from appropriations under such subsection for fiscal years beginning after June 30, 1975.

Amendment by section 501(b) of Pub. L. 94–63 effective July 1, 1975, see section 608 of Pub. L. 94–63, set out as a note under section 247b of this title.

EFFECTIVE DATE OF 1971 AMENDMENT

Repeal of subsec. (f) of this section (less applicability to commissioned officers of the Public Health Service) by section 403(a) of Pub. L. 91–648, as amended by Pub. L. 94–454, § 602(c), effective sixty days after Jan. 5, 1971, see section 404 of Pub. L. 91–648, set out as an Effective Date note under section 3371 of Title 5, Government Organization and Employees.

EFFECTIVE DATE OF 1970 AMENDMENTS

Section 260(c)(2) of Pub. L. 91–515 provided that: ''The amendment made by paragraph (1) [amending this section] shall be effective with respect to grants under section 314(c) of the Public Health Service Act [subsec. (e) of this section] which are made after the date of enactment of this Act [Oct. 30, 1970.]''

Section 401(b)(1) of Pub. L. 91–296 provided that the amendment made by that section is effective with respect to appropriations for fiscal years beginning after June 30, 1970.

EFFECTIVE DATE OF 1967 AMENDMENT

Section 2(d)(2), (f) of Pub. L. 90–174 provided that the amendments made by that section are effective July 1, 1968.

Section 3(b) of Pub. L. 90–174 provided that the amendment of this section, the repeal of section 291n of this title, and the enactment of provisions set out as a note under section 242b of this title by such section 3(b) is effective with respect to appropriations for fiscal years ending after June 30, 1967.

EFFECTIVE DATE OF 1966 AMENDMENT

Section 6 of Pub. L. 89–749 provided in part that: ''The amendments made by section 3 [amending this section] shall become effective as of July 1, 1966, except that the provisions of section 314 of the Public Health Service Act [this section] as in effect prior to the enactment of this Act shall be effective until July 1, 1967, in lieu of the provisions of subsections (d) and (e), and the provisions of subsections (g) insofar as they relate to such subsections (d) and (e), of section 314 of the Public Health Service Act [this section] as amended by this Act.''

EFFECTIVE DATE OF 1962 AMENDMENT

Section 4(b) of Pub. L. 87–688 provided that: ''The amendments made by this section [amending this section and sections 291g, 291i, and 291t of this title] shall become effective July 1, 1962.''

EFFECTIVE AND TERMINATION DATE OF 1958 AMENDMENT

Section 2 of Pub. L. 85–544 provided that: ''The amendment made by the first section of this Act [amending this section] shall be applicable only to the fiscal years beginning July 1, 1958, and July 1, 1959.''

EFFECTIVE DATE OF 1956 AMENDMENT

Section 18 of act Aug. 1, 1956, provided that the amendment made by that section is effective July 1, 1956.

REPEALS

The directory language of, but not the amendment made by, Pub. L. 96–398, title I, § 107(d), cited as a credit to this section and set out as an Effective Date of 1980 Amendment note above, which provided for repeal of subsec. (g) of this section, effective Sept. 30, 1981, was repealed by section 902(e)(1) of Pub. L. 97–35, title IX, Aug. 13, 1981, 95 Stat. 560, effective Oct. 1, 1981.

TRANSFER OF FUNCTIONS

Functions, powers, and duties of Secretary of Health and Human Services under subsecs. (a)(2)(F) and (d)(2)(F) of this section, insofar as relates to the prescription of personnel standards on a merit basis, transferred to Office of Personnel Management, see section 4728(a)(3)(C) of this title.

Functions of Federal Security Administrator transferred to Secretary of Health, Education, and Welfare and all agencies of Federal Security Agency transferred to Department of Health, Education, and Welfare by section 5 of Reorg. Plan No. 1 of 1953, set out as a note under section 3501 of this title. Federal Security Agency and office of Administrator abolished by section 8 of Reorg. Plan No. 1 of 1953. Secretary and Department of Health, Education, and Welfare redesignated Secretary and Department of Health and Human Services by section 509(b) of Pub. L. 96–88 which is classified to section 3508(b) of Title 20, Education.

YEAR 2000 HEALTH OBJECTIVES PLANNING

Pub. L. 101–582, Nov. 15, 1990, 104 Stat. 2867, provided for grants for State plans regarding health objectives for year 2000, prior to repeal by Pub. L. 102–531, title I, § 105, Oct. 27, 1992, 106 Stat. 3474.

CONGRESSIONAL FINDINGS AND DECLARATION

Section 201(b)(1) of Pub. L. 95–626 provided that: ''The Congress finds and declares that—

''(A) individual health status can be effectively and economically improved through an adequate invest-

ment in community public health programs and services;

''(B) the Federal Government and the States and their communities share in the financial responsibility for funding public health programs;

''(C) the Federal contribution to funds for public health programs should serve as an incentive to an additional investment by State and local governments;

''(D) existing categorical programs of Federal financial assistance to combat specific public health problems should be supplemented by a national program of stable generic support for such public health activities as the prevention and control of environmental health hazards, prevention and control of diseases, prevention and control of health problems of particularly vulnerable population groups, and development and regulation of health care facilities and health services delivery systems; and

''(E) the States and their communities, not the Federal Government, should have primary responsibility for identifying and measuring the impact of public health problems and the allocation of resources for their amelioration.''

Section 2 of Pub. L. 89–749 provided that:

''(a) The Congress declares that fulfillment of our national purpose depends on promoting and assuring the highest level of health attainable for every person, in an environment which contributes positively to healthful individual and family living; that attainment of this goal depends on an effective partnership, involving close intergovernmental collaboration, official and voluntary efforts, and participation of individuals and organizations; that Federal financial assistance must be directed to support the marshaling of all health resources—national, State, and local—to assure comprehensive health services of high quality for every person, but without interference with existing patterns of private professional practice of medicine, dentistry, and related healing arts.

''(b) To carry out such purpose, and recognizing the changing character of health problems, the Congress finds that comprehensive planning for health services, health manpower, and health facilities is essential at every level of government; that desirable administration requires strengthening the leadership and capacities of State health agencies; and that support of health services provided people in their communities should be broadened and made more flexible.''

Section 2 of act July 3, 1956, provided that:

''(a) The Congress hereby finds and declares—

''(1) that the latest information on the number and relevant characteristics of persons in the country suffering from heart disease, cancer, diabetes, arthritis and rheumatism, and other diseases, injuries, and handicapping conditions is now seriously out of date; and

''(2) that periodic inventories providing reasonably current information on these matters are urgently needed for purposes such as (A) appraisal of the true state of health of our population (including both adults and children), (B) adequate planning of any programs to improve their health, (C) research in the field of chronic diseases, and (D) measurement of the numbers of persons in the working ages so disabled as to be unable to perform gainful work.

''(b) It is, therefore, the purpose of this Act [see Short Title of 1956 Amendment note set out under section 201 of this title] to provide (1) for a continuing survey and special studies to secure on a non-compulsory basis accurate and current statistical information on the amount, distribution, and effects of illness and disability in the United States and the services received for or because of such conditions; and (2) for studying methods and survey techniques for securing such statistical information, with a view toward their continuing improvement.''

LIMITATION ON GRANTS-IN-AID TO SCHOOLS OF PUBLIC HEALTH

Section 2 of Pub. L. 85–544, which had limited the authority of the Surgeon General to make grants-in-aid totaling not to exceed $1,000,000 annually to schools of public health for fiscal year beginning July 1, 1958, and July 1, 1959, was repealed by section 2 of Pub. L. 86–720, Sept. 8, 1960, 74 Stat. 820.

GRANTS TO STATES TO PROVIDE FOR VACCINATION AGAINST POLIOMYELITIS

The Poliomyelitis Vaccination Assistance Act of 1955, act Aug. 12, 1955, ch. 863, 69 Stat. 704, as amended Feb. 15, 1956, ch. 39, 70 Stat. 18, authorized appropriations to remain available until close of June 30, 1957 and provided for allotments to States, State application for funds, payments to States, use of funds paid to States, furnishing of vaccine by Surgeon General, diversion of Federal funds, supervision over exercise of functions, and definitions.

APPLICABILITY OF REORGANIZATION PLAN NO. 3 OF 1966

Section 7 of Pub. L. 89–749 provided that: ''The provisions enacted by this Act [amending this section and sections 242g and 243 of this title] shall be subject to the provisions of Reorganization Plan No. 3 of 1966 [set out as a note under section 202 of this title].''

§ 246a. Bureau of State Services management fund; establishment; advancements; availability

For the purpose of facilitating the economical and efficient conduct of operations in the Bureau of State Services which are financed by two or more appropriations where the costs of operation are not readily susceptible of distribution as charges to such appropriations, there is established the Bureau of State Services management fund. Such amounts as the Secretary may determine to represent a reasonable distribution of estimated costs among the various appropriations involved may be advanced each year to this fund and shall be available for expenditure for such costs under such regulations as may be prescribed by the Secretary: *Provided*, That funds advanced to this fund shall be available only in the fiscal year in which they are advanced: *Provided further*, That final adjustments of advances in accordance with actual costs shall be effected wherever practicable with the appropriations from which such funds are advanced.

(Pub. L. 86–703, title II, § 201, Sept. 2, 1960, 74 Stat. 765; Pub. L. 91–515, title II, § 282, Oct. 30, 1970, 84 Stat. 1308.)

CODIFICATION

Section was not enacted as part of the Public Health Service Act which comprises this chapter.

AMENDMENTS

1970—Pub. L. 91–515 substituted ''Secretary'' for ''Surgeon General'' wherever appearing.

§ 247. Omitted

Section, act July 1, 1944, ch. 373, title III, § 315, as added Oct. 4, 1988, Pub. L. 100–471, § 1, 102 Stat. 2284, which related to grants for treatment drugs for acquired immune deficiency syndrome, ceased to exist Mar. 31, 1989, pursuant to subsec. (d) thereof.

PRIOR PROVISIONS

A prior section 247, act July 1, 1944, ch. 373, title III, § 315, as added Nov. 10, 1978, Pub. L. 95–626, title II, § 203,

92 Stat. 3578; amended July 10, 1979, Pub. L. 96–32, § 6(h), 93 Stat. 83, related to formula grants to States for preventive health service programs, prior to repeal by Pub. L. 99–117, § 12(b), Oct. 7, 1985, 99 Stat. 495.

Another prior section 247, acts July 1, 1944, ch. 373, title III, § 315, 58 Stat. 695; Oct. 30, 1970, Pub. L. 91–515, title II, § 282, 84 Stat. 1308, provided for publication of health educational information, prior to repeal by Pub. L. 93–353, title I, § 102(a), July 23, 1974, 88 Stat. 362. See section 242*o*(b) of this title.

§ 247a. Family support groups for Alzheimer's disease patients

(a) Establishment; priorities

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) National network to coordinate groups

The Secretary shall promote the establishment of a national network to coordinate the family support groups described in subsection (a) of this section.

(July 1, 1944, ch. 373, title III, § 316, as added Pub. L. 99–319, title IV, § 401, May 23, 1986, 100 Stat. 489; amended Pub. L. 103–43, title XX, § 2008(a), June 10, 1993, 107 Stat. 210.)

PRIOR PROVISIONS

A prior section 247a, act July 1, 1944, ch. 373, title III, § 316, as added Nov. 10, 1978, Pub. L. 95–626, title II, § 208(a), 92 Stat. 3586; amended Aug. 13, 1981, Pub. L. 97–35, title XXI, § 2193(a)(1)(A), 95 Stat. 826, related to lead-based paint poisoning prevention programs, prior to repeal by Pub. L. 97–35, title XXI, § 2193(b)(1), Aug. 13, 1981, 95 Stat. 827.

Another prior section 247a, act July 1, 1944, ch. 373, title III, § 316, as added Oct. 30, 1970, Pub. L. 91–515, title II, § 281, 84 Stat. 1307, provided for establishment, composition, qualifications of members, terms of office, vacancies, reappointment, compensation, travel expenses, and functions of National Advisory Council on Comprehensive Health Planning Programs, prior to repeal by Pub. L. 93–641, § 5(d), Jan. 4, 1975, 88 Stat. 2275.

AMENDMENTS

1993—Subsec. (c). Pub. L. 103–43 struck out subsec. (c) which read as follows: ''The Secretary shall report to Congress, not later than one year after May 23, 1986, on family support groups and the network of such groups established pursuant to this section.''

§ 247b. Project grants for preventive health services

(a) Grant authority

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) Application

No grant may be made under subsection (a) of this section 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) of this section;

(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) of this section will be provided in a manner consistent with the State health plan in effect under section 300m–3(c)[1] of this title 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 247[1] of this title;

(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) of this section;

(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) Approval; annual project review

(1) The Secretary shall not approve an application submitted under subsection (b) of this sec-

[1] See References in Text note below.

tion for a grant for a program for which a grant was previously made under subsection (a) of this section 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) of this section 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) Amount of grant; payment

The amount of a grant under subsection (a) of this section 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) Reduction

The Secretary, at the request of a recipient of a grant under subsection (a) of this section, 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) of 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 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) Recordkeeping; audit authority

(1) Each recipient of a grant under subsection (a) of this section 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) of this section that are pertinent to such grants.

(g) Use of grant funds; mandatory treatment prohibited

(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 in connection with programs assisted through grants under subsection (a) of this section.

(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) Reports

The Secretary shall include, as part of the report required by section 300u–4 of this title, a report on the extent of the problems presented by the diseases and conditions referred to in subsection (j) of this section; on the amount of funds obligated under grants under subsection (a) of this section in the preceding fiscal year for each of the programs listed in subsection (j) of this section; and on the effectiveness of the activities assisted under grants under subsection (a) of this section in controlling such diseases and conditions.

(i) Technical assistance

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) Authorization of appropriations

(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) of this section for preventive health service programs to immunize without charge children, adolescents, and adults against vaccine-preventable diseases, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1998 through 2005. Not more than 10 percent of the total amount appropriated under the preceding sentence for any fiscal year shall be available for grants under subsection (k)(1) of this section for such fiscal year.

(2) For grants under subsection (a) of this section for preventive health service programs for the provision without charge of immunizations with vaccines approved for use, and recommended for routine use, after October 1, 1997, there are authorized to be appropriated such sums as may be necessary.

(k) Additional grants to States, political subdivisions, and other public and nonprofit private entities

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

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

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

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

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

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

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

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

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

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

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

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

(July 1, 1944, ch. 373, title III, § 317, as added Pub. L. 87–868, § 2, Oct. 23, 1962, 76 Stat. 1155; amended Pub. L. 89–109, § 2, Aug. 5, 1965, 79 Stat. 435; Pub. L. 91–464, § 2, Oct. 16, 1970, 84 Stat. 988; Pub. L. 92–449, title I, § 101, Sept. 30, 1972, 86 Stat. 748; Pub. L. 93–354, § 4, July 23, 1974, 88 Stat. 376; Pub. L. 94–63, title VI, § 601, July 29, 1975, 89 Stat. 346; Pub. L. 94–317, title II, § 202(a), June 23, 1976, 90 Stat. 700; Pub. L. 94–380, § 2, Aug. 12, 1976, 90 Stat. 1113; Pub. L. 95–626, title II, §§ 202, 204(b)(2), Nov. 10, 1978, 92 Stat. 3574, 3583; Pub. L. 96–32, § 6(i), July 10, 1979, 93 Stat. 83; Pub. L. 97–35, title IX, § 928, Aug. 13, 1981, 95 Stat. 569; Pub. L. 98–555, § 2, Oct. 30, 1984, 98 Stat. 2854; Pub. L. 99–117, § 11(c), Oct. 7, 1985, 99 Stat. 495; Pub. L. 100–177, title I, §§ 110(a), 111, Dec. 1, 1987, 101 Stat. 990, 991; Pub. L. 101–368, § 2, Aug. 15, 1990, 104 Stat. 446; Pub. L. 101–502, § 2(a), Nov. 3, 1990, 104 Stat. 1285; Pub. L. 103–183, title III, § 301(b), Dec. 14, 1993, 107 Stat. 2235; Pub. L. 105–392, title III, § 303, Nov. 13, 1998, 112 Stat. 3586; Pub. L. 106–310, div. A, title XVII, § 1711, Oct. 17, 2000, 114 Stat. 1152.)

REFERENCES IN TEXT

Section 300m–3 of this title, referred to in subsec. (b)(3), was repealed by Pub. L. 99–660, title VII, § 701(a), Nov. 14, 1986, 100 Stat. 3799.

Section 247 of this title, referred to in subsec. (b)(3), was repealed by Pub. L. 99–117, § 12(b), Oct. 7, 1985, 99 Stat. 495.

AMENDMENTS

2000—Subsec. (j)(1). Pub. L. 106–310 substituted ''1998 through 2005'' for ''1998 through 2002'' in first sentence.

1998—Subsec. (j)(1). Pub. L. 105–392, § 303(1), substituted ''children, adolescents, and adults against vaccine-preventable diseases, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1998 through 2002.'' for ''individuals against vaccine-preventable diseases, there are authorized to be appropriated $205,000,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 through 1995.''

Subsec. (j)(2). Pub. L. 105–392, § 303(2), substituted ''1997'' for ''1990''.

1993—Subsec. (j). Pub. L. 103–183, § 301(b)(1), redesignated subpars. (A) and (B) of par. (1) as pars. (1) and (2), respectively, substituted ''established in paragraph (2)'' for ''established in subparagraph (B)'' in par. (1), and struck out former par. (2), which read as follows: ''For grants under subsection (a) of this section for preventive health service programs for the prevention, control, and elimination of tuberculosis, and for grants under subsection (k)(2) of this section, there are authorized to be appropriated $24,000,000 for fiscal year 1988, $31,000,000 for fiscal year 1989, $36,000,000 for fiscal year 1990, $36,000,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 through 1995. Not more than 10 percent of the total amount appropriated under the preceding sentence for any fiscal year shall be available for grants under subsection (k)(2) of this section for such fiscal year.''

Subsec. (k)(2). Pub. L. 103–183, § 301(b)(2)(A), (B), redesignated par. (3) as (2) and struck out former par. (2) which read as follows: ''The Secretary may make grants to States, political subdivisions of States, and other public and nonprofit private entities for—

''(A) research into the prevention, control, and elimination of tuberculosis, especially research concerning strains of tuberculosis resistant to drugs and research concerning cases of tuberculosis that affect certain populations;

''(B) demonstration projects for the prevention, control, and elimination of tuberculosis;

''(C) public information and education programs for prevention, control, and elimination of tuberculosis; and

''(D) education, training, and clinical skills improvement activities in the prevention, control, and elimination of tuberculosis for health professionals, including allied health personnel.''

Subsec. (k)(3). Pub. L. 103–183, § 301(b)(2)(B), redesignated par. (4) as (3). Former par. (3) redesignated (2).

Subsec. (k)(4), (5). Pub. L. 103–183, § 301(b)(2)(B), (C), redesignated par. (5) as (4) and made technical amendments to references to subsections (d), (e), and (f) of this section and subsection (a) of this section, to reflect change in references to corresponding provisions of original act. Former par. (4) redesignated (3).

Subsec. (*l*). Pub. L. 103–183, § 301(b)(3), struck out subsec. (*l*) which related to establishment and function of Advisory Council for the Elimination of Tuberculosis.

1990—Subsec. (j)(1)(A). Pub. L. 101–502, § 2(a)(1), substituted provisions authorizing appropriations for fiscal years 1991 through 1995 for provisions authorizing appropriations for fiscal years 1988 through 1990.

Subsec. (j)(1)(B). Pub. L. 101–502, § 2(a)(2), substituted Oct. 1, 1990, for Dec. 1, 1987, and provisions authorizing appropriations as may be necessary for provisions authorizing appropriations for fiscal years 1988 to 1990.

Subsec. (j)(1)(C). Pub. L. 101–502, § 2(a)(3), struck out subpar. (C) which, on the implementation of part 2 of subchapter XIX of this chapter, authorized appropriations for grants under subsec. (a) of this section for fiscal years 1988 to 1990.

Subsec. (j)(2). Pub. L. 101–368, § 2(c), inserted provisions authorizing appropriations of $36,000,000 for fiscal

year 1991, and such sums as may be necessary for fiscal years 1992 through 1995.

Pub. L. 101–368, § 2(a)(1), substituted ''preventive health service programs for the prevention, control, and elimination of tuberculosis'' for ''preventive health service programs for tuberculosis''.

Subsec. (k)(2)(A) to (D). Pub. L. 101–368, § 2(a)(2), substituted ''prevention, control, and elimination'' for ''prevention and control''.

Subsec. (*l*). Pub. L. 101–368, § 2(b), added subsec. (*l*).

1987—Subsec. (j). Pub. L. 100–177, §§ 110(a), 111(a), amended subsec. (j) generally, substituting provisions authorizing appropriations for fiscal years 1988 to 1990 for grants under subsecs. (a) and (k) of this section for former provisions authorizing appropriations for fiscal years 1982 to 1987 for grants under subsec. (a) of this section.

Subsec. (k). Pub. L. 100–177, § 111(b), added subsec. (k).

1985—Subsec. (j). Pub. L. 99–117 amended directory language of Pub. L. 97–35, § 928(b), to correct a technical error. See 1981 Amendment note below.

1984—Subsec. (j)(1). Pub. L. 98–555, § 2(a), substituted ''immunize individuals against vaccine-preventable diseases'' for ''immunize children against immunizable diseases'' and inserted provisions authorizing appropriations for fiscal years ending Sept. 30, 1985, 1986, and 1987.

Subsec. (j)(2). Pub. L. 98–555, § 2(b), inserted provisions authorizing appropriations for fiscal years ending Sept. 30, 1985, 1986, and 1987.

1981—Subsec. (a). Pub. L. 97–35, § 928(a), struck out par. (1) which related to grants to State health authorities, and redesignated par. (2) as entire section and, as so redesignated, struck out reference to former par. (1).

Subsec. (j). Pub. L. 97–35, § 928(b), as amended by Pub. L. 99–117, substituted provisions authorizing appropriations for fiscal years ending Sept. 30, 1982, 1983, and 1984, for provisions setting forth appropriations through fiscal year ending Sept. 30, 1981, and provisions setting forth limitations, conditions, etc., for appropriations.

1979—Subsec. (j)(4), (5). Pub. L. 96–32 added par. (4), redesignated former par. (4) as (5) and, in par. (5) as so redesignated, substituted ''paragraph (1), (2), (3), or (4)'' for ''paragraph (1), (2), or (3)''.

1978—Pub. L. 95–626, § 202, amended section generally, substituting provisions relating to project grants for preventive health services for provisions relating to grants for disease control programs.

Subsec. (g)(2). Pub. L. 95–626, § 204(b)(2), struck out ''Except as provided in section 247c of this title,'' before ''No funds appropriated under any provision of this chapter''.

1976—Pub. L. 94–317 amended section generally to include many non-communicable diseases as well as expanding coverage of communicable diseases, increased appropriations for grants, widened scope of Secretary's authority to make grants and enter into contracts to include nonprofit private entities, and required a report from the Secretary on the effectiveness of all Federal and other public and private activities in controlling the diseases covered under this section.

Subsecs. (j) to (*l*). Pub. L. 94–380 added subsecs. (j) to (*l*).

1975—Subsec. (d)(3). Pub. L. 94–63, § 601(b), inserted authorization of appropriation for fiscal year 1976.

Subsec. (h)(1). Pub. L. 94–63, § 601(a), inserted reference to diseases borne by rodents.

1974—Subsec. (a). Pub. L. 93–354, § 4(1)–(3), substituted ''communicable and other disease control'' for ''communicable disease control'', ''communicable and other diseases'' for ''communicable diseases'', and ''communicable and other disease control program'' for ''communicable disease program''.

Subsec. (b)(2)(C). Pub. L. 93–354, § 4(1), (4), substituted ''communicable or other disease'' for ''communicable disease'' in cl. (i) and ''communicable and other disease control'' for ''communicable disease control'' in cl. (ii).

Subsecs. (b)(3), (d)(1), (2), (3), (f)(1). Pub. L. 93–354, § 4(1), substituted ''communicable and other disease control'' for ''communicable disease control''.

Subsec. (h)(1). Pub. L. 93–354, § 4(1), (5), substituted ''communicable and other disease control'' for ''communicable disease control'' in two places and inserted reference to diabetes mellitus.

Subsec. (i). Pub. L. 93–354, § 4(1), substituted ''communicable and other disease control'' for ''communicable disease control''.

1972—Subsec. (a). Pub. L. 92–449 substituted provision for grants by the Secretary in consultation with the State health authority to agencies and political subdivisions of States, for former provision for grants by the Secretary with the approval of the State health authority to political subdivisions or instrumentalities of States, incorporated existing provisions in provision designated as cl. (1), inserting '', in the area served by the applicant for the grant,'', substituted a cl. (2) reading ''design of the applicant's communicable disease program to determine its effectiveness'', for former provision reading ''levels of performance in preventing and controlling such diseases'', struck out appropriations authorization of $75,000,000 and $90,000,000 for fiscal years ending June 30, 1971, and 1972, now covered for subsequent years in subsec. (d), and struck out provision for use of grants to meet cost of studies to determine the control needs of communities and the means of best meeting such needs, now covered in subsec. (h)(1) of this section.

Subsec. (b). Pub. L. 92–449 substituted provisions of par. (1) respecting applications for grants, submission, approval, form, and content of applications; par. (2) respecting application requirements; and par. (3) incorporating former subsec. (g) provisions respecting consent of individuals for former definitions provision now incorporated in subsec. (h) of this section.

Subsec. (c). Pub. L. 92–449 designated existing provisions as par. (1) and among minor punctuation changes inserted ''under grants'' after ''Payments''; and redesignated former subsec. (d) as par. (2), inserted ''of the Government'' after ''officer or employee'', substituted ''in detailing the personnel'' for ''personal services'', and struck out provision that reduced amount shall, for purposes of subsec. (c), be deemed to have been paid to the agency.

Subsec. (d). Pub. L. 92–449 substituted provisions respecting authorization of appropriations and limitation on use of funds for provisions respecting grant reduction.

Subsec. (e). Pub. L. 92–449 substituted provisions for emergency plan development and authorization of appropriations for provisions relating to use of funds.

Subsec. (f). Pub. L. 92–449 substituted provisions respecting conditional limitation on use of funds for provisions for an annual report.

Subsec. (g). Pub. L. 92–449 incorporated former subsec. (f) provisions in introductory text and cl. (3), prescribed a January 1 submission date, and inserted provisions of cls. (1), (2), and (4). Former subsec. (g) consent of individuals provision respecting communicable disease control and vaccination assistance were covered in subsec. (b)(3) of this section and section 247c(h) of this title.

Subsec. (h). Pub. L. 92–449 redesignated former subsec. (b) as (h), substituted in introductory text ''this section'' for ''this subsection'', and in par. (1) struck out ''venereal disease'' after ''tuberculosis,'', inserted ''(other than venereal disease)'' after ''other communicable diseases'', and included in definition of ''communicable disease control program'' vaccination programs, laboratory services, and control studies.

Subsec. (i). Pub. L. 92–449 redesignated former subsec. (e) as (i), inserted reference to agency of a State, and substituted ''under provisions of Federal law (other than this chapter)'' for ''under other provisions of this chapter or other Federal law''.

1970—Subsec. (a). Pub. L. 91–464 authorized appropriation of $75,000,000 for fiscal year ending June 30, 1971, and $90,000,000 for fiscal year ending June 30, 1972, and made award of grants dependent upon extent of communicable disease and success of programs and permitted use of grants for meeting cost of programs and

studies to control communicable diseases and struck out reference to purchase of vaccines and use of grants for salaries and expenses of personnel and to authority of the Surgeon General.

Subsec. (b). Pub. L. 91–464 substituted definitions of ''communicable disease control program'' and ''State'' for definition of ''immunization program''.

Subsec. (c). Pub. L. 91–464 substituted reference to Secretary for reference to Surgeon General and struck out provisions relating to purchasing and furnishing of vaccines and requirement of obtaining assurances from recipients of grants.

Subsec. (d). Pub. L. 91–464 substituted reference to Secretary for reference to Surgeon General and struck out reference to Public Health Service.

Subsec. (e). Pub. L. 91–464 struck out reference to title V of the Social Security Act and substituted provisions for the use of funds for the conduct of communicable disease control programs for provisions for the purchase of vaccine or for organizing, promoting, conducting, or participating in immunization programs.

Subsecs. (f), (g). Pub. L. 91–464 added subsecs. (f) and (g).

1965—Subsec. (a). Pub. L. 89–109, § 2(a), (b), (d)(1), inserted ''and each of the next three fiscal years'', substituted ''any fiscal year ending prior to July 1, 1968'' for ''the fiscal years ending June 30, 1963, and June 30, 1964'', ''tetanus, and measles'' for ''and tetanus'', ''of preschool age'' for ''under the age of five years'', and ''immunization'' for ''intensive community vaccination'', and permitted grants to be used to pay costs in connection with immunization of other infectious diseases.

Subsec. (b). Pub. L. 89–109, § 2(c), (d)(1), substituted ''against the diseases referred to in subsection (a) of this section'' for ''against poliomyelitis, diphtheria, whooping cough, and tetanus'', ''of preschool age'' for ''who are under the age of five years'' and ''immunization'' for ''intensive community vaccination'' in two places.

Subsec. (c). Pub. L. 89–109, § 2(d)(1), (e), inserted ''on the basis of estimates'' and ''(with necessary adjustments on account of underpayments or overpayments)'' in par. (1), and substituted ''immunization'' for ''intensive community vaccination'' in pars. (2) and (3).

EFFECTIVE DATE OF 1978 AMENDMENT

Section 202 of Pub. L. 95–626, as amended by Pub. L. 96–32, § 6(g), July 10, 1979, 93 Stat. 83, provided that the amendment made by that section is effective Oct. 1, 1978.

EFFECTIVE DATE OF 1976 AMENDMENT

Section 202(a) of Pub. L. 94–317 provided that the amendment made by that section is effective with respect to grants under this section for fiscal years beginning after June 30, 1975.

EFFECTIVE DATE OF 1975 AMENDMENT

Section 608 of title VI of Pub. L. 94–63 provided that: ''Except as may otherwise be specifically provided, the amendments made by this title [enacting sections 300c–21 and 300c–22 of this title, amending this section, and enacting provisions set out as notes under sections 289, 289k–2, and 1395x of this title] and by titles I [amending section 246 of this title and enacting provisions set out as notes under section 246 of this title], II [enacting sections 300a–6a and 300a–8 of this title, amending sections 300 and 300a–1 to 300a–4 of this title, repealing section 3505c of this title, and enacting provision set out as a note under section 300 of this title], III [enacting sections 2689 to 2689aa of this title, amending sections 2691 and 2693 to 2696 of this title, and enacting provisions set out as notes under section 2689 of this title], IV [amending sections 218 and 254b of this title and enacting provision set out as a note under section 254b of this title], and V [enacting section 254c of this title and amending section 246 of this title] of this Act shall take effect July 1, 1975. The amendments made by this title and by such titles to the provisions of law amended by this title and by such titles are made to such provisions as amended by title VII of this Act [amending sections 246, 254b, 300, 300a–1 to 300a–3 of this title and sections 2681, 2687, 2688a, 2688d, 2688j–1, 2688j–2, 2688*l*, 2688*l*–1, 2688n–1, 2688*o*, and 2688u of this title].''

EFFECTIVE DATE OF 1972 AMENDMENT

Section 102 of Pub. L. 92–449 provided that: ''The amendment made by section 101 of this title [amending this section] shall apply to grants made under section 317 of the Public Health Service Act [this section] after June 30, 1972, except that subsection (d) of such section as amended by section 101 [subsec. (d) of this section] shall take effect on the date of enactment of this Act [Sept. 30, 1972].''

ASSISTANCE OF ADMINISTRATOR OF VETERANS' AFFAIRS IN ADMINISTRATION OF NATIONAL SWINE FLU IMMUNIZATION PROGRAM OF 1976; CLAIMS FOR DAMAGES

Pub. L. 94–420, § 3, Sept. 23, 1976, 90 Stat. 1301, provided that, in order to assist Secretary of Health, Education, and Welfare in carrying out National Swine Flu Immunization Program of 1976 pursuant to 42 U.S.C. 247b(j), as added by Pub. L. 94–380, Administrator of Veterans' Affairs, in accordance with 42 U.S.C. 2476(j), could authorize administration of vaccine, procured under such program and provided by Secretary at no cost to Veterans' Administration, to eligible veterans (voluntarily requesting such vaccine) in connection with provision of care for a disability under chapter 17 of title 38, in any health care facility under jurisdiction of Administrator, and provided for consideration and processing of claims and suits for damages for personal injury or death, in connection with administration of vaccine.

STUDY BY SECRETARY OF SCOPE AND EXTENT OF LIABILITY ARISING OUT OF IMMUNIZATION PROGRAM; ALTERNATIVE PROTECTIVE APPROACHES; REPORT TO CONGRESS

Section 3 of Pub. L. 94–380 directed Secretary to conduct a study of liability for personal injuries or death arising out of immunization programs and of alternative approaches to provide protection against such liability and report to Congress on findings of such study by Aug. 12, 1977.

§ 247b–1. Screenings, referrals, and education regarding lead poisoning

(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 254b, 254b, or 256a of this title[1] 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) of this section 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 [42 U.S.C. 1396 et seq.] 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) of this section, 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) of this section, 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) of this section with related activities and services carried out in the State by grantees under title V or XIX of the Social Security Act [42 U.S.C. 701 et seq., 1396 et seq.].

(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) of this section.

(8) Such other information as the Secretary may prescribe.

[1] See References in Text notes below.

(e) Relationship to services and activities under other programs

(1) In general

A recipient of a grant under subsection (a) of this section 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) of this section provides services under such subsection if the Secretary has provided a waiver under subsection (b)(2) of this section regarding the provider.

(f) Method and amount of payment

The Secretary shall determine the amount of a grant made under subsection (a) of this section. 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) of this section, 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) of 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 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) of this section shall keep such records as the Secretary shall prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of such grant, the total cost of the 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) of this section, 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) of this section and of any programs that are carried out by the Secretary pursuant to subsection (*l*)(2) of this section.

(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) of this section 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.

(July 1, 1944, ch. 373, title III, § 317A, as added Pub. L. 100–572, § 3, Oct. 31, 1988, 102 Stat. 2887; amended Pub. L. 102–531, title III, § 303(a), Oct. 27, 1992, 106 Stat. 3484; Pub. L. 103–183, title VII, § 705(a), Dec. 14, 1993, 107 Stat. 2241; Pub. L. 105–392, title IV, § 404, Nov. 13, 1998, 112 Stat. 3588; Pub. L. 106–310, div. A, title XXV, §§ 2501(a), (b), 2504, Oct. 17, 2000, 114 Stat. 1161, 1164; Pub. L. 107–251, title VI, § 601(a), Oct. 26, 2002, 116 Stat. 1664; Pub. L. 108–163, § 2(m)(1), Dec. 6, 2003, 117 Stat. 2023.)

REFERENCES IN TEXT

The reference to section 254b of this title the first place appearing, referred to in subsec. (a)(2), was in the original a reference to section 329, meaning section 329 of act July 1, 1944, which was omitted in the general amendment of subpart I (§ 254b et seq.) of part D of this subchapter by Pub. L. 104–299, § 2, Oct. 11, 1996, 110 Stat. 3626.

Section 256a of this title, referred to in subsec. (a)(2), was repealed by Pub. L. 104–299, § 4(a)(3), Oct. 11, 1996, 110 Stat. 3645.

The Social Security Act, referred to in subsecs. (b)(1) and (d)(5), is act Aug. 14, 1935, ch. 531, 49 Stat. 620, as amended. Titles V and XIX of the Act are classified generally to subchapters V (§ 701 et seq.) and XIX (§ 1396 et seq.), respectively, of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

PRIOR PROVISIONS

A prior section 247b–1, Pub. L. 95–626, title IV, § 401, Nov. 10, 1978, 92 Stat. 3590; S. Res. 30, Mar. 7, 1979; Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695; H. Res. 549, Mar. 25, 1980, related to demonstration and evaluation of optimal methods for organizing and delivering comprehensive preventive health services to defined populations, prior to repeal by Pub. L. 97–35, title IX, § 902(a), (h), Aug. 13, 1981, 95 Stat. 559, 561, eff. Oct. 1, 1981.

AMENDMENTS

2003—Subsec. (a)(2). Pub. L. 108–163 substituted ''254b'' for ''254c, 254b(h)'' before '', or''.

2002—Subsec. (a)(2). Pub. L. 107–251 substituted ''254b(h)'' for ''256''.

2000—Subsec. (d)(7), (8). Pub. L. 106–310, § 2501(a)(1), added par. (7) and redesignated former par. (7) as (8).

Subsec. (j)(2)(F), (G). Pub. L. 106–310, § 2501(a)(2), added subpar. (F), redesignated former subpar. (F) as (G), and substituted ''(F)'' for ''(E)''.

Subsec. (*l*)(1). Pub. L. 106–310, § 2504, substituted ''1994 through 2005'' for ''1994 through 2002''.

Subsec. (m). Pub. L. 106–310, § 2501(b), added subsec. (m).

1998—Subsec. (*l*)(1). Pub. L. 105–392 substituted ''2002'' for ''1998''.

1993—Subsec. (*l*)(1). Pub. L. 103–183 substituted ''through 1998'' for ''through 1997''.

1992—Pub. L. 102–531 amended section generally, substituting present provisions for provisions relating to grants to States for lead poisoning prevention, grant applications, conditions for approval, method and amount of payment, reduction of amount, recordkeeping and audits, inclusion of Indian tribes as grant recipients, and authorization of appropriations.

EFFECTIVE DATE OF 2003 AMENDMENT

Amendment by Pub. L. 108–163 deemed to have taken effect immediately after the enactment of Pub. L. 107–251, see section 3 of Pub. L. 108–163, set out as a note under section 233 of this title.

DEVELOPMENT AND IMPLEMENTATION OF EFFECTIVE DATA MANAGEMENT BY THE CENTERS FOR DISEASE CONTROL AND PREVENTION

Pub. L. 106–310, div. A, title XXV, § 2501(c), Oct. 17, 2000, 114 Stat. 1161, provided that:

''(1) IN GENERAL.—The Director of the Centers for Disease Control and Prevention shall—

''(A) assist with the improvement of data linkages between State and local health departments and between State health departments and the Centers for Disease Control and Prevention;

''(B) assist States with the development of flexible, comprehensive State-based data management systems for the surveillance of children with lead poisoning that have the capacity to contribute to a national data set;

''(C) assist with the improvement of the ability of State-based data management systems and federally-funded means-tested public benefit programs (including the special supplemental food program for women, infants and children (WIC) under section 17 of the Child Nutrition Act of 1966 (42 U.S.C. 1786) and the early head start program under section 645A of the Head Start Act (42 U.S.C. 9840a(h)) to respond to ad hoc inquiries and generate progress reports regarding the lead blood level screening of children enrolled in those programs;

''(D) assist States with the establishment of a capacity for assessing how many children enrolled in the Medicaid, WIC, early head start, and other federally-funded means-tested public benefit programs are being screened for lead poisoning at age-appropriate intervals;

''(E) use data obtained as result of activities under this section to formulate or revise existing lead blood screening and case management policies; and

''(F) establish performance measures for evaluating State and local implementation of the requirements and improvements described in subparagraphs (A) through (E).

''(2) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this subsection such sums as may be necessary for each [sic] the fiscal years 2001 through 2005.

''(3) EFFECTIVE DATE.—This subsection takes effect on the date of the enactment of this Act [Oct. 17, 2000].''

§ 247b–2. Repealed. Pub. L. 97–35, title IX, § 902(a), Aug. 13, 1981, 95 Stat. 559

Section, Pub. L. 95–626, title IV, § 402, Nov. 10, 1978, 92 Stat. 3591; Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695, related to deterrence of smoking and alcoholic beverage use among children and adolescents.

EFFECTIVE DATE OF REPEAL

Repeal effective Oct. 1, 1981, see section 902(h) of Pub. L. 97–35, set out as an Effective Date of 1981 Amendment note under section 300aaa–12 of this title.

§ 247b–3. Education, technology assessment, and epidemiology regarding lead poisoning

(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 October 27, 1992, the Secretary shall establish a council to be known as the Interagency Task Force on the Prevention of Lead Poisoning (in this paragraph referred to as the ''Task Force''). The Task Force shall coordinate the efforts of Federal agencies to prevent lead poisoning.

(B) The Task Force shall be composed of—

(i) the Secretary, who shall serve as the chair of the Task Force;

(ii) the Secretary of Housing and Urban Development;

(iii) the Administrator of the Environmental Protection Agency; and

(iv) senior staff of each of the officials specified in clauses (i) through (iii), as selected by the officials respectively.

(C) The Task Force shall—

(i) review, evaluate, and coordinate current strategies and plans formulated by the officials serving as members of the Task Force, including—

(I) the plan of the Secretary of Health and Human Services entitled ''Strategic Plan for the Elimination of Lead Poisoning'', dated February 21, 1991;

(II) the plan of the Secretary of Housing and Urban Development entitled ''Comprehensive and Workable Plan for the Abatement of Lead-Based Paint in Privately Owned Housing'', dated December 7, 1990; and

(III) the strategy of the Administrator of the Environmental Protection Agency entitled ''Strategy for Reducing Lead Exposures'', dated February 21, 1991;

(ii) develop a unified implementation plan for programs that receive Federal financial assistance for activities related to the prevention of lead poisoning;

(iii) establish a mechanism for sharing and disseminating information among the agencies represented on the Task Force;

(iv) identify the most promising areas of research and education concerning lead poisoning;

(v) identify the practical and technological constraints to expanding lead poisoning prevention;

(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.

(July 1, 1944, ch. 373, title III, § 317B, as added Pub. L. 102–531, title III, § 303(b), Oct. 27, 1992, 106 Stat. 3488; amended Pub. L. 103–43, title XX, § 2008(i)(1)(B)(i), June 10, 1993, 107 Stat. 212.)

AMENDMENTS

1993—Pub. L. 103–43 made technical amendment to directory language of Pub. L. 102–531, § 303(b), which enacted this section.

CHANGE OF NAME

Committee on Labor and Human Resources of Senate changed to Committee on Health, Education, Labor, and Pensions of Senate by Senate Resolution No. 20, One Hundred Sixth Congress, Jan. 19, 1999.

Committee on Energy and Commerce of House of Representatives treated as referring to Committee on Commerce of House of Representatives by section 1(a) of Pub. L. 104–14, set out as a note preceding section 21 of Title 2, The Congress. Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

§ 247b–3a. Training and reports by the Health Resources and Services Administration

(a) Training

The Secretary of Health and Human Services, acting through the Administrator of the Health Resources and Services Administration and in collaboration with the Administrator of the Centers for Medicare & Medicaid Services and the Director of the Centers for Disease Control and Prevention, shall conduct education and training programs for physicians and other health care providers regarding childhood lead

poisoning, current screening and treatment recommendations and requirements, and the scientific, medical, and public health basis for those policies.

(b) Report

The Secretary of Health and Human Services, acting through the Administrator of the Health Resources and Services Administration, annually shall report to Congress on the number of children who received services through health centers established under section 254b of this title and received a blood lead screening test during the prior fiscal year, noting the percentage that such children represent as compared to all children who received services through such health centers.

(c) Authorization of appropriations

There are authorized to be appropriated to carry out this section such sums as may be necessary for each[1] the fiscal years 2001 through 2005.

(Pub. L. 106–310, div. A, title XXV, § 2503, Oct. 17, 2000, 114 Stat. 1163; Pub. L. 108–173, title IX, § 900(e)(6)(E), Dec. 8, 2003, 117 Stat. 2374.)

CODIFICATION

Section was enacted as part of the Children's Health Act of 2000, and not as part of the Public Health Service Act which comprises this chapter.

AMENDMENTS

2003—Subsec. (a). Pub. L. 108–173 substituted ''Centers for Medicare & Medicaid Services'' for ''Health Care Financing Administration''.

§ 247b–4. National Center on Birth Defects and Developmental Disabilities

(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) of this section), 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 247b–11 of this title 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 October 17, 2000.

(B) Relevant programs

The programs and functions described in this subparagraph are all programs and functions that—

(i) relate to birth defects; folic acid; cerebral palsy; mental retardation; child development; newborn screening; autism; fragile X syndrome; fetal alcohol syndrome; pediatric genetic disorders; disability prevention; or other relevant diseases, disorders, or conditions as determined[1] the Secretary; and

(ii) were carried out through the National Center for Environmental Health as of the day before October 17, 2000.

(C) Related transfers

Personnel employed in connection with the programs and functions specified in subparagraph (B), and amounts available for carrying out the programs and functions, are transferred to the Center, effective upon the expiration of the 180-day period beginning on October 17, 2000. 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) of this section, 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 de-

[1] So in original. Probably should be followed by ''of''.

[1] So in original. Probably should be followed by the word ''by''.

tailing 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. 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 December 3, 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.

(July 1, 1944, ch. 373, title III, § 317C, as added Pub. L. 102–531, title III, § 306(a), Oct. 27, 1992, 106 Stat. 3494; amended Pub. L. 103–43, title XX, § 2008(i)(1)(B)(iii), June 10, 1993, 107 Stat. 213; Pub. L. 105–168, § 2, Apr. 21, 1998, 112 Stat. 43; Pub. L. 106–310, div. A, title VI, § 611, Oct. 17, 2000, 114 Stat. 1119; Pub. L. 108–154, § 2, Dec. 3, 2003, 117 Stat. 1933.)

AMENDMENTS

2003—Subsec. (a)(2)(A). Pub. L. 108–154, § 2(1)(A), substituted ‘‘, developmental disabilities, and disabilities and health’’ for ‘‘and developmental disabilities’’ and ‘‘subsection (c)(2)’’ for ‘‘subsection (d)(2)’’.

Subsec. (a)(2)(D), (E). Pub. L. 108–154, § 2(1)(B)–(D), added subpars. (D) and (E).

Subsecs. (b), (c). Pub. L. 108–154, § 2(2),(4), redesignated subsecs. (c) and (d) as (b) and (c), respectively, and struck out former subsec. (b) which related to additional provisions regarding collection of data.

Subsec. (d). Pub. L. 108–154, § 2(4), redesignated subsec. (e) as (d). Former subsec. (d) redesignated (c).

Subsec. (d)(1). Pub. L. 108–154, § 2(3)(A), added par. (1) and struck out former par. (1) which read as follows: ‘‘contains information regarding the incidence and prevalence of birth defects and the extent to which birth defects have contributed to the incidence and prevalence of infant mortality;’’.

Subsec. (d)(3). Pub. L. 108–154, § 2(3)(B), inserted ‘‘, developmental disabilities, and secondary health conditions among individuals with disabilities’’ after ‘‘defects’’.

Subsec. (d)(5) to (7). Pub. L. 108–154, § 2(3)(C)–(E), added pars. (5) and (6) and redesignated former par. (5) as (7).

Subsec. (e). Pub. L. 108–154, § 2(5), added subsec. (e). Former subsec. (e) redesignated (d).

Subsec. (f). Pub. L. 108–154, § 2(6) substituted ‘‘such sums as may be necessary for each of fiscal years 2003 through 2007.’’ for ‘‘$30,000,000 for fiscal year 1999, $40,000,000 for fiscal year 2000, and such sums as may be necessary for each of the fiscal years 2001 and 2002.’’

2000—Pub. L. 106–310, § 611(1), substituted ‘‘National Center on Birth Defects and Developmental Disabilities’’ for ‘‘Programs regarding birth defects’’ in section catchline.

Subsec. (a). Pub. L. 106–310, § 611(2), added subsec. (a) and struck out heading and text of former subsec. (a) relating to Secretary’s responsibility, acting through the Centers for Disease Control and Prevention, to carry out programs regarding birth defects.

Subsec. (b)(1). Pub. L. 106–310, § 611(3), substituted ‘‘subsection (a)(2)(A) of this section’’ for ‘‘subsection (a)(1) of this section’’ in introductory provisions.

1998—Pub. L. 105–168 amended section generally, substituting present provisions for provisions which directed Secretary to encourage and assist States in collection and analysis of epidemiological data on birth defects and to establish and maintain National Information Clearinghouse on Birth Defects, required report not later than July 1, 1993, and biennially thereafter, and authorized appropriations for fiscal years 1993, 1994, and 1995.

1993—Pub. L. 103–43 made technical amendment to directory language of Pub. L. 102–531, § 306(a), which enacted this section.

CHANGE OF NAME

Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

Committee on Labor and Human Resources of Senate changed to Committee on Health, Education, Labor, and Pensions of Senate by Senate Resolution No. 20, One Hundred Sixth Congress, Jan. 19, 1999.

CONGRESSIONAL FINDINGS

Pub. L. 105–168, § 1(b), Apr. 21, 1998, 112 Stat. 43, provided that: ''Congress makes the following findings:

''(1) Birth defects are the leading cause of infant mortality, directly responsible for one out of every five infant deaths.

''(2) Thousands of the 150,000 infants born with a serious birth defect annually face a lifetime of chronic disability and illness.

''(3) Birth defects threaten the lives of infants of all racial and ethnic backgrounds. However, some conditions pose excess risks for certain populations. For example, compared to all infants born in the United States, Hispanic-American infants are more likely to be born with anencephaly spina bifida and other neural tube defects and African-American infants are more likely to be born with sickle-cell anemia.

''(4) Birth defects can be caused by exposure to environmental hazards, adverse health conditions during pregnancy, or genetic mutations. Prevention efforts are slowed by lack of information about the number and causes of birth defects. Outbreaks of birth defects may go undetected because surveillance and research efforts are underdeveloped and poorly coordinated.

''(5) Public awareness strategies, such as programs using folic acid vitamin supplements to prevent spina bifida and alcohol avoidance programs to prevent Fetal Alcohol Syndrome, are essential to prevent the heartache and costs associated with birth defects.''

§ 247b–4a. Early detection, diagnosis, and interventions for newborns and infants with hearing loss

(a) Definitions

For the purposes of this section only, the following terms in this section are defined as follows:

(1) Hearing screening

Newborn and infant hearing screening consists of objective physiologic procedures to detect possible hearing loss and to identify newborns and infants who, after rescreening, require further audiologic and medical evaluations.

(2) Audiologic evaluation

Audiologic evaluation consists of procedures to assess the status of the auditory system; to establish the site of the auditory disorder; the type and degree of hearing loss, and the potential effects of hearing loss on communication; and to identify appropriate treatment and referral options. Referral options should include linkage to State IDEA part C coordinating agencies or other appropriate agencies, medical evaluation, hearing aid/sensory aid assessment, audiologic rehabilitation treatment, national and local consumer, self-help, parent, and education organizations, and other family-centered services.

(3) Medical evaluation

Medical evaluation by a physician consists of key components including history, examination, and medical decision making focused on symptomatic and related body systems for the purpose of diagnosing the etiology of hearing loss and related physical conditions, and for identifying appropriate treatment and referral options.

(4) Medical intervention

Medical intervention is the process by which a physician provides medical diagnosis and direction for medical and/or surgical treatment options of hearing loss and/or related medical disorder associated with hearing loss.

(5) Audiologic rehabilitation

Audiologic rehabilitation (intervention) consists of procedures, techniques, and technologies to facilitate the receptive and expressive communication abilities of a child with hearing loss.

(6) Early intervention

Early intervention (e.g., nonmedical) means providing appropriate services for the child with hearing loss and ensuring that families of the child are provided comprehensive, consumer-oriented information about the full range of family support, training, information services, communication options and are given the opportunity to consider the full range of educational and program placements and options for their child.

(b) Purposes

The purposes of this section are to clarify the authority within the Public Health Service Act [42 U.S.C. 201 et seq.] to authorize statewide newborn and infant hearing screening, evaluation and intervention programs and systems, technical assistance, a national applied research program, and interagency and private sector collaboration for policy development, in order to assist the States in making progress toward the following goals:

(1) All babies born in hospitals in the United States and its territories should have a hearing screening before leaving the birthing facility. Babies born in other countries and residing in the United States via immigration or adoption should have a hearing screening as early as possible.

(2) All babies who are not born in hospitals in the United States and its territories should have a hearing screening within the first 3 months of life.

(3) Appropriate audiologic and medical evaluations should be conducted by 3 months for all newborns and infants suspected of having hearing loss to allow appropriate referral and provisions for audiologic rehabilitation, medical and early intervention before the age of 6 months.

(4) All newborn and infant hearing screening programs and systems should include a component for audiologic rehabilitation, medical and early intervention options that ensures linkage to any new and existing statewide systems of intervention and rehabilitative services for newborns and infants with hearing loss.

(5) Public policy in regard to newborn and infant hearing screening and intervention should be based on applied research and the recognition that newborns, infants, toddlers, and children who are deaf or hard-of-hearing have unique language, learning, and communication needs, and should be the result of consultation with pertinent public and private sectors.

(c) Statewide newborn and infant hearing screening, evaluation and intervention programs and systems

Under the existing authority of the Public Health Service Act [42 U.S.C. 201 et seq.], the Secretary of Health and Human Services (in this section referred to as the ''Secretary''), acting through the Administrator of the Health Resources and Services Administration, shall make awards of grants or cooperative agreements to develop statewide newborn and infant hearing screening, evaluation and intervention programs and systems for the following purposes:

(1) To develop and monitor the efficacy of statewide newborn and infant hearing screening, evaluation and intervention programs and systems. Early intervention includes referral to schools and agencies, including community, consumer, and parent-based agencies and organizations and other programs mandated by part C of the Individuals with Disabilities Education Act [20 U.S.C. 1431 et seq.], which offer programs specifically designed to meet the unique language and communication needs of deaf and hard-of-hearing newborns, infants, toddlers, and children.

(2) To collect data on statewide newborn and infant hearing screening, evaluation and intervention programs and systems that can be used for applied research, program evaluation and policy development.

(d) Technical assistance, data management, and applied research

(1) Centers for Disease Control and Prevention

Under the existing authority of the Public Health Service Act [42 U.S.C. 201 et seq.], the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall make awards of grants or cooperative agreements to provide technical assistance to State agencies to complement an intramural program and to conduct applied research related to newborn and infant hearing screening, evaluation and intervention programs and systems. The program shall develop standardized procedures for data management and program effectiveness and costs, such as—

(A) to ensure quality monitoring of newborn and infant hearing loss screening, evaluation, and intervention programs and systems;

(B) to provide technical assistance on data collection and management;

(C) to study the costs and effectiveness of newborn and infant hearing screening, evaluation and intervention programs and systems conducted by State-based programs in order to answer issues of importance to State and national policymakers;

(D) to identify the causes and risk factors for congenital hearing loss;

(E) to study the effectiveness of newborn and infant hearing screening, audiologic and medical evaluations and intervention programs and systems by assessing the health, intellectual and social developmental, cognitive, and language status of these children at school age; and

(F) to promote the sharing of data regarding early hearing loss with State-based birth defects and developmental disabilities monitoring programs for the purpose of identifying previously unknown causes of hearing loss.

(2) National Institutes of Health

Under the existing authority of the Public Health Service Act, 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.

(e) Coordination and collaboration

(1) In general

Under the existing authority of the Public Health Service Act [42 U.S.C. 201 et seq.], in carrying out programs under this section, the Administrator of the Health Resources and Services Administration, the Director of the Centers for Disease Control and Prevention, and the Director of the National Institutes of Health shall collaborate and consult with other Federal agencies; State and local agencies, including those responsible for early intervention services pursuant to title XIX of the Social Security Act [42 U.S.C. 1396 et seq.] (Medicaid Early and Periodic Screening, Diagnosis and Treatment Program); title XXI of the Social Security Act [42 U.S.C. 1397aa et seq.], (State Children's Health Insurance Program); title V of the Social Security Act [42 U.S.C. 701 et seq.] (Maternal and Child Health Block Grant Program); and part C of the Individuals with Disabilities Education Act [20 U.S.C. 1431 et seq.]; consumer groups of and that serve individuals who are deaf and hard-of-hearing and their families; appropriate national medical and other health and education specialty organizations; persons who are deaf and hard-of-hearing and their families; other qualified professional personnel who are proficient in deaf or hard-of-hearing children's language and who possess the specialized knowledge, skills, and attributes needed to serve deaf and hard-of-hearing newborns, infants, toddlers, children, and their families; third-party payers and managed care organizations; and related commercial industries.

(2) Policy development

Under the existing authority of the Public Health Service Act, the Administrator of the Health Resources and Services Administration, the Director of the Centers for Disease Control and Prevention, and the Director of

the National Institutes of Health shall coordinate and collaborate on recommendations for policy development at the Federal and State levels and with the private sector, including consumer, medical and other health and education professional-based organizations, with respect to newborn and infant hearing screening, evaluation and intervention programs and systems.

(3) State early detection, diagnosis, and intervention programs and systems; data collection

Under the existing authority of the Public Health Service Act, the Administrator of the Health Resources and Services Administration and the Director of the Centers for Disease Control and Prevention shall coordinate and collaborate in assisting States to establish newborn and infant hearing screening, evaluation and intervention programs and systems under subsection (c) of this section and to develop a data collection system under subsection (d) of this section.

(f) Rule of construction

Nothing in this section shall be construed to preempt any State law.

(g) Authorization of appropriations

(1) Statewide newborn and infant hearing screening, evaluation and intervention programs and systems

For the purpose of carrying out subsection (c) of this section under the existing authority of the Public Health Service Act [42 U.S.C. 201 et seq.], there are authorized to the Health Resources and Services Administration appropriations in the amount of $5,000,000 for fiscal year 2000, $8,000,000 for fiscal year 2001, and such sums as may be necessary for fiscal year 2002.

(2) Technical assistance, data management, and applied research; Centers for Disease Control and Prevention

For the purpose of carrying out subsection (d)(1) of this section under the existing authority of the Public Health Service Act, there are authorized to the Centers for Disease Control and Prevention, appropriations in the amount of $5,000,000 for fiscal year 2000, $7,000,000 for fiscal year 2001, and such sums as may be necessary for fiscal year 2002.

(3) Technical assistance, data management, and applied research; National Institute on Deafness and Other Communication Disorders

For the purpose of carrying out subsection (d)(2) of this section under the existing authority of the Public Health Service Act, there are authorized to the National Institute on Deafness and Other Communication Disorders appropriations for such sums as may be necessary for each of the fiscal years 2000 through 2002.

(Pub. L. 106–113, div. B, § 1000(a)(4) [title VI, § 601], Nov. 29, 1999, 113 Stat. 1535, 1501A–276.)

REFERENCES IN TEXT

The Public Health Service Act, referred to in subsecs. (b) to (e) and (g), is act July 1, 1944, ch. 373, 58 Stat. 682, as amended, which is classified generally to this chapter (§ 201 et seq.). For complete classification of this Act to the Code, see Short Title note set out under section 201 of this title and Tables.

The Individuals with Disabilities Education Act, referred to in subsecs. (c)(1) and (e)(1), is title VI of Pub. L. 91–230, Apr. 13, 1970, 84 Stat. 175, as amended. Part C of the Act is classified generally to subchapter III (§ 1431 et seq.) of chapter 33 of Title 20, Education. For complete classification of this Act to the Code, see section 1400 of Title 20 and Tables.

The Social Security Act, referred to in subsec. (e)(1), is act Aug. 14, 1935, ch. 531, 49 Stat. 620, as amended. Titles V, XIX, and XXI of the Act are classified generally to subchapters V (§ 701 et seq.), XIX (§ 1396 et seq.), and XXI (§ 1397aa et seq.), respectively, of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

CODIFICATION

Section was enacted as part of the Departments of Labor, Health, and Human Services, and Education, and Related Agencies Appropriations Act, 2000, and not as part of the Public Health Service Act which comprises this chapter.

§§ 247b–4b to 247b–4d. Repealed. Pub. L. 109–416, § 3(b)(1)–(3), Dec. 19, 2006, 120 Stat. 2829

Section 247b–4b, Pub. L. 106–310, div. A, title I, § 102, Oct. 17, 2000, 114 Stat. 1107, related to developmental disabilities surveillance and research programs.

Section 247b–4c, Pub. L. 106–310, div. A, title I, § 103, Oct. 17, 2000, 114 Stat. 1108, related to information and education.

Section 247b–4d, Pub. L. 106–310, div. A, title I, § 104, Oct. 17, 2000, 114 Stat. 1109, related to Inter-agency Autism Coordinating Committee.

§ 247b–4e. Repealed. Pub. L. 109–416, § 3(b)(4), Dec. 19, 2006, 120 Stat. 2829; Pub. L. 109–482, title I, § 104(b)(3)(D), Jan. 15, 2007, 120 Stat. 3694

Section, Pub. L. 106–310, div. A, title I, § 105, Oct. 17, 2000, 114 Stat. 1109, related to annual report to Congress concerning the implementation of this section and sections 247b–4b to 247b–4d and 284g of this title.

EFFECTIVE DATE OF REPEAL

Repeal by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as an Effective Date of 2007 Amendment note under section 281 of this title.

§ 247b–4f. Research relating to preterm labor and delivery and the care, treatment, and outcomes of preterm and low birthweight infants

(a) Omitted

(b) Studies on relationship between prematurity and birth defects

(1) In general

The Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control and Prevention, shall, subject to the availability of appropriations, conduct ongoing epidemiological studies on the relationship between prematurity, birth defects, and developmental disabilities.

(2) Report

Not later than 2 years after December 22, 2006, and every 2 years thereafter, the Sec-

retary of Health and Human Services, acting through the Director of the Centers for Disease Control and Prevention, shall submit to the appropriate committees of Congress reports concerning the progress and any results of studies conducted under paragraph (1).

(c) Pregnancy risk assessment monitoring survey

(1) In general

The Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control and Prevention, shall establish systems for the collection of maternal-infant clinical and biomedical information, including electronic health records, electronic databases, and biobanks, to link with the Pregnancy Risk Assessment Monitoring System (PRAMS) and other epidemiological studies of prematurity in order to track pregnancy outcomes and prevent preterm birth.

(2) Authorization of appropriations

There is authorized to be appropriated to carry out paragraph (1) $3,000,000 for each of fiscal years 2007 through 2011.

(d) Evaluation of existing tools and measures

The Secretary of Health and Human Services shall review existing tools and measures to ensure that such tools and measures include information related to the known risk factors of low birth weight and preterm birth.

(e) Authorization of appropriations

There is authorized to be appropriated to carry out this section, except for subsection (c), $5,000,000 for each of fiscal years 2007 through 2011.

(Pub. L. 109–450, § 3, Dec. 22, 2006, 120 Stat. 3341.)

CODIFICATION

Section is comprised of section 3 of Pub. L. 109–450. Subsec. (a) of section 3 of Pub. L. 109–450 amended section 241 of this title.

Section was enacted as part of the Prematurity Research Expansion and Education for Mothers who deliver Infants Early Act or the PREEMIE Act, and not as part of the Public Health Service Act which comprises this chapter.

PURPOSE

Pub. L. 109–450, § 2, Dec. 22, 2006, 120 Stat. 3341, provided that: ''It is the purpose of this Act [enacting this section and sections 247b–4g and 280g–5 of this title and amending sections 241 and 280g–4 of this title] to—

''(1) reduce rates of preterm labor and delivery;

''(2) work toward an evidence-based standard of care for pregnant women at risk of preterm labor or other serious complications, and for infants born preterm and at a low birthweight; and

''(3) reduce infant mortality and disabilities caused by prematurity.''

§ 247b–4g. Interagency Coordinating Council on Prematurity and Low Birthweight

(a) Purpose

It is the purpose of this section to stimulate multidisciplinary research, scientific exchange, and collaboration among the agencies of the Department of Health and Human Services and to assist the Department in targeting efforts to achieve the greatest advances toward the goal of reducing prematurity and low birthweight.

(b) Establishment

The Secretary of Health and Human Services shall establish an Interagency Coordinating Council on Prematurity and Low Birthweight (referred to in this section as the Council) to carry out the purpose of this section.

(c) Composition

The Council shall be composed of members to be appointed by the Secretary, including representatives of the agencies of the Department of Health and Human Services.

(d) Activities

The Council shall—

(1) annually report to the Secretary of Health and Human Services and Congress on current Departmental activities relating to prematurity and low birthweight;

(2) carry out other activities determined appropriate by the Secretary of Health and Human Services; and

(3) oversee the coordination of the implementation of this Act.

(Pub. L. 109–450, § 5, Dec. 22, 2006, 120 Stat. 3343.)

REFERENCES IN TEXT

This Act, referred to in subsec. (d)(3), is Pub. L. 109–450, Dec. 22, 2006, 120 Stat. 3341, known as the Prematurity Research Expansion and Education for Mothers who deliver Infants Early Act and also as the PREEMIE Act. For complete classification of this Act to the Code, see Short Title of 2006 Amendment note set out under section 201 of this title and Tables.

CODIFICATION

Section was enacted as part of the Prematurity Research Expansion and Education for Mothers who deliver Infants Early Act or the PREEMIE Act, and not as part of the Public Health Service Act which comprises this chapter.

§ 247b–5. Preventive health measures with respect to prostate cancer

(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[1] cancer screening and follow-up.

(4) To develop and disseminate public information and education programs for prostate cancer, including appropriate messages about the risks and benefits of prostate cancer

[1] So in original. Probably should be ''prostate''.

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) of this section 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) of this section 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 [42 U.S.C. 1396 et seq.] by the applicant involved toward the purpose described in paragraphs (1) and (2) of subsection (a) of this section.

(c) Education on significance of early detection

The Secretary may not make a grant under subsection (a) of this section unless the applicant involved agrees that, in carrying out subsection (a)(3) of this section, 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) of this section 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.[2]

(e) Additional required agreements

(1) Priority for low-income men

The Secretary may not make a grant under subsection (a) of this section 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) of this section 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 9902(2) of this title.

[2] So in original. Probably should be ''subsection.''

(3) Relationship to items and services under other programs

The Secretary may not make a grant under subsection (a) of this section 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) of this section 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) of this section 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) of this section 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) of this section 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;[3] 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) of this section 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) of this section 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[4] with a need for the services or activities described in subsection (a) of this section;

(3) the description provides information relating to the services and activities to be provided, including a description of the manner in which the services and activities will be coordinated with any similar services or activities of public or nonprivate entities; and

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

(h) Requirement of submission of application

The Secretary may not make a grant under subsection (a) of this section unless an application for the grant is submitted to the Secretary, the application contains the description of intended uses required in subsection (g) of this section, 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) of this section. 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) of this section. 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) of this section, 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) of this section 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 in-

[3] So in original. Probably should be ''subsection;''.

[4] So in original. Probably should be ''application''.

curred in complying with such request, expend the amounts withheld.

(k) "Units of local government" defined

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) of this section.

(July 1, 1944, ch. 373, title III, § 317D, as added Pub. L. 102–531, title III, § 308, Oct. 27, 1992, 106 Stat. 3495; amended Pub. L. 103–43, title XX, § 2010(i)(1)(B)(iv), June 10, 1993, 107 Stat. 213; Pub. L. 103–183, title VII, § 705(b), Dec. 14, 1993, 107 Stat. 2241; Pub. L. 105–392, title IV, § 401(a)(3), Nov. 13, 1998, 112 Stat. 3587; Pub. L. 106–505, title VI, § 602(a), Nov. 13, 2000, 114 Stat. 2345.)

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (b)(2)(C), is act Aug. 14, 1935, ch. 531, 49 Stat. 620, as amended. Title XIX of the Act is classified generally to subchapter XIX (§ 1396 et seq.) of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

AMENDMENTS

2000—Subsec. (a). Pub. L. 106–505, § 602(a)(1), added subsec. (a) and struck out heading and text of former subsec. (a). Text read as follows: ''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—

''(1) to screen men for prostate cancer as a preventive health measure;

''(2) to provide appropriate referrals for medical treatment of men screened pursuant to paragraph (1) and to ensure, to the extent practicable, the provision of appropriate follow-up services;

''(3) to develop and disseminate public information and education programs for the detection and control of prostate cancer;

''(4) to improve the education, training, and skills of health professionals (including appropriate allied health professionals) in the detection and control of prostate cancer;

''(5) to establish mechanisms through which the States and such departments can monitor the quality of screening procedures for prostate cancer, including the interpretation of such procedures; and

''(6) to evaluate activities conducted under paragraphs (1) through (5) through appropriate surveillance or program monitoring activities.''

Subsec. (*l*)(1). Pub. L. 106–505, § 602(a)(2), substituted ''2004'' for ''1998''.

1998—Subsec. (*l*)(1). Pub. L. 105–392 made technical amendment to directory language of Pub. L. 103–183. See 1993 Amendment note below.

1993—Pub. L. 103–43 made technical amendment to directory language of Pub. L. 102–531, § 308, which enacted this section.

Subsec. (*l*)(1). Pub. L. 103–183, as amended by Pub. L. 105–392, substituted ''through 1998'' for ''through 1996''.

EFFECTIVE DATE OF 1998 AMENDMENT

Amendment by Pub. L. 105–392 deemed to have taken effect immediately after enactment of Pub. L. 103–183, see section 401(e) of Pub. L. 105–392, set out as a note under section 242m of this title.

§ 247b–6. Preventive health services regarding tuberculosis

(a) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make grants to States, political subdivisions, and other public entities for preventive health service programs for the prevention, control, and elimination of tuberculosis.

(b) Research, demonstration projects, education, and training

With respect to the prevention, control, and elimination of tuberculosis, the Secretary may, directly or through grants to public or nonprofit private entities, carry out the following:

(1) Research, with priority given to research concerning strains of tuberculosis resistant to drugs and research concerning cases of tuberculosis that affect certain populations.

(2) Demonstration projects.

(3) Public information and education programs.

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

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

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

(c) Cooperation with providers of primary health services

The Secretary may make a grant under subsection (a) or (b) of this section 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 254b, 254b, or 256a of this title[1] or under subchapter III–A or XVII of this chapter.

(d) Application for grant

(1) In general

The Secretary may make a grant under subsection (a) or (b) of this section 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) of this section only if the application under paragraph (1) contains a plan re-

[1] See References in Text notes below.

garding the prevention, control, and elimination of tuberculosis in the geographic area with respect to which the grant is sought.

(e) Supplies and services in lieu of grant funds

(1) In general

Upon the request of a grantee under subsection (a) or (b) of this section, the Secretary may, subject to paragraph (2), provide supplies, equipment, and services for the purpose of aiding the grantee in carrying out the subsection involved and, for such purpose, may detail to the State any officer or employee of the Department of Health and Human Services.

(2) Corresponding reduction in payments

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

(f) Advisory Council

(1) In general

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

(2) General duties

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

(3) Certain activities

With respect to the elimination of tuberculosis, the Council shall—

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

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

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

(4) Composition

The Secretary shall determine the size and composition of the Council, and the frequency and scope of official meetings of the Council.

(5) Staff, information, and other assistance

The Secretary shall provide to the Council such staff, information, and other assistance as may be necessary to carry out the duties of the Council.

(g) Funding

(1) In general; allocation for emergency grants

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

(B) Of the amounts appropriated under subparagraph (A) for a fiscal year, the Secretary may reserve not more than 25 percent for emergency grants under subsection (a) of this section for any geographic area in which there is, relative to other areas, a substantial number of cases of tuberculosis or a substantial rate of increase in such cases.

(2) Research, demonstration projects, education, and training

For the purpose of carrying out subsection (b) of this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1994 through 2002.

(July 1, 1944, ch. 373, title III, § 317E, as added Pub. L. 103–183, title III, § 301(a), Dec. 14, 1993, 107 Stat. 2233; amended Pub. L. 105–392, title IV, §§ 401(b)(1), 405, Nov. 13, 1998, 112 Stat. 3587, 3588; Pub. L. 107–251, title VI, § 601(a), Oct. 26, 2002, 116 Stat. 1664; Pub. L. 108–163, § 2(m)(1), Dec. 6, 2003, 117 Stat. 2023.)

REFERENCES IN TEXT

The reference to section 254b of this title the first place appearing, referred to in subsec. (c), was in the original a reference to section 329, meaning section 329 of act July 1, 1944, which was omitted in the general amendment of subpart I (§ 254b et seq.) of part D of this subchapter by Pub. L. 104–299, § 2, Oct. 11, 1996, 110 Stat. 3626.

Section 256a of this title, referred to in subsec. (c), was repealed by Pub. L. 104–299, § 4(a)(3), Oct. 11, 1996, 110 Stat. 3645.

AMENDMENTS

2003—Subsec. (c). Pub. L. 108–163 substituted ''254b'' for ''254c, 254b(h)'' before '', or''.

2002—Subsec. (c). Pub. L. 107–251 substituted ''254b(h)'' for ''256''.

1998—Subsec. (g)(1)(A). Pub. L. 105–392, § 405(1)(A), substituted ''2002'' for ''1998''.

Subsec. (g)(1)(B). Pub. L. 105–392, § 405(1)(B), substituted ''25 percent'' for ''$50,000,000''.

Subsec. (g)(2). Pub. L. 105–392, § 405(2), substituted ''2002'' for ''1998''.

Pub. L. 105–392, § 401(b)(1), substituted ''carrying out subsection (b)'' for ''making grants under subsection (b)''.

EFFECTIVE DATE OF 2003 AMENDMENT

Amendment by Pub. L. 108–163 deemed to have taken effect immediately after the enactment of Pub. L. 107–251, see section 3 of Pub. L. 108–163, set out as a note under section 233 of this title.

EFFECTIVE DATE OF 1998 AMENDMENT

Amendment by section 401(b)(1) of Pub. L. 105–392 deemed to have taken effect immediately after enactment of Pub. L. 103–183, see section 401(e) of Pub. L. 105–392, set out as a note under section 242m of this title.

TERMINATION OF ADVISORY COUNCILS

Advisory councils established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless, in the case of a council established by the President or an officer of the Federal Government, such council is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a council established by Congress, its duration is otherwise provided by law. See sections 3(2) and 14 of Pub. L. 92–463, Oct. 6, 1972, 86 Stat. 770, 776, set out in the Appendix to Title 5, Government Organization and Employees.

Pub. L. 93–641, § 6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

§ 247b–7. Loan repayment program

(a) In general

(1) Authority

Subject to paragraph (2), the Secretary may carry out a program of entering into contracts with appropriately qualified health professionals under which such health professionals agree to conduct prevention activities, as employees of the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry, in consideration of the Federal Government agreeing to repay, for each year of such service, not more than $35,000 of the principal and interest of the educational loans of such health professionals.

(2) Limitation

The Secretary may not enter into an agreement with a health professional pursuant to paragraph (1) unless such professional—

(A) has a substantial amount of educational loans relative to income; and

(B) agrees to serve as an employee of the Centers for Disease Control and Prevention or the Agency for Toxic Substances and Disease Registry for purposes of paragraph (1) for a period of not less than 3 years.

(b) Applicability of certain provisions

With respect to the National Health Service Corps Loan Repayment Program established in subpart III of part D of this subchapter, the provisions of such subpart shall, except as inconsistent with subsection (a) of this section, apply to the program established in this section in the same manner and to the same extent as such provisions apply to the National Health Service Corps Loan Repayment Program.

(c) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated $500,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 through 2002.

(d) Availability of appropriations

Amounts appropriated for a fiscal year for contracts under subsection (a) of this section shall remain available until the expiration of the second fiscal year beginning after the fiscal year for which the amounts were appropriated.

(July 1, 1944, ch. 373, title III, § 317F, as added Pub. L. 103–183, title VII, § 703, Dec. 14, 1993, 107 Stat. 2240; amended Pub. L. 105–392, title IV, § 406, Nov. 13, 1998, 112 Stat. 3588.)

AMENDMENTS

1998—Subsec. (a)(1). Pub. L. 105–392, § 406(1), substituted "$35,000" for "$20,000".

Subsec. (c). Pub. L. 105–392, § 406(2), substituted "2002" for "1998".

Subsec. (d). Pub. L. 105–392, § 406(3), added subsec. (d).

§ 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.

(July 1, 1944, ch. 373, title III, § 317G, as added Pub. L. 105–115, title IV, § 408(b)(1), Nov. 21, 1997, 111 Stat. 2371.)

EFFECTIVE DATE

Section 408(b)(2) of Pub. L. 105–115 provided that: "The amendment made by this subsection [enacting this section] is deemed to have taken effect July 1, 1995."

§ 247b–9. Diabetes in children and youth

(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.

(July 1, 1944, ch. 373, title III, § 317H, as added Pub. L. 106–310, div. A, title IV, § 401, Oct. 17, 2000, 114 Stat. 1112.)

§ 247b–10. Compilation of data on asthma

(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) of this section, provide an update on surveillance activities at each Committee meeting.

(c) Collaborative efforts

The activities described in subsection (a)(1) of this section may be conducted in collaboration with eligible entities awarded a grant under section 280g of this title.

(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.

(July 1, 1944, ch. 373, title III, § 317I, as added Pub. L. 106–310, div. A, title V, § 531, Oct. 17, 2000, 114 Stat. 1117.)

§ 247b–11. Effects of folic acid in prevention of birth defects

(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) of this section, 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) of this section.

(d) Evaluations

The Secretary shall (directly or through grants or contracts) provide for the evaluation of activities under subsection (a) of this section in order to determine the extent to which such activities have been effective in carrying out the purposes of the program under such subsection, including the effects on various demographic populations. Methods of evaluation under the preceding sentence may include surveys of knowledge and attitudes on the consumption of folic acid and on blood folate levels. Such methods may include complete and timely monitoring of infants who are born with neural tube defects.

(e) Authorization of appropriations

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

(July 1, 1944, ch. 373, title III, § 317J, as added Pub. L. 106–310, div. A, title VI, § 601, Oct. 17, 2000, 114 Stat. 1118.)

§ 247b–12. Safe motherhood

(a) Surveillance

(1) Purpose

The purpose of this subsection is to develop surveillance systems at the local, State, and national level to better understand the burden of maternal complications and mortality and to decrease the disparities among population at risk of death and complications from pregnancy.

(2) Activities

For the purpose described in paragraph (1), the Secretary, acting through the Director of the Centers for Disease Control and Prevention, may carry out the following activities:

(A) The Secretary may establish and implement a national surveillance program to identify and promote the investigation of deaths and severe complications that occur during pregnancy.

(B) The Secretary may expand the Pregnancy Risk Assessment Monitoring System to provide surveillance and collect data in each State.

(C) The Secretary may expand the Maternal and Child Health Epidemiology Program to provide technical support, financial assistance, or the time-limited assignment of senior epidemiologists to maternal and child health programs in each State.

(b) Prevention research

(1) Purpose

The purpose of this subsection is to provide the Secretary with the authority to further expand research concerning risk factors, prevention strategies, and the roles of the family, health care providers and the community in safe motherhood.

(2) Research

The Secretary may carry out activities to expand research relating to—

(A) encouraging preconception counseling, especially for at risk populations such as diabetics;

(B) the identification of critical components of prenatal delivery and postpartum care;

(C) the identification of outreach and support services, such as folic acid education, that are available for pregnant women;

(D) the identification of women who are at high risk for complications;

(E) preventing preterm delivery;

(F) preventing urinary tract infections;

(G) preventing unnecessary caesarean sections;

(H) an examination of the higher rates of maternal mortality among African American women;

(I) an examination of the relationship between domestic violence and maternal complications and mortality;

(J) preventing and reducing adverse health consequences that may result from smoking, alcohol and illegal drug use before, during and after pregnancy;

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

(L) other areas determined appropriate by the Secretary.

(c) Prevention programs

(1) In general

The Secretary may carry out activities to promote safe motherhood, including—

(A) public education campaigns on healthy pregnancies and the building of partnerships with outside organizations concerned about safe motherhood;

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

(C) activities to promote community support services for pregnant women.

(d) Authorization of appropriations

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

(July 1, 1944, ch. 373, title III, § 317K, as added Pub. L. 106–310, div. A, title IX, § 901, Oct. 17, 2000, 114 Stat. 1125.)

§ 247b–13. Prenatal and postnatal health

(a) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall carry out programs—

(1) to collect, analyze, and make available data on prenatal smoking, alcohol and illegal drug use, including data on the implications of such activities and on the incidence and prevalence of such activities and their implications;

(2) to conduct applied epidemiological research on the prevention of prenatal and postnatal smoking, alcohol and illegal drug use;

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

(4) to provide information and education to the public on the prevention and implications of prenatal and postnatal smoking, alcohol and illegal drug use.

(b) Grants

In carrying out subsection (a) of this section, the Secretary may award grants to and enter into contracts with States, local governments, scientific and academic institutions, federally qualified health centers, and other public and nonprofit entities, and may provide technical and consultative assistance to such entities.

(c) Authorization of appropriations

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

(July 1, 1944, ch. 373, title III, § 317L, as added Pub. L. 106–310, div. A, title IX, § 911, Oct. 17, 2000, 114 Stat. 1127.)

§ 247b–14. Oral health promotion and disease prevention

(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 sys-

tems in improving the effectiveness of water fluoridation and to meet the recommendations of the EARWF.

(C) Fluoridation specialists

(i) In general

In carrying out this subsection, the Secretary shall provide for the establishment of fluoridation specialist engineering positions in each of the Dental Clinical and Preventive Support Centers through which technical assistance and training will be provided to tribal water operators, tribal utility operators and other Indian Health Service personnel working directly with fluoridation projects.

(ii) Liaison

A fluoridation specialist shall serve as the principal technical liaison between the Indian Health Service and the Centers for Disease Control and Prevention with respect to engineering and fluoridation issues.

(iii) CDC

The Director of the Centers for Disease Control and Prevention shall appoint individuals to serve as the fluoridation specialists.

(D) Implementation

The project established under this subsection shall be planned, implemented and evaluated over the 5-year period beginning on the date on which funds are appropriated under this section and shall be designed to serve as a model for improving the effectiveness of water fluoridation systems of small rural communities.

(3) Evaluation

In conducting the ongoing evaluation as provided for in paragraph (2)(D), the Secretary shall ensure that such evaluation includes—

(A) the measurement of changes in water fluoridation compliance levels resulting from assistance provided under this section;

(B) the identification of the administrative, technical and operational challenges that are unique to the fluoridation of small water systems;

(C) the development of a practical model that may be easily utilized by other tribal, State, county or local governments in improving the quality of water fluoridation with emphasis on small water systems; and

(D) the measurement of any increased percentage of Native Americans or Alaskan Natives who receive the benefits of optimally fluoridated water.

(c) School-based dental sealant program

(1) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention and in collaboration with the Administrator of the Health Resources and Services Administration, may award grants to States and Indian tribes to provide for the development of school-based dental sealant programs to improve the access of children to sealants.

(2) Use of funds

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

(3) Eligibility

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

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

(B) be a public elementary or secondary school—

(i) that is located in an urban area in which and[1] 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 9902(2) of this title.

(d) Definitions

For purposes of this section, the term ''Indian tribe'' means an Indian tribe or tribal organization as defined in section 450b(b) and section 450b(c)[2] of title 25.

(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.

(July 1, 1944, ch. 373, title III, § 317M, as added Pub. L. 106–310, div. A, title XVI, § 1602, Oct. 17, 2000, 114 Stat. 1148.)

REFERENCES IN TEXT

Section 450b of title 25, referred to in subsec. (d), has been amended, and subsecs. (b) and (c) of section 450b no longer define the terms ''Indian tribe'' and ''tribal organization''. However, such terms are defined elsewhere in that section.

§ 247b–14a. Identification of interventions that reduce the burden and transmission of oral, dental, and craniofacial diseases in high risk populations; development of approaches for pediatric oral and craniofacial assessment

(a) In general

The Secretary of Health and Human Services, through the Maternal and Child Health Bureau, the Indian Health Service, and in consultation with the National Institutes of Health and the Centers for Disease Control and Prevention, shall—

(1) support community-based research that is designed to improve understanding of the

[1] So in original. The word ''and'' probably should not appear.

[2] See References in Text note below.

etiology, pathogenesis, diagnosis, prevention, and treatment of pediatric oral, dental, craniofacial diseases and conditions and their sequelae in high risk populations;

(2) support demonstrations of preventive interventions in high risk populations including nutrition, parenting, and feeding techniques; and

(3) develop clinical approaches to assess individual patients for the risk of pediatric dental disease.

(b) Compliance with State practice laws

Treatment and other services shall be provided pursuant to this section by licensed dental health professionals in accordance with State practice and licensing laws.

(c) Authorization of appropriations

There are authorized to be appropriated such sums as may be necessary to carry out this section for each[1] the fiscal years 2001 through 2005.

(Pub. L. 106–310, div. A, title XVI, § 1601, Oct. 17, 2000, 114 Stat. 1148.)

CODIFICATION

Section was enacted as part of the Children's Health Act of 2000, and not as part of the Public Health Service Act which comprises this chapter.

§ 247b–15. Surveillance and education regarding hepatitis C virus

(a) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may (directly and through grants to public and nonprofit private entities) provide for programs to carry out the following:

(1) To cooperate with the States in implementing a national system to determine the incidence of hepatitis C virus infection (in this section referred to as ''HCV infection'') and to assist the States in determining the prevalence of such infection, including the reporting of chronic HCV cases.

(2) To identify, counsel, and offer testing to individuals who are at risk of HCV infection as a result of receiving blood transfusions prior to July 1992, or as a result of other risk factors.

(3) To provide appropriate referrals for counseling, testing, and medical treatment of individuals identified under paragraph (2) and to ensure, to the extent practicable, the provision of appropriate follow-up services.

(4) To develop and disseminate public information and education programs for the detection and control of HCV infection, with priority given to high risk populations as determined by the Secretary.

(5) To improve the education, training, and skills of health professionals in the detection and control of HCV infection, with priority given to pediatricians and other primary care physicians, and obstetricians and gynecologists.

(b) Laboratory procedures

The Secretary may (directly and through grants to public and nonprofit private entities) carry out programs to provide for improvements in the quality of clinical-laboratory procedures regarding hepatitis C, including reducing variability in laboratory results on hepatitis C antibody and PCR testing.

(c) Authorization of appropriations

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

(July 1, 1944, ch. 373, title III, § 317N, as added Pub. L. 106–310, div. A, title XVIII, § 1801, Oct. 17, 2000, 114 Stat. 1152.)

STUDY AND DEMONSTRATION PROJECTS REGARDING CASES OF HEPATITIS C AMONG CERTAIN EMERGENCY RESPONSE EMPLOYEES

Pub. L. 106–398, § 1 [[div. A], title XVII, § 1704], Oct. 30, 2000, 114 Stat. 1654, 1654A–365, provided that:

''(a) STUDY REGARDING PREVALENCE AMONG CERTAIN EMERGENCY RESPONSE EMPLOYEES.—

''(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the 'Secretary'), in consultation with the Secretary of Labor, shall conduct a study to determine—

''(A) an estimate of the prevalence of hepatitis C among designated emergency response employees in the United States; and

''(B) the likely means through which such employees become infected with such disease in the course of performing their duties as such employees.

''(2) DESIGNATED EMERGENCY RESPONSE EMPLOYEES.—For purposes of this section, the term 'designated emergency response employees' means firefighters, paramedics, and emergency medical technicians who are employees or volunteers of units of local government.

''(3) DATE CERTAIN FOR COMPLETION; REPORT TO CONGRESS.—The Secretary shall commence the study under paragraph (1) not later than 90 days after the date of the enactment of this Act [Oct. 30, 2000]. Not later than one year after such date, the Secretary shall complete the study and submit to the Congress a report describing the findings of the study.

''(b) DEMONSTRATION PROJECTS REGARDING TRAINING AND TREATMENT.—

''(1) IN GENERAL.—The Secretary, in consultation with the Secretary of Labor, shall make grants to qualifying local governments for the purpose of carrying out demonstration projects that (directly or through arrangements with nonprofit private entities) carry out each of the following activities:

''(A) Training designated emergency response employees in minimizing the risk of infection with hepatitis C in performing their duties as such employees.

''(B) Testing such employees for infection with the disease.

''(C) Treating the employees for the disease.

''(2) QUALIFYING LOCAL GOVERNMENTS.—For purposes of this section, the term 'qualifying local government' means a unit of local government whose population of designated emergency response employees has a prevalence of hepatitis C that is not less than 200 percent of the national average for the prevalence of such disease in such populations.

''(3) CONFIDENTIALITY.—A grant may be made under paragraph (1) only if the qualifying local government involved agrees to ensure that information regarding the testing or treatment of designated emergency response employees pursuant to the grant is maintained confidentially in a manner not inconsistent with applicable law.

''(4) EVALUATIONS.—The Secretary shall provide for an evaluation of each demonstration project under paragraph (1) in order to determine the extent to

[1] So in original. Probably should be followed by ''of''.

which the project has been effective in carry [sic] out the activities described in such paragraph.

''(5) REPORT TO CONGRESS.—Not later than 180 days after the date on which all grants under paragraph (1) have been expended, the Secretary shall submit to Congress a report providing—

''(A) a summary of evaluations under paragraph (4); and

''(B) the recommendations of the Secretary for administrative or legislative initiatives regarding the activities described in paragraph (1).

''(c) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there is authorized to be appropriated to the Department of Health and Human Services and the Department of Labor $10,000,000 for fiscal year 2001.''

§ 247b–16. Grants for lead poisoning related activities

(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 [42 U.S.C. 701 et seq., 1396 et seq., 1397aa et seq.]; 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 [42 U.S.C. 620 et seq., 670 et seq.];

(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 1786 of this title;

(D) local public and private elementary or secondary schools; or

(E) public housing agencies, as defined in section 1437a of this title.

(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.

(July 1, 1944, ch. 373, title III, § 317O, as added Pub. L. 106–310, div. A, title XXV, § 2502(a), Oct. 17, 2000, 114 Stat. 1162.)

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (b)(1), (2)(A), is act Aug. 14, 1935, ch. 531, 49 Stat. 620, as amended. Parts B and E of title IV of the Act are classified generally to parts B (§ 620 et seq.) and E (§ 670 et seq.), respectively, of subchapter IV of chapter 7 of this title. Titles V, XIX, and XXI of the Act are classified generally to subchapters V (§ 701 et seq.), XIX (§ 1396 et seq.), and XXI (§ 1397aa et seq.), respectively, of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

The Head Start Act, referred to in subsec. (b)(2)(B), is subchapter B (§§ 635–657) of chapter 8 of subtitle A of title VI of Pub. L. 97–35, Aug. 13, 1981, 95 Stat. 499, as amended, which is classified generally to subchapter II (§ 9831 et seq.) of chapter 105 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 9801 of this title and Tables.

§ 247b–17. Human papillomavirus (Johanna's Law)

(a) Surveillance

(1) In general

The Secretary, acting through the Centers for Disease Control and Prevention, shall—

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

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

(2) Report

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

(b) Prevention activities; education program

(1) In general

The Secretary, acting through the Centers for Disease Control and Prevention, shall conduct prevention research on HPV, including—

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

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

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

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

(d) Johanna's Law

(1) National public awareness campaign

(A) In general

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

(B) Written materials

Activities under the national campaign under subparagraph (A) shall include—

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

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

(C) Public service announcements

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

(2) Report and strategy

(A) Report

Not later than 6 months after January 12, 2007, 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) 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.

(July 1, 1944, ch. 373, title III, § 317P, as added Pub. L. 106–554, § 1(a)(1) [title V, § 516(a)], Dec. 21, 2000, 114 Stat. 2763, 2763A–72; amended Pub. L. 109–475, § 2, Jan. 12, 2007, 120 Stat. 3565.)

REFERENCES IN TEXT

Johanna's Law, referred to in section catchline and subsec. (d), is Pub. L. 109–475, Jan. 12, 2007, 120 Stat. 3565, also known as the Gynecologic Cancer Education and Awareness Act of 2005, which amended this section. For complete classification of this Act to the Code, see Short Title of 2007 Amendment note set out under section 201 of this title and Tables.

The effective date of this section, referred to in subsecs. (a)(2) and (b)(2), is the date of enactment of Pub. L. 106–554, which was approved Dec. 21, 2000.

AMENDMENTS

2007—Pub. L. 109–475, § 2(1), inserted "(Johanna's Law)" after "papillomavirus" in section catchline.

Subsec. (d). Pub. L. 109–475, § 2(2), added subsec. (d).

§ 247b–18. Surveillance and research regarding muscular dystrophy

(a) In general

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

(b) National muscular dystrophy epidemiology program

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may award grants to public or nonprofit private entities (including health departments of States and political subdivisions of States, and including universities and other educational entities) for the purpose of carrying out epidemiological activities regarding Duchenne and other forms of muscular dystrophies, including collecting and analyzing information on the number, incidence, correlates, and symptoms of cases. In carrying out the preceding sentence, the Secretary shall provide for a national surveillance program. In making awards under this 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) of this section is made available to centers of excellence supported under section 283g(b) of this title by the Director of the National Institutes of Health.

(d) Authorization of appropriations

There are authorized to be appropriated such sums as may be necessary to carry out this section.

(July 1, 1944, ch. 373, title III, § 317Q, as added Pub. L. 107–84, § 4, Dec. 18, 2001, 115 Stat. 828.)

FINDINGS

Pub. L. 107–84, § 2, Dec. 18, 2001, 115 Stat. 823, provided that: "Congress makes the following findings:

"(1) Of the childhood muscular dystrophies, Duchenne Muscular Dystrophy (DMD) is the world's most common and catastrophic form of genetic childhood disease, and is characterized by a rapidly progressive muscle weakness that almost always results in death, usually by 20 years of age.

"(2) Duchenne muscular dystrophy is genetically inherited, and mothers are the carriers in approximately 70 percent of all cases.

"(3) If a female is a carrier of the dystrophin gene, there is a 50 percent chance per birth that her male

offspring will have Duchenne muscular dystrophy, and a 50 percent chance per birth that her female offspring will be carriers.

''(4) Duchenne is the most common lethal genetic disorder of childhood worldwide, affecting approximately 1 in every 3,500 boys worldwide.

''(5) Children with muscular dystrophy exhibit extreme symptoms of weakness, delay in walking, waddling gait, difficulty in climbing stairs, and progressive mobility problems often in combination with muscle hypertrophy.

''(6) Other forms of muscular dystrophy affecting children and adults include Becker, limb girdle, congenital, facioscapulohumeral, myotonic, oculopharyngeal, distal, and Emery-Dreifuss muscular dystrophies.

''(7) Myotonic muscular dystrophy (also known as Steinert's disease and dystrophia myotonica) is the second most prominent form of muscular dystrophy and the type most commonly found in adults. Unlike any of the other muscular dystrophies, the muscle weakness is accompanied by myotonia (delayed relaxation of muscles after contraction) and by a variety of abnormalities in addition to those of muscle.

''(8) Facioscapulohumeral muscular dystrophy (referred to in this section as 'FSHD') is a neuromuscular disorder that is inherited genetically and has an estimated frequency of 1 in 20,000. FSHD, affecting between 15,000 to 40,000 persons, causes a progressive and sever [sic] loss of skeletal muscle gradually bringing weakness and reduced mobility. Many persons with FSHD become severely physically disabled and spend many decades in a wheelchair.

''(9) FSHD is regarded as a novel genetic phenomenon resulting from a crossover of subtelomeric DNA and may be the only human disease caused by a deletion-mutation.

''(10) Each of the muscular dystrophies, though distinct in progressivity and severity of symptoms, have a devastating impact on tens of thousands of children and adults throughout the United States and worldwide and impose severe physical and economic burdens on those affected.

''(11) Muscular dystrophies have a significant impact on quality of life—not only for the individual who experiences its painful symptoms and resulting disability, but also for family members and caregivers.

''(12) Development of therapies for these disorders, while realistic with recent advances in research, is likely to require costly investments and infrastructure to support gene and other therapies.

''(13) There is a shortage of qualified researchers in the field of neuromuscular research.

''(14) Many family physicians and health care professionals lack the knowledge and resources to detect and properly diagnose the disease as early as possible, thus exacerbating the progressiveness of symptoms in cases that go undetected or misdiagnosed.

''(15) There is a need for efficient mechanisms to translate clinically relevant findings in muscular dystrophy research from basic science to applied work.

''(16) Educating the public and health care community throughout the country about this devastating disease is of paramount importance and is in every respect in the public interest and to the benefit of all communities.''

REPORT TO CONGRESS

Pub. L. 107–84, § 6, Dec. 18, 2001, 115 Stat. 829, which directed the Secretary of Health and Human Services to prepare and submit to appropriate committees of Congress a report concerning the implementation of Pub. L. 107–84 not later than Jan. 1, 2003, and each Jan. 1 thereafter, was repealed by Pub. L. 109–482, title I, § 104(b)(3)(H), Jan. 15, 2007, 120 Stat. 3694.

§ 247b–19. Information and education

(a) In general

The Secretary of Health and Human Services (referred to in this Act as the ''Secretary'') shall establish and implement a program to provide information and education on muscular dystrophy to health professionals and the general public, including information and education on advances in the diagnosis and treatment of muscular dystrophy and training and continuing education through programs for scientists, physicians, medical students, and other health professionals who provide care for patients with muscular dystrophy.

(b) Stipends

The Secretary may use amounts made available under this section provides[1] stipends for health professionals who are enrolled in training programs under this section.

(c) Authorization of appropriations

There are authorized to be appropriated such sums as may be necessary to carry out this section.

(Pub. L. 107–84, § 5, Dec. 18, 2001, 115 Stat. 828.)

REFERENCES IN TEXT

This Act, referred to in subsec. (a), is Pub. L. 107–84, Dec. 18, 2001, 115 Stat. 823, known as the Muscular Dystrophy Community Assistance, Research and Education Amendments of 2001 and also as the MD–CARE Act. For complete classification of this Act to the Code, see Short Title of 2001 Amendment note set out under section 201 of this title and Tables.

CODIFICATION

Section was enacted as part of the Muscular Dystrophy Community Assistance, Research and Education Amendments of 2001, also known as the MD–CARE Act, and not as part of the Public Health Service Act which comprises this chapter.

§ 247b–20. Food safety grants

(a) In general

The Secretary may award grants to States and Indian tribes (as defined in section 450b(e) of title 25) to expand participation in networks to enhance Federal, State, and local food safety efforts, including meeting the costs of establishing and maintaining the food safety surveillance, technical, and laboratory capacity needed for such participation.

(b) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated $19,500,000 for fiscal year 2002, and such sums as may be necessary for each of the fiscal years 2003 through 2006.

(July 1, 1944, ch. 373, title III, § 317R, as added Pub. L. 107–188, title III, § 312, June 12, 2002, 116 Stat. 674; amended Pub. L. 108–75, § 2(1), Aug. 15, 2003, 117 Stat. 898.)

AMENDMENTS

2003—Pub. L. 108–75 made technical amendment relating to placement of section within original act.

[1] So in original. Probably should be ''to provide''.

§ 247b–21. Mosquito-borne diseases; coordination grants to States; assessment and control grants to political subdivisions

(a) Coordination grants to States; assessment grants to political subdivisions

(1) In general

With respect to mosquito control programs to prevent and control mosquito-borne diseases (referred to in this section as ''control programs''), the Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make grants to States for the purpose of—

(A) coordinating control programs in the State involved; and

(B) assisting such State in making grants to political subdivisions of the State to conduct assessments to determine the immediate needs in such subdivisions for control programs, and to develop, on the basis of such assessments, plans for carrying out control programs in the subdivisions.

(2) Preference in making grants

In making grants under paragraph (1), the Secretary shall give preference to States that have one or more political subdivisions with an incidence, prevalence, or high risk of mosquito-borne disease, or a population of infected mosquitoes, that is substantial relative to political subdivisions in other States.

(3) Certain requirements

A grant may be made under paragraph (1) only if—

(A) the State involved has developed, or agrees to develop, a plan for coordinating control programs in the State, and the plan takes into account any assessments or plans described in subsection (b)(3) of this section 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) of this section from such subdivisions.

(5) Number of grants

A State may not receive more than one grant under paragraph (1).

(b) Prevention and control grants to political subdivisions

(1) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make grants to political subdivisions of States or consortia of political subdivisions of States, for the operation of control programs.

(2) Preference in making grants

In making grants under paragraph (1), the Secretary shall give preference to a political subdivision or consortium of political subdivisions that—

(A) has—

(i) a history of elevated incidence or prevalence of mosquito-borne disease;

(ii) a population of infected mosquitoes; or

(iii) met criteria determined by the Secretary to suggest an increased risk of elevated incidence or prevalence of mosquito-borne disease in the pending fiscal year;

(B) demonstrates to the Secretary that such political subdivision or consortium of political subdivisions will, if appropriate to the mosquito circumstances involved, effectively coordinate the activities of the control programs with contiguous political subdivisions;

(C) demonstrates to the Secretary (directly or through State officials) that the State in which such a political subdivision or consortium of political subdivisions is located has identified or will identify geographic areas in such State that have a significant need for control programs and will effectively coordinate such programs in such areas; and

(D) is located in a State that has received a grant under subsection (a) of this section.

(3) Requirement of assessment and plan

A grant may be made under paragraph (1) only if the political subdivision or consortium of political subdivisions involved—

(A) has conducted an assessment to determine the immediate needs in such subdivision or consortium for a control program, including an entomological survey of potential mosquito breeding areas; and

(B) has, on the basis of such assessment, developed a plan for carrying out such a program.

(4) Requirement of matching funds

(A) In general

With respect to the costs of a control program to be carried out under paragraph (1)

by a political subdivision or consortium of political subdivisions, a grant under such paragraph may be made only if the subdivision or consortium agrees to make available (directly or through donations from public or private entities) non-Federal contributions toward such costs in an amount that is not less than ⅓ of such costs ($1 for each $2 of Federal funds provided in the grant).

(B) Determination of amount contributed

Non-Federal contributions required in subparagraph (A) may be in cash or in kind, fairly evaluated, including plant, equipment, or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

(C) Waiver

The Secretary may waive the requirement established in subparagraph (A) if the Secretary determines that extraordinary economic conditions in the political subdivision or consortium of political subdivisions involved justify the waiver.

(5) Reports to Secretary

A grant may be made under paragraph (1) only if the political subdivision or consortium of political subdivisions involved agrees that, promptly after the end of the fiscal year for which the grant is made, the subdivision or consortium will submit to the Secretary, and to the State within which the subdivision or consortium is located, a report that describes the control program and contains an evaluation of whether the program was effective.

(6) Amount of grant; number of grants

(A) Amount of grant

(i) Single political subdivision

A grant under paragraph (1) awarded to a political subdivision for a fiscal year may not exceed $100,000.

(ii) Consortium

A grant under paragraph (1) awarded to a consortium of 2 or more political subdivisions may not exceed $110,000 for each political subdivision. A consortium is not required to provide matching funds under paragraph (4) for any amounts received by such consortium in excess of amounts each political subdivision would have received separately.

(iii) Waiver of requirement

A grant may exceed the maximum amount in clause (i) or (ii) if the Secretary determines that the geographical area covered by a political subdivision or consortium awarded a grant under paragraph (1) has an extreme need due to the size or density of—

(I) the human population in such geographical area; or

(II) the mosquito population in such geographical area.

(B) Number of grants

A political subdivision or a consortium of political subdivisions may not receive more than one grant under paragraph (1).

(c) Applications for grants

A grant may be made under subsection (a) or (b) of this section 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) of this section 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) of this section and control programs under subsection (b) of this section. The Secretary may provide such technical assistance directly or through awards of grants or contracts to public and private entities.

(e) Definition of political subdivision

In this section, the term ''political subdivision'' means the local political jurisdiction immediately below the level of State government, including counties, parishes, and boroughs. If State law recognizes an entity of general government that functions in lieu of, and is not within, a county, parish, or borough, the Secretary may recognize an area under the jurisdiction of such other entities of general government as a political subdivision for purposes of this section.

(f) Authorization of appropriations

(1) In general

For the purpose of carrying out this section, there are authorized to be appropriated $100,000,000 for fiscal year 2003, and such sums as may be necessary for each of fiscal years 2004 through 2007.

(2) Public health emergencies

In the case of control programs carried out in response to a mosquito-borne disease that constitutes a public health emergency, the authorization of appropriations under paragraph (1) is in addition to applicable authorizations of appropriations under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

(3) Fiscal year 2004 appropriations

For fiscal year 2004, 50 percent or more of the funds appropriated under paragraph (1) shall be used to award grants to political subdivisions or consortia of political subdivisions under subsection (b) of this section.

(July 1, 1944, ch. 373, title III, § 317S, as added Pub. L. 108–75, § 2(2), Aug. 15, 2003, 117 Stat. 898.)

REFERENCES IN TEXT

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, referred to in subsec. (f)(2), is Pub. L. 107–188, June 12, 2002, 116 Stat. 594, as amended. For complete classification of this Act to the Code, see Short Title of 2002 Amendments note set out under section 201 of this title and Tables.

§ 247c. Sexually transmitted diseases; prevention and control projects and programs

(a) Technical assistance to public and nonprofit private entities and scientific institutions

The Secretary may provide technical assistance to appropriate public and nonprofit 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) Research, demonstration, and public information and education projects

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) Project grants to States

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) Grants for innovative, interdisciplinary approaches

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) Authorization of appropriations; terms and conditions; payments; recordkeeping; audit; grant reduction; information disclosure

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

(2) Each recipient of a grant under this section shall keep such records as the Secretary shall prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of such grant, the total cost of the project or undertaking in connection with which such grant was given or used, and the amount of that portion of the cost of the project or undertaking supplied by other sources, and such other records as will facilitate an effective audit.

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

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

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

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

(B) for clinical or research purposes;

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

(f) Consent of individuals

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.

(July 1, 1944, ch. 373, title III, § 318, as added Pub. L. 92–449, title II, § 203, Sept. 30, 1972, 86 Stat. 751; amended Pub. L. 94–317, title II, § 203(b)–(i), June 23, 1976, 90 Stat. 704, 705; Pub. L. 94–484, title IX, § 905(b)(2), Oct. 12, 1976, 90 Stat. 2325; Pub. L. 95–626, title II, § 204(b)(1), (c), (d), Nov. 10, 1978, 92 Stat. 3583; Pub. L. 96–32, § 6(j), July 10, 1979, 93 Stat. 84; Pub. L. 97–35, title IX, § 929, Aug. 13, 1981, 95 Stat. 569; Pub. L. 98–555, § 3, Oct. 30, 1984, 98 Stat. 2854; Pub. L. 100–607, title III, § 311, Nov. 4, 1988, 102 Stat. 3112; Pub. L. 103–183, title IV,

§ 401, Dec. 14, 1993, 107 Stat. 2236; Pub. L. 105–392, title IV, § 401(b)(2), (c), Nov. 13, 1998, 112 Stat. 3587.)

PRIOR PROVISIONS

A prior section 247c, act July 1, 1944, ch. 373 title III, § 318, as added Aug. 18, 1964, Pub. L. 88–443, § 2, 78 Stat. 447, related to grants for assisting in the areawide planning of health and related facilities, prior to repeal by Pub. L. 89–749, § 6, Nov. 3, 1966, 80 Stat. 1190 eff. July 1, 1967.

AMENDMENTS

1998—Subsec. (e). Pub. L. 105–392, § 401(b)(2), redesignated subsec. (e), relating to consent of individuals, as (f).

Subsec. (e)(5). Pub. L. 105–392, § 401(c), made technical amendment to directory language of Pub. L. 103–183, § 401(c)(3). See 1993 Amendment note below.

Subsec. (f). Pub. L. 105–392, § 401(b)(2), redesignated subsec. (e), relating to consent of individuals, as (f).

1993—Subsec. (b)(3). Pub. L. 103–183, § 401(c)(1), substituted ''; and'' for '', and''.

Subsec. (c)(3). Pub. L. 103–183, § 401(c)(2), which directed the substitution of ''; and'' for '', and'', could not be executed because '', and'' did not appear.

Subsec. (d). Pub. L. 103–183, § 401(a)(2), added subsec. (d). Former subsec. (d) redesignated (e).

Subsec. (e). Pub. L. 103–183, § 401(a)(1), redesignated subsec. (d), relating to authorization of appropriations, etc., as (e).

Subsec. (e)(1). Pub. L. 103–183, § 401(b), amended par. (1) generally. Prior to amendment, par. (1) read as follows: ''For the purpose of making grants under subsections (b) and (c) of this section there are authorized to be appropriated $45,000,000 for the fiscal year ending September 30, 1979, $51,500,000 for the fiscal year ending September 30, 1980, $59,000,000 for the fiscal year ending September 30, 1981, $40,000,000 for the fiscal year ending September 30, 1982, $46,500,000 for the fiscal year ending September 30, 1983, $50,000,000 for the fiscal year ending September 30, 1984, $57,000,000 for the fiscal year ending September 30, 1985, $62,500,000 for the fiscal year ending September 30, 1986, $68,000,000 for the fiscal year ending September 30, 1987, $78,000,000 for fiscal year 1989, and such sums as may be necessary for each of the fiscal years 1990 and 1991. For grants under subsection (b) of this section in any fiscal year, the Secretary shall obligate not less than 10 per centum of the amount appropriated for such fiscal year under the preceding sentence. Grants made under subsection (b) or (c) of this section shall be made on such terms and conditions as the Secretary finds necessary to carry out the purposes of such subsection, and payments under any such grants shall be made in advance or by way of reimbursement and in such installments as the Secretary finds necessary.''

Subsec. (e)(5). Pub. L. 103–183, § 401(c)(3), as amended by Pub. L. 105–392, § 401(c), substituted ''form; or'' for ''form, or'' in subpar. (A) and ''purposes;'' for ''purposes,'' in subpar. (B).

1988—Pub. L. 100–607, § 311(1), amended section catchline.

Subsec. (d). Pub. L. 100–607, § 311(2), (3), redesignated subsec. (e) as (d) and struck out former subsec. (d) which related to acquired immune deficiency syndrome.

Subsec. (d)(1). Pub. L. 100–607, § 311(4), substituted ''(b) and (c)'' for ''(b), (c), and (d)'', struck out ''and'' after ''1986,'', and inserted '', $78,000,000 for fiscal year 1989, and such sums as may be necessary for each of the fiscal years 1990 and 1991'' before period at end of first sentence; substituted ''(b) or (c)'' for ''(b), (c), or (d)'' in third sentence; and struck out at end ''If the appropriations under the first sentence for fiscal year 1985 exceed $50,000,000, one-half of the amount in excess of $50,000,000 shall be made available for grants under subsection (d) of this section; if the appropriations under the first sentence for fiscal year 1986 exceed $52,500,000, one-half of the amount in excess of $52,500,000 shall be made available for such grants; and if the appropriations under the first sentence for fiscal year 1987 exceed $55,000,000, one-half of the amount in excess of $55,000,000 shall be made available for such grants.''

Subsecs. (e) to (g). Pub. L. 100–607, § 311(2), (3), struck out subsec. (f) which related to conditional limitation on use of funds and redesignated subsecs. (e) and (g) as (d) and (e), respectively.

1984—Subsec. (a). Pub. L. 98–555, § 3(b)(1), substituted ''research in, and training and public health programs for, the prevention and control of sexually transmitted diseases'' for ''research, training, and public health programs for the prevention and control of venereal disease''.

Subsec. (b). Pub. L. 98–555, § 3(b)(2), in amending subsec. (b) generally, designated existing provisions as pars. (1) to (3), added par. (4), and substituted references to sexually transmitted diseases for reference to venereal disease.

Subsec. (c). Pub. L. 98–555, § 3(b)(3), (6)(A), substituted ''sexually transmitted diseases'' for ''venereal disease'' wherever appearing, struck out par. (4) relating to professional venereal disease education, training and clinical skills improvement activities, and redesignated par. (5) as (4).

Subsec. (d). Pub. L. 98–555, § 3(b)(5)(A), added subsec. (d). Former subsec. (d) redesignated (e).

Subsec. (e). Pub. L. 98–555, § 3(a), (b)(4), (5), redesignated subsec. (d) as (e), and in par. (1) of subsec. (e) as so redesignated, substituted ''(b), (c), and (d)'' for ''(b) and (c)'', inserted provisions authorizing appropriations for fiscal years ending Sept. 30, 1985, 1986, and 1987, substituted ''10 per centum'' for ''5 per centum'', and inserted provisions directing that one-half the excess of appropriations in fiscal years 1985, 1986, and 1987 over certain amounts be made available for grants under subsec. (d). Notwithstanding language of section 3(b)(5)(B)(ii) directing the substitution of ''(b), (c), or (d)'' for ''(b) or (c)'' in second sentence of subsec. (e)(1), the amendment was executed by making the substitution in third sentence of subsec. (e)(1) to reflect the probable intent of Congress because ''(b) or (c)'' did not appear in second sentence. Former subsec. (e) redesignated (f).

Subsecs. (f), (g). Pub. L. 98–555, § 3(b)(5)(A), (6)(A), (C), redesignated subsecs. (e) and (f) as (f) and (g), respectively, in subsecs. (f) and (g) as so redesignated, substituted ''sexually transmitted diseases'' for ''venereal disease'', and struck out former subsec. (g) which defined venereal disease.

1981—Subsec. (d)(1). Pub. L. 97–35 inserted provisions authorizing appropriations for fiscal years ending Sept. 30, 1982, 1983, and 1984.

1979—Subsec. (b). Pub. L. 96–32 amended directory language of Pub. L. 95–626, § 204(c)(2), and required no change in text. See 1978 Amendment note below.

1978—Subsec. (b). Pub. L. 95–626, § 204(c)(2), as amended by Pub. L. 96–32, substituted ''research, demonstrations, and public information and education for the prevention and control of venereal disease'' for ''research, demonstrations, education, and training for the prevention and control of venereal disease'', struck out ''(1)'' preceding provisions thus amended, and struck out par. (2) which authorized appropriation of $5,000,000 for fiscal year 1976, $6,600,000 for fiscal year 1977, and $7,600,000 for fiscal year 1978 for purpose of carrying out this subsection.

Subsec. (c). Pub. L. 95–626, § 204(d), struck out ''(1)'' after ''(c)'' at beginning of existing provisions, changed designations at beginning of each of the five clauses from ''(A)'', ''(B)'', ''(C)'', ''(D)'', and ''(E)'' to ''(1)'', ''(2)'', ''(3)'', ''(4)'', and ''(5)'', respectively, substituted ''The Secretary is also authorized'' for ''The Secretary is authorized'' in provisions preceding cl. (1) as redesignated, substituted ''professional (including appropriate allied health personnel) venereal disease education, training and clinical skills improvement activities'' for ''professional and public venereal disease education activities'' in cl. (4) as redesignated, and struck out

former par. (2) which had authorized appropriations of $32,000,000 for fiscal year 1976, $41,500,000 for fiscal year 1977, and $43,500,000 for fiscal year 1978.

Subsec. (d)(1). Pub. L. 95–626, § 204(c)(1), inserted provisions authorizing appropriations of $45,000,000 for fiscal year ending Sept. 30, 1979, $51,500,000 for fiscal year ending Sept. 30, 1980, and $59,000,000 for fiscal year ending Sept. 30, 1981, for purpose of making grants under subsecs. (b) and (c) of this section, and inserted provisions directing Secretary to obligate not less than 5 per centum of amount appropriated for any fiscal year.

Subsec. (f). Pub. L. 95–626, § 204(b)(1), redesignated subsec. (g) as (f). Former subsec. (f), requiring that not to exceed 50 per centum of amounts appropriated for any fiscal year under subsecs. (b) and (c) of this section could be used by Secretary for grants for such fiscal year under section 247b of this title, was struck out.

Subsec. (g). Pub. L. 95–626, § 204(b)(1), redesignated subsec. (h) as (g). Former subsec. (g) redesignated (f).

1976—Subsec. (a). Pub. L. 94–317, § 203(c), substituted ''public and nonprofit private entities and to'' for ''public authorities and''.

Subsec. (b)(1). Pub. L. 94–317, § 203(i), inserted ''education,'' before ''and training''.

Subsec. (b)(2). Pub. L. 94–317, § 203(b)(1), substituted provisions authorizing appropriations of $5,000,000 for fiscal year 1976, $6,600,000 for fiscal year 1977, and $7,600,000 for fiscal year 1978, for provisions authorizing appropriations of $7,500,000 for fiscal year ending June 30, 1973, and for each of the next two fiscal years.

Subsec. (c). Pub. L. 94–484, purported to amend former subsec. (c)(1) by defining ''State'' to include the Northern Mariana Islands. Former subsec. (c) of this section had been previously repealed by section 203(f)(1) of Pub. L. 94–317. See par. below.

Pub. L. 94–317, § 203(b)(2), (d), (e), (f)(1), (3), (8), redesignated subsec. (d) as (c), inserted, in par. (1)(B), reference to routine testing, including laboratory tests and followup systems and substituted in par. (1)(E). ''prevention and control strategies and activities'' for ''control'' and, in par. (2), provisions authorizing appropriations of $32,000,000 for fiscal year 1976, $41,500,000 for fiscal year 1977, and $43,500,000 for fiscal year 1978, for provisions authorizing appropriations of $30,000,000 for the fiscal year ending June 30, 1973, and for each of the next two succeeding fiscal years. Former subsec. (c), which provided for authorization of appropriations to enable the Secretary to make grants to state health authorities to establish and maintain programs for diagnosis and treatment of venereal disease was amended by striking out reference to dark-field microscope techniques for diagnosis of both gonorrhea an syphilis, and as so amended, was repealed.

Subsec. (d). Pub. L. 94–317, § 203(f)(2), (4), (5), (8), redesignated subsec. (e) as (d), substituted in par. (1) ''or (c)'' for ''or (d)'', struck out in par. (4) provisions relating to the amount of reduction of a grant under former subsec. (c) whereby such amount shall be deemed a part of the grant to the recipient of the grant and shall be deemed to have been paid to such recipient, and inserted in par. (5) reference to requirement by law of a State or political subdivision of a state. Former subsec. (d) redesignated (c).

Subsec. (e). Pub. L. 94–317, § 203(f)(8), (g), redesignated subsec. (f) as (e) and substituted ''247b(g)(2) of this title'' for ''247b(d)(4) of this title''. Former subsec. (e) redesignated (d).

Subsec. (f). Pub. L. 94–317, § 203(f)(6), (8), redesignated subsec. (g) as (f) and substituted ''and (c)'' for '', (c), and (d)''. Former subsec. (f) redesignated (e).

Subsec. (g). Pub. L. 94–317, § 203(f)(7), (8), redesignated subsec. (h) as (g) and struck out ''treated or to have any child or ward of his'' after ''a program, to be''. Former subsec. (g) redesignated (f).

Subsec. (h). Pub. L. 94–317, § 203(h), added subsec. (h). Former subsec. (h) redesignated (g).

EFFECTIVE DATE OF 1998 AMENDMENT

Amendment by Pub. L. 105–392 deemed to have taken effect immediately after enactment of Pub. L. 103–183, see section 401(e) of Pub. L. 105–392, set out as a note under section 242m of this title.

DISTRIBUTION OF INFORMATION ON ACQUIRED IMMUNE DEFICIENCY SYNDROME BY DIRECTOR OF CENTERS FOR DISEASE CONTROL TO EVERY AMERICAN HOUSEHOLD

Pub. L. 100–202, § 101(h) [title II], Dec. 22, 1987, 101 Stat. 1329–256, 1329–365, provided: ''That the Director shall cause to be distributed without necessary clearance of the content by any official, organization or office, an AIDS mailer to every American household by June 30, 1988, as approved and funded by the Congress in Public Law 100–71 [July 11, 1987, 101 Stat. 391].''

CONGRESSIONAL FINDINGS AND DECLARATIONS

Section 204(a) of Pub. L. 95–626 provided that: ''The Congress finds and declares that—

''(1) the number of reported cases of venereal disease persists in epidemic proportions in the United States;

''(2) the number of persons affected by venereal disease and reported to public health authorities is only a fraction of those actually affected;

''(3) the incidence of venereal disease continues to be particularly high among American youth, ages fifteen to twenty-nine, and among populations in metropolitan areas;

''(4) venereal disease accounts for severe permanent disabilities and sometimes death in newborns and causes reproductive dysfunction in women of childbearing age;

''(5) it is conservatively estimated that the public cost of health care for persons suffering from complications of venereal disease exceeds one-half billion dollars annually;

''(6) the number of trained Federal venereal disease prevention and control personnel has fallen to a dangerously inadequate level;

''(7) no vaccine for syphilis, gonorrhea, or any other venereal disease has yet been developed, nor does a blood test for the detection of asymptomatic gonorrhea in women exist, nor are safe and effective therapeutic agents available for some other venereal diseases;

''(8) school health education programs, public information and awareness campaigns, mass diagnostic screening and case followup have all been found to be effective venereal disease prevention and control methodologies;

''(9) skilled and knowledgeable health care providers, informed and concerned individuals and active, well-coordinated voluntary groups are fundamental to venereal disease prevention and control;

''(10) biomedical research toward improved diagnostic and therapeutic tools is of singular importance to the elimination of venereal disease; and

''(11) an increasing number of sexually transmissible diseases besides syphilis and gonorrhea have become a public health hazard.''

Section 203(a) of Pub. L. 94–317 provided that: ''The Congress finds and declares that—

''(1) the number of reported cases of venereal disease continues in epidemic proportions in the United States;

''(2) the number of patients with venereal disease reported to public health authorities is only a fraction of those actually infected;

''(3) the incidence of venereal disease is particularly high in the 15–29-year age group, and in metropolitan areas;

''(4) venereal disease accounts for needless deaths and leads to such severe disabilities as sterility, insanity, blindness, and crippling conditions;

''(5) the number of cases of congenital syphilis, a preventable disease, tends to parallel the incidence of syphilis in adults;

''(6) it is conservatively estimated that the public cost of care for persons suffering the complications of venereal disease exceed $80,000,000 annually;

''(7) medical researchers have no successful vaccine for syphilis or gonorrhea, and have no blood test for the detection of gonorrhea among the large reservoir of asymptomatic females;

''(8) school health education programs, public information and awareness campaigns, mass diagnostic screening and case followup activities have all been found to be effective disease intervention methodologies;

''(9) knowledgeable health providers and concerned individuals and groups are fundamental to venereal disease prevention and control;

''(10) biomedical research leading to the development of vaccines for syphilis and gonorrhea is of singular importance for the eventual eradication of these dreaded diseases; and

''(11) a variety of other sexually transmitted diseases, in addition to syphilis and gonorrhea, have become of public health significance.''

Section 202 of Pub. L. 92–449 provided that:

''(a) The Congress finds and declares that—

''(1) the number or reported cases of venereal disease has reached epidemic proportions in the United States;

''(2) the number of patients with venereal disease reported to public health authorities is only a fraction of those treated by physicians;

''(3) the incidence of venereal disease is particularly high among individuals in the 20–24 age group, and in metropolitan areas;

''(4) venereal disease accounts for needless deaths and leads to such severe disabilities as sterility, insanity, blindness, and crippling conditions;

''(5) the number of cases of congenital syphilis, a preventable disease, in infants under one year of age increased by 33⅓ per centum between 1970 and 1971;

''(6) health education programs in schools and through the mass media may prevent a substantial portion of the venereal disease problem; and

''(7) medical authorities have no successful vaccine for syphilis or gonorrhea and no blood test for the detection of gonorrhea among the large reservoir of asymptomatic females.

''(b) In order to preserve and protect the health and welfare of all citizens, it is the purpose of this Act [this chapter] to establish a national program for the prevention and control of venereal disease.''

§ 247c–1. Infertility and sexually transmitted diseases

(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) of this section 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) of this section, 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) of this section, 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) of this section;

(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) of this section only if the applicant involved agrees that each activity authorized in subsection (c) of this section 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) of this section only if the applicant involved agrees that, in expending the grant to carry out activities authorized in subsection (c) of this section, 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 254b, 254b, 256a, or 300 of this title,[1] 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

[1] See References in Text notes below.

of screening procedures for diseases described in subsection (a) of this section.

(g) Confidentiality

The Secretary may make a grant under subsection (a) of this section 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) of this section.

(h) Limitation on imposition of fees for services

The Secretary may make a grant under subsection (a) of this section 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 9902(2) of this title.

(i) Limitations on certain expenditures

The Secretary may make a grant under subsection (a) of this section 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) of this section.

(j) Reports to Secretary

(1) Collection of data

The Secretary may make a grant under subsection (a) of this section only if the applicant involved agrees, with respect to any disease selected under subsection (b) of this section 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) of this section;

(D) an assessment of the extent to which the activities carried pursuant to subsection (a) of this section 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) of this section is authorized to be expended, the Secretary may make such a grant only if the applicant involved agrees to maintain expenditures of non-Federal amounts for such activities at a level that is not less than the average level of such expenditures maintained by the applicant for the 2-year period preceding the fiscal year for which the applicant is applying to receive such a grant.

***(l)* Requirement of application**

(1) In general

The Secretary may make a grant under subsection (a) of this section 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) of this section 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) of this section will be provided.

(B) Participation of certain entities

The Secretary may make a grant under subsection (a) of this section 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) of this section 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) of this section with respect to the planning, development, and operation of any program or service carried out under such sub-

section. 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) of this section, 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) of 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 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) of this section 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) of this section, 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) of this section, including information on the incidence of sexually transmitted diseases described in subsection (a) of this section; 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) of this section, 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) of this section may be improved. The Secretary may make such grants only to grantees under such subsection and to public and nonprofit private entities that are carrying out programs substantially similar to programs carried out under such subsection.

(2) Authorization of appropriations

For the purpose of carrying out paragraph (1), there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1993 through 1998.

(July 1, 1944, ch. 373, title III, § 318A, as added Pub. L. 102–531, title III, § 304, Oct. 27, 1992, 106 Stat. 3490; amended Pub. L. 103–43, title XX, § 2008(i)(1)(B)(ii), June 10, 1993, 107 Stat. 212; Pub. L. 103–183, title IV, § 402, Dec. 14, 1993, 107 Stat. 2236; Pub. L. 107–251, title VI, § 601(a), Oct. 26, 2002, 116 Stat. 1664; Pub. L. 108–163, § 2(m)(1), Dec. 6, 2003, 117 Stat. 2023.)

REFERENCES IN TEXT

The reference to section 254b of this title the first place appearing, referred to in subsec. (e), was in the original a reference to section 329, meaning section 329 of act July 1, 1944, which was omitted in the general amendment of subpart I (§ 254b et seq.) of part D of this subchapter by Pub. L. 104–299, § 2, Oct. 11, 1996, 110 Stat. 3626.

Section 256a of this title, referred to in subsec. (e), was repealed by Pub. L. 104–299, § 4(a)(3), Oct. 11, 1996, 110 Stat. 3645.

AMENDMENTS

2003—Subsec. (e). Pub. L. 108–163 substituted ''254b'' for ''254c, 254b(h)'' before '', 256a''.

2002—Subsec. (e). Pub. L. 107–251 substituted ''254b(h)'' for ''256''.

1993—Pub. L. 103–43 made technical amendment to directory language of Pub. L. 102–531, § 304, which enacted this section.

Subsec. (*o*)(2). Pub. L. 103–183, § 402(a), substituted ''subsection (q)'' for ''subsection (s)''.

Subsec. (q). Pub. L. 103–183, § 402(b)(1), substituted ''through 1998'' for ''and 1995''.

Subsec. (r)(2). Pub. L. 103–183, § 402(b)(2), substituted ''1998'' for ''1995''.

CHANGE OF NAME

Committee on Labor and Human Resources of Senate changed to Committee on Health, Education, Labor, and Pensions of Senate by Senate Resolution No. 20, One Hundred Sixth Congress, Jan. 19, 1999.

Committee on Energy and Commerce of House of Representatives treated as referring to Committee on Commerce of House of Representatives by section 1(a) of Pub. L. 104–14, set out as a note preceding section 21 of Title 2, The Congress. Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

EFFECTIVE DATE OF 2003 AMENDMENT

Amendment by Pub. L. 108–163 deemed to have taken effect immediately after the enactment of Pub. L. 107–251, see section 3 of Pub. L. 108–163, set out as a note under section 233 of this title.

§ 247c–2. Data collection regarding programs under subchapter XXIV

For the purpose of collecting and providing data for program planning and evaluation activities under subchapter XXIV of this chapter, 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.

(July 1, 1944, ch. 373, title III, § 318B, as added Pub. L. 106–345, title IV, § 412, Oct. 20, 2000, 114 Stat. 1350.)

§ 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) of this section only if a public health emergency has been declared by the Secretary under such subsection. There is authorized to be appropriated to the Fund such sums as may be necessary.

(2) Report

Not later than 90 days after the end of each fiscal year, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Commerce and the Committee on Appropriations of the House of Representatives a report describing—

(A) the expenditures made from the Public Health Emergency Fund in such fiscal year; and

(B) each public health emergency for which the expenditures were made and the activities undertaken with respect to each emergency which was conducted or supported by expenditures from the Fund.

(c) Supplement not supplant

Funds appropriated under this section shall be used to supplement and not supplant other Federal, State, and local public funds provided for activities under this section.

(d) Data submittal and reporting deadlines

In any case in which the Secretary determines that, wholly or partially as a result of a public health emergency that has been determined pursuant to subsection (a) of this section, 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.

(July 1, 1944, ch. 373, title III, § 319, as added Pub. L. 106–505, title I, § 102, Nov. 13, 2000, 114 Stat. 2315; amended Pub. L. 107–188, title I, §§ 141, 144(a), 158, June 12, 2002, 116 Stat. 626, 630, 633.)

PRIOR PROVISIONS

A prior section 247d, act July 1, 1944, ch. 373, title III, § 319, as added Pub. L. 98–49, July 13, 1983, 97 Stat. 245; amended Pub. L. 100–607, title II, § 256(a), Nov. 4, 1988, 102 Stat. 3110; Pub. L. 102–321, title I, § 163(b)(2), July 10, 1992, 106 Stat. 376; Pub. L. 102–531, title III, § 312(d)(2), Oct. 27, 1992, 106 Stat. 3504, authorized the Secretary to take appropriate action relating to public health emergencies, prior to repeal by Pub. L. 106–505, title I, § 102, Nov. 13, 2000, 114 Stat. 2315.

Another prior section 247d, act July 1, 1944, ch. 373, title III, § 319, formerly § 310, as added Sept. 25, 1962, Pub. L. 87–692, 76 Stat. 592, and amended and renumbered, which related to migrant health centers, was renumbered section 329 of act July 1, 1944, by Pub. L. 95–626, title I, § 102(a), Nov. 10, 1978, 92 Stat. 3551, and transferred to section 254b of this title, prior to being omitted in the general amendment of subpart I (§ 254b et seq.) of part D of this subchapter by Pub. L. 104–299, § 2.

CHANGE OF NAME

Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

AMENDMENTS

2002—Subsec. (a). Pub. L. 107–188, § 158, substituted ''grants, providing awards for expenses, and'' for ''grants and'' in concluding provisions.

Pub. L. 107–188, § 144(a), inserted at end of concluding provisions ''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.''

Subsec. (d). Pub. L. 107–188, § 141, added subsec. (d).

EFFECTIVE DATE OF 2002 AMENDMENT

Pub. L. 107–188, title I, § 144(b), June 12, 2002, 116 Stat. 630, provided that: ''The amendment made by subsection (a) [amending this section] applies to any public health emergency under section 319(a) of the Public Health Service Act [subsec. (a) of this section], including any such emergency that was in effect as of the day before the date of the enactment of this Act [June 12, 2002]. In the case of such an emergency that was in effect as of such day, the 90-day period described in such section with respect to the termination of the emergency is deemed to begin on such date of enactment.''

§ 247d–1. Vaccine tracking and distribution

(a) Tracking

The Secretary, together with relevant manufacturers, wholesalers, and distributors as may agree to cooperate, may track the initial distribution of federally purchased influenza vaccine in an influenza pandemic. Such tracking information shall be used to inform Federal, State, local, and tribal decision makers during an influenza pandemic.

(b) Distribution

The Secretary shall promote communication between State, local, and tribal public health officials and such manufacturers, wholesalers, and distributors as agree to participate, regarding the effective distribution of seasonal influenza vaccine. Such communication shall include estimates of high priority populations, as determined by the Secretary, in State, local, and tribal jurisdictions in order to inform Federal, State, local, and 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 chapter 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, and subject to the penalties and exceptions under sections 1832 and 1833 of title 18 relating to the protection and theft of trade secrets, and subject to privacy protections that are consistent with the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996. None of such information provided by a manufacturer, wholesaler, or distributor shall be disclosed without its consent to another manufacturer, wholesaler, or distributor, or shall be used in any manner to give a manufacturer, wholesaler, or distributor a proprietary advantage.

(d) Guidelines

The Secretary, in order to maintain the confidentiality of relevant information and ensure that none of the information contained in the systems involved may be used to provide proprietary advantage within the vaccine market, while allowing State, local, and tribal health officials access to such information to maximize the delivery and availability of vaccines to high priority populations, during times of influenza pandemics, vaccine shortages, and supply disruptions, in consultation with manufacturers, distributors, wholesalers and State, local, and tribal health departments, shall develop guidelines for subsections (a) and (b).

(e) Authorization of appropriations

There are authorized to be appropriated to carry out this section, such sums for each of fiscal years 2007 through 2011.

(f) Report to Congress

As part of the National Health Security Strategy described in section 300hh–1 of this title, the Secretary shall provide an update on the implementation of subsections (a) through (d).

(July 1, 1944, ch. 373, title III, § 319A, as added Pub. L. 106–505, title I, § 102, Nov. 13, 2000, 114 Stat. 2316; amended Pub. L. 107–188, title I, § 111(1), June 12, 2002, 116 Stat. 611; Pub. L. 109–417, title II, § 204(a), Dec. 19, 2006, 120 Stat. 2850.)

REFERENCES IN TEXT

Section 264 of the Health Insurance Portability and Accountability Act of 1996, referred to in subsec. (c), is section 264 of Pub. L. 104–191, which is set out as a note under section 1320d–2 of this title.

AMENDMENTS

2006—Pub. L. 109–417 amended section catchline and text generally, substituting provisions relating to vaccine tracking and distribution for provisions relating to establishment of capacities to combat threats to public health.

2002—Subsec. (a)(1). Pub. L. 107–188 substituted ''five years'' for ''10 years''.

§§ 247d–2, 247d–3. Repealed. Pub. L. 109–417, title II, § 204(b)(1), Dec. 19, 2006, 120 Stat. 2851

Section 247d–2, act July 1, 1944, ch. 373, title III, § 319B, as added Pub. L. 106–505, title I, § 102, Nov. 13, 2000, 114 Stat. 2317; amended Pub. L. 107–188, title I, § 111(2), June 12, 2002, 116 Stat. 611, related to grants to States to assess public health needs.

Section 247d–3, act July 1, 1944, ch. 373, title III, § 319C, as added Pub. L. 106–505, title I, § 102, Nov. 13, 2000, 114 Stat. 2317; amended Pub. L. 107–188, title I, § 131(b), June 12, 2002, 116 Stat. 626, related to grants to improve State and local public health agencies.

§ 247d–3a. Improving State and local public health security

(a) In general

To enhance the security of the United States with respect to public health emergencies, the

Secretary shall award cooperative agreements to eligible entities to enable such entities to conduct the activities described in subsection (d).

(b) Eligible entities

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

(1)(A) be a State;

(B) be a political subdivision determined by the Secretary to be eligible for an award under this section (based on criteria described in subsection (i)(4)); or

(C) be a consortium of entities described in subparagraph (A); 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 300hh–1 of this title;

(ii) a pandemic influenza plan consistent with the requirements of paragraphs (2) and (5) of subsection (g);

(iii) preparedness and response strategies and capabilities that take into account the medical and public health needs of at-risk individuals in the event of a public health emergency;

(iv) a description of the mechanism the entity will implement to utilize the Emergency Management Assistance Compact or other mutual aid agreements for medical and public health mutual aid; and

(v) a description of how the entity will include the State Unit on Aging in public health emergency preparedness;

(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, and that the entity will report back to the Secretary within the application of the following year on the strengths and weaknesses identified through such exercise or drill, and corrective actions taken to address material weaknesses;

(D) an assurance that the entity will provide to the Secretary the data described under section 247d–4(d)(3) of this title as determined feasible by the Secretary;

(E) an assurance that the entity will conduct activities to inform and educate the hospitals within the jurisdiction of such entity on the role of such hospitals in the plan required under subparagraph (A);

(F) an assurance that the entity, with respect to the plan described under subparagraph (A), has developed and will implement an accountability system to ensure that such entity make[1] satisfactory annual improvement and describe[2] such system in the plan under subparagraph (A);

(G) a description of the means by which to obtain public comment and input on the plan described in subparagraph (A) and on the implementation of such plan, that shall include an advisory committee or other similar mechanism for obtaining comment from the public and from other State, local, and tribal stakeholders; and

(H) as relevant, a description of the process used by the entity to consult with local departments of public health to reach consensus, approval, or concurrence on the relative distribution of amounts received under this section.

(c) Limitation

Beginning in fiscal year 2009, the Secretary may not award a cooperative agreement to a State unless such State is a participant in the Emergency System for Advance Registration of Volunteer Health Professionals described in section 247d–7b of this title.

(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 300hh–1(b) of this title.

(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, and local emergency plans.

(f) Consultation with Homeland Security

In making awards under subsection (a), the Secretary shall consult with the Secretary of Homeland Security to—

(1) ensure maximum coordination of public health and medical preparedness and response activities with the Metropolitan Medical Response System, and other relevant activities;

(2) minimize duplicative funding of programs and activities;

(3) analyze activities, including exercises and drills, conducted under this section to develop recommendations and guidance on best practices for such activities; and

(4) disseminate such recommendations and guidance, including through expanding existing lessons learned information systems to create a single Internet-based point of access for sharing and distributing medical and pub-

[1] So in original. Probably should be ''makes''.

[2] So in original. Probably should be ''describes''.

lic health best practices and lessons learned from drills, exercises, disasters, and other emergencies.

(g) Achievement of measurable evidence-based benchmarks and objective standards

(1) In general

Not later than 180 days after December 19, 2006, 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 247d–3b of this title. 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 achievement of the National Preparedness Goals developed under section 300hh–1(b) of this title; 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 December 19, 2006, 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.

(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 December 19, 2006.[3]

(3) Technical assistance

The Secretary shall, as determined appropriate by the Secretary, provide to a State, upon request, technical assistance in meeting the requirements of this section, including the provision of advice by experts in the development of high-quality assessments, the setting of State objectives and assessment methods, the development of measures of satisfactory annual improvement that are valid and reliable, and other relevant areas.

(4) Notification of failures

The Secretary shall develop and implement a process to notify entities that are determined by the Secretary to have failed to meet the requirements of paragraph (1) or (2). Such process shall provide such entities with the opportunity to correct such noncompliance. An entity that fails to correct such noncompliance shall be subject to paragraph (5).

(5) Withholding of amounts from entities that fail to achieve benchmarks or submit influenza plan

Beginning with fiscal year 2009, and in each succeeding fiscal year, the Secretary shall—

(A) withhold from each entity that has failed substantially to meet the benchmarks and performance measures described in paragraph (1) for the immediately preceding fiscal year (beginning with fiscal year 2008), pursuant to the process developed under paragraph (4), the amount described in paragraph (6); and

(B) withhold from each entity that has failed to submit to the Secretary a plan for responding to pandemic influenza that meets the criteria developed under paragraph (2), the amount described in paragraph (6).

(6) Amounts described

(A) In general

The amounts described in this paragraph are the following amounts that are payable to an entity for activities described in this section or section 247d–3b of this title:

(i) For the fiscal year immediately following a fiscal year in which an entity experienced a failure described in subparagraph (A) or (B) of paragraph (5) by the entity, an amount equal to 10 percent of the amount the entity was eligible to receive for such fiscal year.

(ii) For the fiscal year immediately following two consecutive fiscal years in which an entity experienced such a failure, an amount equal to 15 percent of the amount the entity was eligible to receive for such fiscal year, taking into account the withholding of funds for the immediately preceding fiscal year under clause (i).

(iii) For the fiscal year immediately following three consecutive fiscal years in which an entity experienced such a failure, an amount equal to 20 percent of the amount the entity was eligible to receive for such fiscal year, taking into account the withholding of funds for the immediately preceding fiscal years under clauses (i) and (ii).

(iv) For the fiscal year immediately following four consecutive fiscal years in which an entity experienced such a failure, an amount equal to 25 percent of the amount the entity was eligible to receive for such a fiscal year, taking into account the withholding of funds for the immediately preceding fiscal years under clauses (i), (ii), and (iii).

(B) Separate accounting

Each failure described in subparagraph (A) or (B) of paragraph (5) shall be treated as a separate failure for purposes of calculating amounts withheld under subparagraph (A).

[3] See Codification note below.

(7) Reallocation of amounts withheld

(A) In general

The Secretary shall make amounts withheld under paragraph (6) available for making awards under section 247d–3b of this title to entities described in subsection (b)(1) of such section.

(B) Preference in reallocation

In making awards under section 247d–3b of this title with amounts described in subparagraph (A), the Secretary shall give preference to eligible entities (as described in section 247d–3b(b)(1) of this title) that are located in whole or in part in States from which amounts have been withheld under paragraph (6).

(8) Waive or reduce withholding

The Secretary may waive or reduce the withholding described in paragraph (6), for a single entity or for all entities in a fiscal year, if the Secretary determines that mitigating conditions exist that justify the waiver or reduction.

(h) Grants for real-time disease detection improvement

(1) In general

The Secretary may award grants to eligible entities to carry out projects described under paragraph (4).

(2) Eligible entity

For purposes of this section, the term ''eligible entity'' means an entity that is—

(A)(i) a hospital, clinical laboratory, university; or

(ii) a poison control center or professional organization in the field of poison control; and

(B) a participant in the network established under subsection[4] 247d–4(d) of this title.

(3) Application

Each eligible entity desiring a grant under this subsection shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

(4) Use of funds

(A) In general

An eligible entity described in paragraph (2)(A)(i) that receives a grant under this subsection shall use the funds awarded pursuant to such grant to carry out a pilot demonstration project to purchase and implement the use of advanced diagnostic medical equipment to analyze real-time clinical specimens for pathogens of public health or bioterrorism significance and report any results from such project to State, local, and tribal public health entities and the network established under section 247d–4(d) of this title.

(B) Other entities

An eligible entity described in paragraph (2)(A)(ii) that receives a grant under this section shall use the funds awarded pursuant to such grant to—

(i) improve the early detection, surveillance, and investigative capabilities of poison control centers for chemical, biological, radiological, and nuclear events by training poison information personnel to improve the accuracy of surveillance data, improving the definitions used by the poison control centers for surveillance, and enhancing timely and efficient investigation of data anomalies;

(ii) improve the capabilities of poison control centers to provide information to health care providers and the public with regard to chemical, biological, radiological, or nuclear threats or exposures, in consultation with the appropriate State, local, and tribal public health entities; or

(iii) provide surge capacity in the event of a chemical, biological, radiological, or nuclear event through the establishment of alternative poison control center worksites and the training of nontraditional personnel.

(i) Funding

(1) Authorization of appropriations

(A) In general

For the purpose of carrying out this section, there is authorized to be appropriated $824,000,000 for fiscal year 2007, of which $35,000,000 shall be used to carry out subsection (h), for awards pursuant to paragraph (3) (subject to the authority of the Secretary to make awards pursuant to paragraphs (4) and (5)), and such sums as may be necessary for each of fiscal years 2008 through 2011.

(B) Coordination

There are authorized to be appropriated, $10,000,000 for fiscal year 2007 to carry out subsection (f)(4) of this section and section 300hh–16 of this title.

(C) 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).

[4] So in original. Probably should be ''section''.

(D) Determination of amount of non-Federal contributions

As determined by the Secretary, non-Federal contributions required in subparagraph (C) 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)(i)(I)[5] for the fiscal year, less an amount equal to the sum of all base amounts determined for the States under subparagraph (B), and less the amount, if any, reserved by the Secretary under paragraphs (4) and (5); and

(ii) subject to paragraph (4)(C), the percentage constituted by the ratio of an amount equal to the population of the State over an amount equal to the total population of the States (as indicated by the most recent data collected by the Bureau of the Census).

(D) Minimum amount

Subject to the amount appropriated under paragraph (1)(A)(i)(I),[5] an award pursuant to subparagraph (A) for a State shall be the greater of the base amount as increased under subparagraph (C), or the minimum amount under this subparagraph. The minimum amount under this subparagraph is—

(i) in the case of each of the several States, the District of Columbia, and the Commonwealth of Puerto Rico, an amount equal to the lesser of—

(I) $5,000,000; or

(II) if the amount appropriated under paragraph (1)(A)(i)(I)[5] 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) of this section to political subdivisions that have a substantial number of residents, have a substantial local infrastructure for responding to public health emergencies, and face a high degree of risk from bioterrorist attacks or other public health emergencies. Not more than three political subdivisions may receive awards pursuant to this subparagraph.

(B) Coordination with Statewide plans

An award pursuant to subparagraph (A) may not be made unless the application of the political subdivision involved is in coordination with, and consistent with, applicable Statewide plans described in subsection (c) of this section.

(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

[5] See References in Text note below.

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) of this section 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) of this section 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.

(j) 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 247d–3b of this title. 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 247d–3b of this title and to assure the proper expenditure of funds under this section and section 247d–3b of this title, such reports shall be in such standardized form and contain such information as the Secretary determines and describes within 180 days of December 19, 2006 (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 247d–3b of this title;

(D) determine the extent to which funds were expended consistent with the entity's application transmitted under this section or section 247d–3b of this title; and

(E) publish such information on a Federal Internet website consistent with subsection (k).

(2) Audits; implementation

(A) In general

Each entity receiving funds under this section or section 247d–3b of this title shall, not less often than once every 2 years, audit its expenditures from amounts received under this section or section 247d–3b of this title. Such audits shall be conducted by an entity independent of the agency administering a program funded under this section or section 247d–3b of this title in accordance with the Comptroller General's standards for auditing governmental organizations, programs, activities, and functions and generally accepted auditing standards. Within 30 days following the completion of each audit report, the entity shall submit a copy of that audit report to the Secretary.

(B) Repayment

Each entity shall repay to the United States amounts found by the Secretary, after notice and opportunity for a hearing to the entity, not to have been expended in accordance with this section or section 247d–3b of this title 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 247d–3b of this title 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 247d–3b of this title 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.

(3) Maximum carryover amount

(A) In general

For each fiscal year, the Secretary, in consultation with the States and political subdivisions, shall determine the maximum percentage amount of an award under this section that an entity may carryover to the succeeding fiscal year.

(B) Amount exceeded

For each fiscal year, if the percentage amount of an award under this section unexpended by an entity exceeds the maximum percentage permitted by the Secretary under subparagraph (A), the entity shall re-

turn to the Secretary the portion of the unexpended amount that exceeds the maximum amount permitted to be carried over by the Secretary.

(C) Action by Secretary

The Secretary shall make amounts returned to the Secretary under subparagraph (B) available for awards under section 247d–3b(b)(1) of this title. In making awards under section 247d–3b(b)(1) of this title with amounts collected under this paragraph the Secretary shall give preference to entities that are located in whole or in part in States from which amounts have been returned under subparagraph (B).

(D) Waiver

An entity may apply to the Secretary for a waiver of the maximum percentage amount under subparagraph (A). Such an application for a waiver shall include an explanation why such requirement should not apply to the entity and the steps taken by such entity to ensure that all funds under an award under this section will be expended appropriately.

(E) Waive or reduce withholding

The Secretary may waive the application of subparagraph (B), or reduce the amount determined under such subparagraph, for a single entity pursuant to subparagraph (D) or for all entities in a fiscal year, if the Secretary determines that mitigating conditions exist that justify the waiver or reduction.

(k) 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).

(July 1, 1944, ch. 373, title III, §319C–1, as added Pub. L. 107–188, title I, §131(a), June 12, 2002, 116 Stat. 617; amended Pub. L. 109–417, title II, §201, Dec. 19, 2006, 120 Stat. 2837.)

REFERENCES IN TEXT

Paragraph (1)(A) of subsec. (i), referred to in subsec. (i)(3)(C), (D), was struck out and a new paragraph (1)(A) added by Pub. L. 109–417, title II, §201(4)(A), Dec. 19, 2006, 120 Stat. 2837. The new paragraph (1)(A) does not contain a clause (i).

CODIFICATION

December 19, 2006, referred to in subsec. (g)(2)(B), was in the original ''the date of enactment of this section'', which was translated as meaning the date of enactment of Pub. L. 109–417, which enacted subsec. (g) of this section, to reflect the probable intent of Congress.

AMENDMENTS

2006—Pub. L. 109–417, §201(1), substituted ''Improving State and local public health security'' for ''Grants to improve State, local, and hospital preparedness for and response to bioterrorism and other public health emergencies'' in section catchline.

Subsecs. (a) to (h). Pub. L. 109–417, §201(2), added subsecs. (a) to (h) and struck out former subsecs. (a) to (h) which related to grants to improve State, local, and hospital preparedness for and response to bioterrorism and other public health emergencies.

Subsec. (i). Pub. L. 109–417, §201(3), redesignated subsec. (j) as (i).

Pub. L. 109–417, §201(2), struck out subsec. (i) which defined ''eligible entity''.

Subsec. (i)(1) to (3)(A). Pub. L. 109–417, §201(4)(A), added pars. (1) to (3)(A) and struck out former pars. (1) to (3)(A) which related to appropriations for fiscal years 2003 through 2006, use of amounts to supplement and not supplant other funds, and conditions for receipt of award in fiscal year 2003.

Subsec. (i)(4)(A). Pub. L. 109–417, §201(4)(B), substituted ''fiscal year 2007'' for ''fiscal year 2003'' and struck out ''(A)(i)(I)'' after ''paragraph (1)''.

Subsec. (i)(4)(D). Pub. L. 109–417, §201(4)(C), substituted ''fiscal year 2006'' for ''fiscal year 2002''.

Subsec. (i)(5)(A). Pub. L. 109–417, §201(4)(D), in introductory provisions, substituted ''fiscal year 2007'' for ''fiscal year 2003'' and struck out ''(A)(i)(I)'' after ''paragraph (1)''.

Subsec. (i)(6). Pub. L. 109–417, §201(4)(E), added par. (6) and struck out heading and text of former par. (6). Text read as follows: ''For fiscal year 2003, the Secretary shall in making awards under this section ensure that appropriate portions of such awards are made available to political subdivisions, local departments of public health, hospitals (including children's hospitals), clinics, health centers, or primary care facilities, or consortia of such entities.''

Subsec. (j). Pub. L. 109–417, §201(5), added subsec. (j).

Pub. L. 109–417, §201(3), redesignated subsec. (j) as (i).

Subsec. (k). Pub. L. 109–417, §201(5), added subsec. (k).

EMERGENCY MEDICAL AND PUBLIC HEALTH COMMUNICATIONS PILOT PROJECTS

Pub. L. 110–53, title XXII, §2201(d), Aug. 3, 2007, 121 Stat. 541, provided that:

''(1) IN GENERAL.—The Assistant Secretary of Commerce for Communications and Information may establish not more than 10 geographically dispersed project grants to emergency medical and public health care facilities to improve the capabilities of emergency communications systems in emergency medical care facilities.

''(2) MAXIMUM AMOUNT.—The Assistant Secretary may not provide more than $2,000,000 in Federal assistance under the pilot program to any applicant.

''(3) COST SHARING.—The Assistant Secretary may not provide more than 20 percent of the cost, incurred during the period of the grant, of any project under the pilot program.

''(4) MAXIMUM PERIOD OF GRANTS.—The Assistant Secretary may not fund any applicant under the pilot program for more than 3 years.

''(5) DEPLOYMENT AND DISTRIBUTION.—The Assistant Secretary shall seek to the maximum extent practicable to ensure a broad geographic distribution of project sites.

''(6) TRANSFER OF INFORMATION AND KNOWLEDGE.—The Assistant Secretary shall establish mechanisms to ensure that the information and knowledge gained by participants in the pilot program are transferred among the pilot program participants and to other interested parties, including other applicants that submitted applications.''

§247d–3b. Partnerships for State and regional hospital preparedness to improve surge capacity

(a) In general

The Secretary shall award competitive grants or cooperative agreements to eligible entities to enable such entities to improve surge capacity and enhance community and hospital preparedness for public health emergencies.

(b) Eligibility

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

(1)(A) be a partnership consisting of—

(i) one or more hospitals, at least one of which shall be a designated trauma center, consistent with section 300d–13(c) of this title;

(ii) one or more other local health care facilities, including clinics, health centers, primary care facilities, mental health centers, mobile medical assets, or nursing homes; and

(iii)(I) one or more political subdivisions;

(II) one or more States; or

(III) one or more States and one or more political subdivisions; and

(B) prepare, in consultation with the Chief Executive Officer and the lead health officials of the State, District, or territory in which the hospital and health care facilities described in subparagraph (A) are located, and submit to the Secretary, an application at such time, in such manner, and containing such information as the Secretary may require; or

(2)(A) be an entity described in section 247d–3a(b)(1) of this title; 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 247d–3a(b)(2) of this title 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 300hh–1(b) of this title.

(d) Preferences

(1) Regional coordination

In making awards under subsection (a), the Secretary shall give preference to eligible entities that submit applications that, in the determination of the Secretary—

(A) will enhance coordination—

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

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

(B) include, in the partnership described in subsection (b)(1)(A), a significant percentage of the hospitals and health care facilities within the geographic area served by such partnership.

(2) Other preferences

In making awards under subsection (a), the Secretary shall give preference to eligible entities that, in the determination of the Secretary—

(A) include one or more hospitals that are participants in the National Disaster Medical System;

(B) are located in a geographic area that faces a high degree of risk, as determined by the Secretary in consultation with the Secretary of Homeland Security; or

(C) have a significant need for funds to achieve the medical preparedness goals described in section 300hh–1(b)(3) of this title.

(e) Consistency of planned activities

The Secretary may not award a cooperative agreement to an eligible entity described in subsection (b)(1) unless the application submitted by the entity is coordinated and consistent with an applicable State All-Hazards Public Health Emergency Preparedness and Response Plan and relevant local plans, as determined by the Secretary in consultation with relevant State health officials.

(f) Limitation on awards

A political subdivision shall not participate in more than one partnership described in subsection (b)(1).

(g) Coordination with 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 Cities Readiness Initiative, and local emergency plans.

(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

The requirements of section 247d–3a(g), (j), and (k) of this title 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 247d–3a of this title. An entity described in subsection (b)(1)(A) shall make such reports available to the lead health official of the State in which such partnership is located.

(j) Authorization of appropriations

(1) In general

For the purpose of carrying out this section, there is authorized to be appropriated $474,000,000 for fiscal year 2007, and such sums as may be necessary for each of fiscal years 2008 through 2011.

(2) Reservation of amounts for partnerships

Prior to making awards described in paragraph (3), the Secretary may reserve from the amount appropriated under paragraph (1) for a fiscal year, an amount determined appropriate by the Secretary for making awards to entities described in subsection (b)(1)(A).

(3) Awards to States and political subdivisions

(A) In general

From amounts appropriated for a fiscal year under paragraph (1) and not reserved under paragraph (2), the Secretary shall make awards to entities described in subsection (b)(2)(A) that have completed an application as described in subsection (b)(2)(B).

(B) Amount

The Secretary shall determine the amount of an award to each entity described in subparagraph (A) in the same manner as such amounts are determined under section 247d–3a(i) of this title.

(July 1, 1944, ch. 373, title III, § 319C–2, as added Pub. L. 107–188, title I, § 131(a), June 12, 2002, 116 Stat. 624; amended Pub. L. 109–417, title III, § 305, Dec. 19, 2006, 120 Stat. 2861; Pub. L. 110–85, title XI, § 1104(1), Sept. 27, 2007, 121 Stat. 975.)

AMENDMENTS

2007—Subsec. (j)(3)(B). Pub. L. 110–85 substituted ''section 247d–3a(i)'' for ''section 247d–3a(h)''.

2006—Pub. L. 109–417 amended section catchline and text generally. Prior to amendment, section consisted of subsecs. (a) to (i) relating to partnerships for community and hospital preparedness.

§ 247d–4. Revitalizing the Centers for Disease Control and Prevention

(a) Facilities; capacities

(1) Findings

Congress finds that the Centers for Disease Control and Prevention has an essential role in defending against and combatting public health threats domestically and abroad and requires secure and modern facilities, and expanded and improved capabilities related to bioterrorism and other public health emergencies, sufficient to enable such Centers to conduct this important mission.

(2) Facilities

(A) In general

The Director of the Centers for Disease Control and Prevention may design, construct, and equip new facilities, renovate existing facilities (including laboratories, laboratory support buildings, scientific communication facilities, transshipment complexes, secured and isolated parking structures, office buildings, and other facilities and infrastructure), and upgrade security of such facilities, in order to better conduct the capacities described in section 247d–1 of this title, and for supporting public health activities.

(B) Multiyear contracting authority

For any project of designing, constructing, equipping, or renovating any facility under subparagraph (A), the Director of the Centers for Disease Control and Prevention may enter into a single contract or related contracts that collectively include the full scope of the project, and the solicitation and contract shall contain the clause ''availability of funds'' found at section 52.232–18 of title 48, Code of Federal Regulations.

(3) Improving the capacities of the Centers for Disease Control and Prevention

The Secretary shall expand, enhance, and improve the capabilities of the Centers for Disease Control and Prevention relating to preparedness for and responding effectively to bioterrorism and other public health emergencies. Activities that may be carried out under the preceding sentence include—

(A) expanding or enhancing the training of personnel;

(B) improving communications facilities and networks, including delivery of necessary information to rural areas;

(C) improving capabilities for public health surveillance and reporting activities, taking into account the integrated system or systems of public health alert communications and surveillance networks under subsection (b) of this section; and

(D) improving laboratory facilities related to bioterrorism and other public health emergencies, including increasing the security of such facilities.

(b) National communications and surveillance networks

(1) In general

The Secretary, directly or through awards of grants, contracts, or cooperative agreements, shall provide for the establishment of an integrated system or systems of public health alert communications and surveillance networks between and among—

(A) Federal, State, and local public health officials;

(B) public and private health-related laboratories, hospitals, and other health care facilities; and

(C) any other entities determined appropriate by the Secretary.

(2) Requirements

The Secretary shall ensure that networks under paragraph (1) allow for the timely sharing and discussion, in a secure manner, of essential information concerning bioterrorism or another public health emergency, or recommended methods for responding to such an attack or emergency.

(3) Standards

Not later than one year after June 12, 2002, the Secretary, in cooperation with health care providers and State and local public health officials, shall establish any additional technical and reporting standards (including standards for interoperability) for networks under paragraph (1).

(c) Authorization of appropriations

(1) Facilities; capacities

(A) Facilities

For the purpose of carrying out subsection (a)(2) of this section, there are authorized to be appropriated $300,000,000 for each of the fiscal years 2002 and 2003, and such sums as may be necessary for each of the fiscal years 2004 through 2006.

(B) Mission; improving capacities

For the purposes of achieving the mission of the Centers for Disease Control and Pre-

vention described in subsection (a)(1) of this section, for carrying out subsection (a)(3) of this section, for better conducting the capacities described in section 247d–1 of this title, and for supporting public health activities, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2002 through 2006.

(2) National communications and surveillance networks

For the purpose of carrying out subsection (b) of this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2002 through 2006.

(d) Public health situational awareness

(1) In general

Not later than 2 years after December 19, 2006, the Secretary, in collaboration with State, local, and tribal public health officials, shall establish a near real-time electronic nationwide public health situational awareness capability through an interoperable network of systems to share data and information to enhance early detection of rapid response to, and management of, potentially catastrophic infectious disease outbreaks and other public health emergencies that originate domestically or abroad. Such network shall be built on existing State situational awareness systems or enhanced systems that enable such connectivity.

(2) Strategic plan

Not later than 180 days after December 19, 2006, the Secretary shall submit to the appropriate committees of Congress, a strategic plan that demonstrates the steps the Secretary will undertake to develop, implement, and evaluate the network described in paragraph (1), utilizing the elements described in paragraph (3).

(3) Elements

The network described in paragraph (1) shall include data and information transmitted in a standardized format from—

(A) State, local, and tribal public health entities, including public health laboratories;

(B) Federal health agencies;

(C) zoonotic disease monitoring systems;

(D) public and private sector health care entities, hospitals, pharmacies, poison control centers or professional organizations in the field of poison control, and clinical laboratories, to the extent practicable and provided that such data are voluntarily provided simultaneously to the Secretary and appropriate State, local, and tribal public health agencies; and

(E) such other sources as the Secretary may deem appropriate.

(4) Rule of construction

Paragraph (3) shall not be construed as requiring separate reporting of data and information from each source listed.

(5) Required activities

In establishing and operating the network described in paragraph (1), the Secretary shall—

(A) utilize applicable interoperability standards as determined by the Secretary through a joint public and private sector process;

(B) define minimal data elements for such network;

(C) in collaboration with State, local, and tribal public health officials, integrate and build upon existing State, local, and tribal capabilities, ensuring simultaneous sharing of data, information, and analyses from the network described in paragraph (1) with State, local, and tribal public health agencies; and

(D) in collaboration with State, local, and tribal public health officials, develop procedures and standards for the collection, analysis, and interpretation of data that States, regions, or other entities collect and report to the network described in paragraph (1).

(e) State and regional systems to enhance situational awareness in public health emergencies

(1) In general

To implement the network described in subsection (d), the Secretary may award grants to States or consortia of States to enhance the ability of such States or consortia of States to establish or operate a coordinated public health situational awareness system for regional or Statewide early detection of, rapid response to, and management of potentially catastrophic infectious disease outbreaks and public health emergencies, in collaboration with appropriate public health agencies, sentinel hospitals, clinical laboratories, pharmacies, poison control centers, other health care organizations, and animal health organizations within such States.

(2) Eligibility

To be eligible to receive a grant under paragraph (1), the State or consortium of States shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require, including an assurance that the State or consortium of States will submit to the Secretary—

(A) reports of such data, information, and metrics as the Secretary may require;

(B) a report on the effectiveness of the systems funded under the grant; and

(C) a description of the manner in which grant funds will be used to enhance the timelines and comprehensiveness of efforts to detect, respond to, and manage potentially catastrophic infectious disease outbreaks and public health emergencies.

(3) Use of funds

A State or consortium of States that receives an award under this subsection—

(A) shall establish, enhance, or operate a coordinated public health situational awareness system for regional or Statewide early detection of, rapid response to, and management of potentially catastrophic infectious disease outbreaks and public health emergencies;

(B) may award grants or contracts to entities described in paragraph (1) within or serving such State to assist such entities in improving the operation of information technology systems, facilitating the secure exchange of data and information, and training personnel to enhance the operation of the system described in subparagraph (A); and

(C) may conduct a pilot program for the development of multi-State telehealth network test beds that build on, enhance, and securely link existing State and local telehealth programs to prepare for, monitor, respond to, and manage the events of public health emergencies, facilitate coordination and communication among medical, public health, and emergency response agencies, and provide medical services through telehealth initiatives within the States that are involved in such a multi-State telehealth network test bed.

(4) Limitation

Information technology systems acquired or implemented using grants awarded under this section must be compliant with—

(A) interoperability and other technological standards, as determined by the Secretary; and

(B) data collection and reporting requirements for the network described in subsection (d).

(5) Independent evaluation

Not later than 4 years after December 19, 2006, the Government Accountability Office shall conduct an independent evaluation, and submit to the Secretary and the appropriate committees of Congress a report concerning the activities conducted under this subsection and subsection (d).

(f) Telehealth enhancements for emergency response

(1) Evaluation

The Secretary, in consultation with the Federal Communications Commission and other relevant Federal agencies, shall—

(A) conduct an inventory of telehealth initiatives in existence on December 19, 2006, including—

(i) the specific location of network components;

(ii) the medical, technological, and communications capabilities of such components;

(iii) the functionality of such components; and

(iv) the capacity and ability of such components to handle increased volume during the response to a public health emergency;

(B) identify methods to expand and interconnect the regional health information networks funded by the Secretary, the State and regional broadband networks funded through the rural health care support mechanism pilot program funded by the Federal Communications Commission, and other telehealth networks;

(C) evaluate ways to prepare for, monitor, respond rapidly to, or manage the events of, a public health emergency through the enhanced use of telehealth technologies, including mechanisms for payment or reimbursement for use of such technologies and personnel during public health emergencies;

(D) identify methods for reducing legal barriers that deter health care professionals from providing telemedicine services, such as by utilizing State emergency health care professional credentialing verification systems, encouraging States to establish and implement mechanisms to improve interstate medical licensure cooperation, facilitating the exchange of information among States regarding investigations and adverse actions, and encouraging States to waive the application of licensing requirements during a public health emergency;

(E) evaluate ways to integrate the practice of telemedicine within the National Disaster Medical System; and

(F) promote greater coordination among existing Federal interagency telemedicine and health information technology initiatives.

(2) Report

Not later than 12 months after December 19, 2006, the Secretary shall prepare and submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives regarding the findings and recommendations pursuant to subparagraphs (A) through (F) of paragraph (1).

(g) Authorization of appropriations

There are authorized to be appropriated to carry out this section, such sums as may be necessary in each of fiscal years 2007 through 2011.

(July 1, 1944, ch. 373, title III, § 319D, as added Pub. L. 106–505, title I, § 102, Nov. 13, 2000, 114 Stat. 2318; amended Pub. L. 107–188, title I, § 103, June 12, 2002, 116 Stat. 603; Pub. L. 109–417, title II, §§ 202, 204(b)(2), Dec. 19, 2006, 120 Stat. 2845, 2851.)

AMENDMENTS

2006—Subsec. (a)(1). Pub. L. 109–417, § 202(1), inserted ''domestically and abroad'' after ''public health threats''.

Subsec. (a)(3). Pub. L. 109–417, § 204(b)(2), struck out '', taking into account evaluations under section 247d–2(a) of this title,'' after ''The Secretary'' in introductory provisions.

Subsecs. (d) to (g). Pub. L. 109–417, § 202(2), added subsecs. (d) to (g).

2002—Pub. L. 107–188 reenacted section catchline without change and amended text generally, substituting detailed provisions relating to facilities, capacities, and national communications and surveillance networks for provisions relating to findings of need for secure and modern facilities.

§ 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 November 13, 2000, to serve as such a task force, if such committee, or other organization meets the requirements of this section.

(2) Members of task force

The task force described in paragraph (1) shall be composed of representatives from such Federal agencies, and shall seek input from public health constituencies, manufacturers, veterinary and medical professional societies and others, as determined to be necessary by the Secretary, to develop and implement a comprehensive plan to address the public health threat of antimicrobial resistance.

(3) Agenda

(A) In general

The task force described in paragraph (1) shall consider factors the Secretary considers appropriate, including—

(i) public health factors contributing to increasing antimicrobial resistance;

(ii) public health needs to detect and monitor antimicrobial resistance;

(iii) detection, prevention, and control strategies for resistant pathogens;

(iv) the need for improved information and data collection;

(v) the assessment of the risk imposed by pathogens presenting a threat to the public health; and

(vi) any other issues which the Secretary determines are relevant to antimicrobial resistance.

(B) Detection and control

The Secretary, in consultation with the task force described in paragraph (1) and State and local public health officials, shall—

(i) develop, improve, coordinate or enhance participation in a surveillance plan to detect and monitor emerging antimicrobial resistance; and

(ii) develop, improve, coordinate or enhance participation in an integrated information system to assimilate, analyze, and exchange antimicrobial resistance data between public health departments.

(4) Meetings

The task force described under paragraph (1) shall convene not less than twice a year, or more frequently as the Secretary determines to be appropriate.

(b) Research and development of new antimicrobial drugs and diagnostics

The Secretary and the Director of Agricultural Research Services, consistent with the recommendations of the task force established under subsection (a) of this section, 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) of this section), 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) of this section, 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) of this section, which may include activities that—

(A) provide training to enable such entity to identify patterns of resistance rapidly and accurately;

(B) develop, improve, coordinate or enhance participation in information systems by which data on resistant infections can be shared rapidly among relevant national, State, and local health agencies and health care providers; and

(C) develop and implement policies to control the spread of antimicrobial resistance.

(e) Grants for demonstration programs

(1) In general

The Secretary shall award competitive grants to eligible entities to establish demonstration programs to promote judicious use of antimicrobial drugs or control the spread of antimicrobial-resistant pathogens.

(2) Eligible entities

Eligible entities for grants under paragraph (1) may include hospitals, clinics, institutions of long-term care, professional medical societies, schools or programs that train medical laboratory personnel, or other public or private nonprofit entities.

(3) Technical assistance

The Secretary shall provide appropriate technical assistance to eligible entities that receive grants under paragraph (1).

(f) Supplement not supplant

Funds appropriated under this section shall be used to supplement and not supplant other Federal, State, and local public funds provided for activities under this section.

(g) Authorization of appropriations

There are authorized to be appropriated to carry out this section, $40,000,000 for fiscal year 2001, $25,000,000 for each of the fiscal years 2002 and 2003, and such sums as may be necessary for each of the fiscal years 2004 through 2006.

(July 1, 1944, ch. 373, title III, § 319E, as added Pub. L. 106–505, title I, § 102, Nov. 13, 2000, 114 Stat. 2318; amended Pub. L. 107–188, title I, § 109, June 12, 2002, 116 Stat. 610.)

AMENDMENTS

2002—Subsec. (b). Pub. L. 107–188, § 109(1)(A), in introductory provisions, substituted ''shall directly or through awards of grants or cooperative agreements to public or private entities provide for the conduct of'' for ''shall conduct and support''.

Subsec. (b)(4). Pub. L. 107–188, § 109(1)(B), amended par. (4) generally. Prior to amendment, par. (4) read as follows: ''the sequencing of the genomes of priority pathogens as determined by the Director of the National Institutes of Health in consultation with the task force established under subsection (a) of this section; and''.

Subsec. (e)(2). Pub. L. 107–188, § 109(2), inserted ''schools or programs that train medical laboratory personnel,'' after ''professional medical societies,''.

Subsec. (g). Pub. L. 107–188, § 109(3), substituted ''$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'' for ''and such sums as may be necessary for each subsequent fiscal year through 2006''.

§ 247d–5a. Identification of clinically susceptible concentrations of antimicrobials

(a) Definition

In this section, the term ''clinically susceptible concentrations'' means specific values which characterize bacteria as clinically susceptible, intermediate, or resistant to the drug (or drugs) tested.

(b) Identification

The Secretary of Health and Human Services (referred to in this section as the ''Secretary''), through the Commissioner of Food and Drugs, shall identify (where such information is reasonably available) and periodically update clinically susceptible concentrations.

(c) Public availability

The Secretary, through the Commissioner of Food and Drugs, shall make such clinically susceptible concentrations publicly available, such as by posting on the Internet, not later than 30 days after the date of identification and any update under this section.

(d) Effect

Nothing in this section shall be construed to restrict, in any manner, the prescribing of antibiotics by physicians, or to limit the practice of medicine, including for diseases such as Lyme and tick-borne diseases.

(Pub. L. 110–85, title XI, § 1111, Sept. 27, 2007, 121 Stat. 975.)

CODIFICATION

Section was enacted as part of the Food and Drug Administration Amendments Act of 2007, and not as part of the Public Health Service Act which comprises this chapter.

§ 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 or medical 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) of this section, 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) of this section.

(2) National Advisory Committee on At-Risk Individuals and Public Health Emergencies

(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 300hh–12 of this title to meet the emergency health security of at-risk individuals.

(C) Composition

The Advisory Committee shall be composed of such Federal officials as may be appropriate to address the special needs of the diverse population groups of at-risk populations.

(D) Termination

The Advisory Committee terminates six years after June 12, 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 June 12, 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 254e(a) of this title), a medically underserved population (as defined under section 254b(b)(3) of this title), or a medically underserved area or area at high risk of a public health emergency as designated by the Secretary.

(d) Centers for Public Health Preparedness; core curricula and training

(1) In general

The Secretary may establish at accredited schools of public health, Centers for Public Health Preparedness (hereafter referred to in this section as the ''Centers'').

(2) Eligibility

To be eligible to receive an award under this subsection to establish a Center, an accredited

school of public health shall agree to conduct activities consistent with the requirements of this subsection.

(3) Core curricula

The Secretary, in collaboration with the Centers and other public or private entities shall establish core curricula based on established competencies leading to a 4-year bachelor's degree, a graduate degree, a combined bachelor and master's degree, or a certificate program, for use by each Center. The Secretary shall disseminate such curricula to other accredited schools of public health and other health professions schools determined appropriate by the Secretary, for voluntary use by such schools.

(4) Core competency-based training program

The Secretary, in collaboration with the Centers and other public or private entities shall facilitate the development of a competency-based training program to train public health practitioners. The Centers shall use such training program to train public health practitioners. The Secretary shall disseminate such training program to other accredited schools of public health, health professions schools, and other public or private entities as determined by the Secretary, for voluntary use by such entities.

(5) Content of core curricula and training program

The Secretary shall ensure that the core curricula and training program established pursuant to this subsection respond to the needs of State, local, and tribal public health authorities and integrate and emphasize essential public health security capabilities consistent with section 300hh–1(b)(2) of this title.

(6) Academic-workforce communication

As a condition of receiving funding from the Secretary under this subsection, a Center shall collaborate with a State, local, or tribal public health department to—

(A) define the public health preparedness and response needs of the community involved;

(B) assess the extent to which such needs are fulfilled by existing preparedness and response activities of such school or health department, and how such activities may be improved;

(C) prior to developing new materials or trainings, evaluate and utilize relevant materials and trainings developed by others Centers; and

(D) evaluate community impact and the effectiveness of any newly developed materials or trainings.

(7) Public health systems research

In consultation with relevant public and private entities, the Secretary shall define the existing knowledge base for public health preparedness and response systems, and establish a research agenda based on Federal, State, local, and tribal public health preparedness priorities. As a condition of receiving funding from the Secretary under this subsection, a Center shall conduct public health systems research that is consistent with the agenda described under this paragraph.

(e) Accelerated research and development on priority pathogens and countermeasures

(1) In general

With respect to pathogens of potential use in a bioterrorist attack, and other agents that may cause a public health emergency, the Secretary, taking into consideration any recommendations of the working group under subsection (a) of this section, 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) of this section), 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 262a(a)(1) of this title, or harm from any other agent that may cause a public health emergency; or

(B) a priority to treat, identify, or prevent conditions that may result in adverse health consequences or death and may be caused by the administering of a drug, biological product, device, vaccine, vaccine adjuvant, antiviral, or diagnostic test that is a priority under subparagraph (A).

(f) Authorization of appropriations

(1) Fiscal year 2007

There are authorized to be appropriated to carry out this section for fiscal year 2007—

(A) to carry out subsection (a)—

(i) $5,000,000 to carry out paragraphs (1) through (4); and

(ii) $7,000,000 to carry out paragraph (5);

(B) to carry out subsection (c), $3,000,000; and

(C) to carry out subsection (d), $31,000,000, of which $5,000,000 shall be used to carry out paragraphs (3) through (5) of such subsection.

(2) Subsequent fiscal years

There are authorized to be appropriated such sums as may be necessary to carry out this section for fiscal year 2008 and each subsequent fiscal year.

(July 1, 1944, ch. 373, title III, § 319F, as added Pub. L. 106–505, title I, § 102, Nov. 13, 2000, 114 Stat. 2321; amended Pub. L. 107–188, title I, §§ 104(a) 105, 108, 111(3), 125, June 12, 2002, 116 Stat. 605, 606, 609, 611, 614; Pub. L. 108–276, § 2(d), July 21, 2004, 118 Stat. 842; Pub. L. 109–417, title III, §§ 301(d), (e), 304, Dec. 19, 2006, 120 Stat. 2854, 2855, 2859.)

AMENDMENTS

2006—Subsec. (a). Pub. L. 109–417, § 304(1), added subsec. (a) and struck out heading and text of former subsec. (a) which established a working group on bioterrorism and other public health emergencies.

Subsec. (b)(2). Pub. L. 109–417, § 301(d)(1), substituted ''At-Risk Individuals and Public Health Emergencies'' for ''Children and Terrorism'' in heading.

Subsec. (b)(2)(A). Pub. L. 109–417, § 301(d)(2), substituted ''At-Risk Individuals and Public Health Emergencies'' for ''Children and Terrorism''.

Subsec. (b)(2)(B)(i). Pub. L. 109–417, § 301(d)(3)(A), substituted ''public health emergencies as they relate to at-risk individuals'' for ''bioterrorism as it relates to children''.

Subsec. (b)(2)(B)(ii), (iii). Pub. L. 109–417, § 301(d)(3)(B), (C), substituted ''at-risk individuals'' for ''children''.

Subsec. (b)(2)(C). Pub. L. 109–417, § 301(d)(4), substituted ''at-risk populations'' for ''children, and child health experts on infectious disease, environmental health, toxicology, and other relevant professional disciplines''.

Subsec. (b)(2)(D). Pub. L. 109–417, § 301(d)(5), substituted ''six years'' for ''one year''.

Subsec. (b)(3)(B). Pub. L. 109–417, § 301(e), struck out ''and the working group under subsection (a) of this section'' after ''Secretary''.

Subsecs. (c) to (h). Pub. L. 109–417, § 304(2)–(4), added subsecs. (c), (d), and (f), redesignated subsec. (h) as (e), and struck out former subsecs. (c) to (g), which related to: in subsec. (c), development of communication strategy; in subsec. (d), Federal Internet site on bioterrorism; in subsec. (e), grants to increase capacity to detect, diagnose, and respond to acts of bioterrorism; in subsec. (f), assistance to State and local health agencies to enable effective response to attacks; and, in subsec. (g), education and training activities.

Subsecs. (i), (j). Pub. L. 109–417, § 304(5), struck out subsecs. (i) and (j) which related to report to congressional committees on public health and medical consequences of a bioterrorist attack and the supplementary nature of funds appropriated under this section, respectively.

2004—Subsec. (a)(1). Pub. L. 108–276, § 2(d)(1), inserted ''the Secretary of Homeland Security,'' after ''Management Agency,'' in introductory provisions.

Subsec. (h)(4)(B). Pub. L. 108–276, § 2(d)(2), substituted ''to treat, identify, or prevent conditions'' for ''to diagnose conditions''.

2002—Subsec. (a). Pub. L. 107–188, § 108, added subsec. (a) and struck out heading and text of former subsec. (a). Text read as follows: ''The Secretary, in coordination with the Secretary of Defense, shall establish a joint interdepartmental working group on preparedness and readiness for the medical and public health effects of a bioterrorist attack on the civilian population. Such joint working group shall—

''(1) coordinate research on pathogens likely to be used in a bioterrorist attack on the civilian population as well as therapies to treat such pathogens;

''(2) coordinate research and development into equipment to detect pathogens likely to be used in a bioterrorist attack on the civilian population and protect against infection from such pathogens;

''(3) develop shared standards for equipment to detect and to protect against infection from pathogens likely to be used in a bioterrorist attack on the civilian population; and

''(4) coordinate the development, maintenance, and procedures for the release of, strategic reserves of vaccines, drugs, and medical supplies which may be needed rapidly after a bioterrorist attack upon the civilian population.''

Subsec. (b). Pub. L. 107–188, § 104(a)(1), (3), added subsec. (b) and struck out former subsec. (b) which related to establishment, functions, membership, and coordination of a working group on the public health and medical consequences of bioterrorism.

Subsecs. (c), (d). Pub. L. 107–188, § 104(a)(3), added subsecs. (c) and (d). Former subsecs. (c) and (d) redesignated (e) and (f), respectively.

Subsec. (e). Pub. L. 107–188, § 104(a)(2), redesignated subsec. (c) as (e). Former subsec. (e) redesignated (g).

Subsec. (e)(2). Pub. L. 107–188, § 111(3), which directed the amendment of section 391F(e)(2) of the Public Health Service Act by striking out ''or'' after ''clinic,'' and inserting before period '', professional organization or society, school or program that trains medical laboratory personnel, private accrediting organization, or other nonprofit private institution or entity meeting criteria established by the Secretary'', was executed to subsec. (e)(2) of this section, which is section 319F(e)(2) of the Act, to reflect the probable intent of Congress.

Subsec. (f). Pub. L. 107–188, § 104(a)(2), redesignated subsec. (d) as (f). Former subsec. (f) redesignated (h).

Subsec. (g). Pub. L. 107–188, § 105, amended heading and text of subsec. (g) generally. Prior to amendment, text read as follows: ''The Secretary, in collaboration with members of the working group described in subsection (b) of this section, and professional organizations and societies, shall—

''(1) develop and implement educational programs to instruct public health officials, medical professionals, and other personnel working in health care facilities in the recognition and care of victims of a bioterrorist attack; and

''(2) develop and implement programs to train laboratory personnel in the recognition and identification of a potential bioweapon.''

Pub. L. 107–188, § 104(a)(2), redesignated subsec. (e) as (g). Former subsec. (g) redesignated (i).

Subsec. (h). Pub. L. 107–188, § 125, amended heading and text of subsec. (h) generally. Prior to amendment, text read as follows: ''The Secretary shall consult with the working group described in subsection (a) of this section, to develop priorities for and conduct research, investigations, experiments, demonstrations, and studies in the health sciences related to—

''(1) the epidemiology and pathogenesis of potential bioweapons;

''(2) the development of new vaccines or other therapeutics against pathogens likely to be used in a bioterrorist attack;

''(3) the development of medical diagnostics to detect potential bioweapons; and

''(4) other relevant research areas.''

Pub. L. 107–188, § 104(a)(2), redesignated subsec. (f) as (h). Former subsec. (h) redesignated (j).

Subsec. (i). Pub. L. 107–188, § 104(a)(1), (2), redesignated subsec. (g) as (i) and struck out heading and text of former subsec. (i). Text read as follows: ''There are authorized to be appropriated to carry out this section $215,000,000 for fiscal year 2001, and such sums as may be necessary for each subsequent fiscal year through 2006.''

Subsec. (j). Pub. L. 107–188, § 104(a)(2), redesignated subsec. (h) as (j).

OTHER REPORTS

Pub. L. 107–188, title I, § 101(b)(1), June 12, 2002, 116 Stat. 598, provided that:

''(1) IN GENERAL.—Not later than one year after the date of the enactment of this Act [June 12, 2002], the Secretary of Health and Human Services (referred to in this subsection as the 'Secretary') shall submit to the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate, a report concerning—

''(A) the recommendations and findings of the National Advisory Committee on Children and Terrorism under section 319F(c)(2) of the Public Health Service Act [probably means subsec. (b)(2) of this section];

''(B) the recommendations and findings of the EPIC Advisory Committee under section 319F(c)(3) of such Act [probably means subsec. (b)(3) of this section];

''(C) the characteristics that may render a rural community uniquely vulnerable to a biological attack, including distance, lack of emergency transport, hospital or laboratory capacity, lack of integration of Federal or State public health networks, workforce deficits, or other relevant characteristics;

''(D) the characteristics that may render areas or populations designated as medically underserved populations (as defined in section 330 of such Act [section 254b of this title]) uniquely vulnerable to a biological attack, including significant numbers of low-income or uninsured individuals, lack of affordable and accessible health care services, insufficient public and primary health care resources, lack of integration of Federal or State public health networks, workforce deficits, or other relevant characteristics;

''(E) the recommendations of the Secretary with respect to additional legislative authority that the Secretary determines is necessary to effectively strengthen rural communities, or medically underserved populations (as defined in section 330 of such Act); and

''(F) the need for and benefits of a National Disaster Response Medical Volunteer Service that would be a private-sector, community-based rapid response corps of medical volunteers.''

STUDY REGARDING COMMUNICATIONS ABILITIES OF PUBLIC HEALTH AGENCIES

Pub. L. 107–188, title I, § 104(b), June 12, 2002, 116 Stat. 606, provided that: ''The Secretary of Health and Human Services, in consultation with the Federal Communications Commission, the National Telecommunications and Information Administration, and other appropriate Federal agencies, shall conduct a study to determine whether local public health entities have the ability to maintain communications in the event of a bioterrorist attack or other public health emergency. The study shall examine whether redundancies are required in the telecommunications system, particularly with respect to mobile communications, for public health entities to maintain systems operability and connectivity during such emergencies. The study shall also include recommendations to industry and public health entities about how to implement such redundancies if necessary.''

§ 247d–6a. Authority for use of certain procedures regarding qualified countermeasure research and development activities

(a) In general

(1) Authority

In conducting and supporting research and development activities regarding countermeasures under section 247d–6(h) of this title, 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 285f of this title, 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 321(g)(1) of title 21), biological product (as that term is defined by section 262(i) of this title), or device (as that term is defined by section 321(h) of title 21), that the Secretary determines to be a priority (consistent with sections 182(2) and 184(a) of title 6) to—

(i) 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; or

(ii) 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.

(B) Infectious disease

The term ''infectious disease'' means a disease potentially caused by a pathogenic organism (including a bacteria, virus, fungus, or parasite) that is acquired by a person and that reproduces in that person.

(3) Interagency cooperation

(A) In general

In carrying out activities under this section, the Secretary is authorized, subject to subparagraph (B), to enter into interagency agreements and other collaborative undertakings with other agencies of the United States Government.

(B) Limitation

An agreement or undertaking under this paragraph shall not authorize another agency to exercise the authorities provided by this section.

(4) Availability of facilities to the Secretary

In any grant, contract, or cooperative agreement entered into under the authority provided in this section with respect to a biocontainment laboratory or other related or ancillary specialized research facility that the Secretary determines necessary for the pur-

pose 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 247d–6(h) of this title 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 403(11) of title 41, as applicable pursuant to section 252a(a) of title 41, shall be deemed to be $25,000,000 in the administration, with respect to such procurement, of—

(i) section 253(g)(1)(A) of title 41 and its implementing regulations; and

(ii) section 252a(b) of title 41 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 (relating to contract work hours and safety standards).

(ii) Subsections (a) and (b) of section 57 of title 41.

(iii) Section 254d of title 41 (relating to the examination of contractor records).

(iv) Section 3131 of title 40 (relating to bonds of contractors of public buildings or works).

(v) Subsection (a) of section 254 of title 41 (relating to contingent fees to middlemen).

(vi) Section 6962 of this title.

(vii) Section 1354 of title 31 (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 253(c)(1) of title 41 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 253(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 253(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 428 of title 41 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) of this section, section 1491 of title 28, and section 3556 of title 31, 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.

(B) Override of stay of contract award or performance committed to agency discretion

Notwithstanding section 1491 of title 28 and section 3553 of title 31, 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 to award a contract for a procurement described in paragraph (1) of this subsection.

(ii) An authorization under section 3553(d)(3)(C) of such title to perform a contract for a procurement described in paragraph (1) of this subsection.

(c) Authority to expedite peer review

(1) In general

The Secretary may, as the Secretary determines necessary to respond to pressing qualified countermeasure research and development needs under this section, employ such expedited peer review procedures (including consultation with appropriate scientific experts) as the Secretary, in consultation with the Director of NIH, deems appropriate to obtain assessment of scientific and technical merit and likely contribution to the field of qualified countermeasure research, in place of the peer review and advisory council review procedures that would be required under sections 241(a)(3), 284(b)(1)(B), 284(b)(2), 284a(a)(3)(A), 289a, and 289c of this title, 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, 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 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 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;

(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.

(July 1, 1944, ch. 373, title III, § 319F–1, as added Pub. L. 108–276, § 2(a), July 21, 2004, 118 Stat. 835; amended Pub. L. 109–417, title IV, § 403(a), Dec. 19, 2006, 120 Stat. 2874.)

REFERENCES IN TEXT

The Project BioShield Act of 2004, referred to in subsec. (b)(1)(D), is Pub. L. 108–276, July 21, 2004, 118 Stat. 835. For complete classification of this Act to the Code, see Short Title of 2004 Amendments note set out under section 201 of this title and Tables.

The Federal Tort Claims Act, referred to in subsec. (d)(2), is title IV of act Aug. 2, 1946, ch. 753, 60 Stat. 842, which was classified principally to chapter 20 (§§ 921, 922, 931–934, 941–946) of former Title 28, Judicial Code and Judiciary. Title IV of act Aug. 2, 1946, was substantially repealed and reenacted as sections 1346(b) and 2671 et seq. of Title 28, Judiciary and Judicial Procedure, by act June 25, 1948, ch. 646, 62 Stat. 992, the first section of which enacted Title 28. The Federal Tort Claims Act is also commonly used to refer to chapter 171 of Title 28, Judiciary and Judicial Procedure. For complete classification of title IV to the Code, see Tables. For distribution of former sections of Title 28 into the revised Title 28, see Table at the beginning of Title 28.

The provisions of title 5 governing appointments in the competitive service, referred to in subsec. (e)(1), are classified generally to section 3301 et seq. of Title 5, Government Organization and Employees.

AMENDMENTS

2006—Subsec. (a)(2). Pub. L. 109–417 added par. (2) and struck out heading and text of former par. (2). Text read as follows: ''For purposes of this section, the term 'qualified countermeasure' means a drug (as that term is defined by section 321(g)(1) of title 21), biological product (as that term is defined by section 262(i) of this title), or device (as that term is defined by section 321(h) of title 21) that the Secretary determines to be a priority (consistent with sections 182(2) and 184(a) of title 6) to—

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

''(B) treat, identify, or prevent harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, biological product, or device that is used as described in subparagraph (A).''

RULE OF CONSTRUCTION

Pub. L. 108–276, § 2(e), July 21, 2004, 118 Stat. 842, provided that: ''Nothing in this section [enacting this section and amending sections 247d–6, 287a–2, and 300aa–6 of this title] has any legal effect on sections 302(2), 302(4), 304(a), or 304(b) of the Homeland Security Act of 2002 [6 U.S.C. 182(2), (4), 184(a), (b)].''

COLLABORATION AND COORDINATION

Pub. L. 109–417, title IV, § 405, Dec. 19, 2006, 120 Stat. 2875, provided that:

''(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 of Health and Human Services (referred to in this subsection as 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 of the Public Health Service Act (42 U.S.C. 247d–6b)) (as amended by this Act), a qualified countermeasure (as defined

in section 319F–1 of the Public Health Service Act (42 U.S.C. 247d–6a)) (as amended by this Act), or a qualified pandemic or epidemic product (as defined in section 319F–3 of the Public Health Service Act (42 U.S.C. 247d–6d)) 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 [Dec. 19, 2006] 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 at the end of the 6-year period that begins on the date of enactment of this Act [Dec. 19, 2006].

''(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.''

OUTREACH

Pub. L. 108–276, § 6, July 21, 2004, 118 Stat. 862, provided that: ''The Secretary of Health and Human Services shall develop outreach measures to ensure to the extent practicable that diverse institutions, including Historically Black Colleges and Universities and those serving large proportions of Black or African Americans, American Indians, Appalachian Americans, Alaska Natives, Asians, Native Hawaiians, other Pacific Islanders, Hispanics or Latinos, or other underrepresented populations, are meaningfully aware of available research and development grants, contracts, cooperative agreements, and procurements conducted under sections 2 and 3 of this Act [enacting this section and section 320 of Title 6, Domestic Security, amending sections 247d–6, 247d–6b, 287a–2, and 300aa–6 of this title and sections 312 and 313 of Title 6, renumbering section 300hh–12 of this title as section 247d–6b of this title, and enacting provisions set out as notes under this section and section 247d–6b of this title].''

RECOMMENDATION FOR EXPORT CONTROLS ON CERTAIN BIOMEDICAL COUNTERMEASURES

Pub. L. 108–276, § 7, July 21, 2004, 118 Stat. 863, provided that: ''Upon the award of any grant, contract, or cooperative agreement under section 2 or 3 of this Act [enacting this section and section 320 of Title 6, Domestic Security, amending sections 247d–6, 247d–6b, 287a–2, and 300aa–6 of this title and sections 312 and 313 of Title 6, renumbering section 300hh–12 of this title as section 247d–6b of this title, and enacting provisions set out as notes under this section and section 247d–6b of this title] for the research, development, or procurement of a qualified countermeasure or a security countermeasure (as those terms are defined in this Act [see Short Title of 2004 Amendments note set out under section 201 of this title]), the Secretary of Health and Human Services shall, in consultation with the heads of other appropriate Federal agencies, determine whether the countermeasure involved in such grant, contract, or cooperative agreement is subject to existing export-related controls and, if not, may make a recommendation to the appropriate Federal agency or agencies that such countermeasure should be included on the list of controlled items subject to such controls.''

ENSURING COORDINATION, COOPERATION AND THE ELIMINATION OF UNNECESSARY DUPLICATION IN PROGRAMS DESIGNED TO PROTECT THE HOMELAND FROM BIOLOGICAL, CHEMICAL, RADIOLOGICAL, AND NUCLEAR AGENTS

Pub. L. 108–276, § 8, July 21, 2004, 118 Stat. 863, provided that:

''(a) ENSURING COORDINATION OF PROGRAMS.—The Secretary of Health and Human Services, the Secretary of Homeland Security, and the Secretary of Defense shall ensure that the activities of their respective Departments coordinate, complement, and do not unnecessarily duplicate programs to identify potential domestic threats from biological, chemical, radiological or nuclear agents, detect domestic incidents involving such agents, analyze such incidents, and develop necessary countermeasures. The aforementioned Secretaries shall further ensure that information and technology possessed by the Departments relevant to these activities are shared with the other Departments.

''(b) DESIGNATION OF AGENCY COORDINATION OFFICER.—The Secretary of Health and Human Services, the Secretary of Homeland Security, and the Secretary of Defense shall each designate an officer or employee of their respective Departments who shall coordinate, through regular meetings and communications, with the other aforementioned Departments such programs and activities carried out by their Departments.''

§ 247d–6b. Strategic National Stockpile and security countermeasure procurements

(a) Strategic National Stockpile

(1) In general

The Secretary, in collaboration with the Director of the Centers for Disease Control and Prevention, and in coordination with the Secretary of Homeland Security (referred to in this section as the ''Homeland Security Secretary''), shall maintain a stockpile or stockpiles of drugs, vaccines and other biological products, medical devices, and other supplies in such numbers, types, and amounts as are determined by the Secretary to be appropriate and practicable, taking into account other available sources, to provide for the emergency health security of the United States, including the emergency health security of children and other vulnerable populations, in the event of a bioterrorist attack or other public

health emergency. The Secretary shall conduct an annual review (taking into account at-risk individuals) of the contents of the stockpile, including non-pharmaceutical supplies, and make necessary additions or modifications to the contents based on such review.

(2) Procedures

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

(A) consult with the working group under section 247d–6(a) of this title;

(B) ensure that adequate procedures are followed with respect to such stockpile for inventory management and accounting, and for the physical security of the stockpile;

(C) in consultation with Federal, State, and local officials, take into consideration the timing and location of special events;

(D) review and revise, as appropriate, the contents of the stockpile on a regular basis to ensure that emerging threats, advanced technologies, and new countermeasures are adequately considered;

(E) devise plans for the effective and timely supply-chain management of the stockpile, in consultation with appropriate Federal, State and local agencies, and the public and private health care infrastructure;

(F) deploy the stockpile as required by the Secretary of Homeland Security to respond to an actual or potential emergency;

(G) deploy the stockpile at the discretion of the Secretary to respond to an actual or potential public health emergency or other situation in which deployment is necessary to protect the public health or safety; and

(H) ensure the adequate physical security of the stockpile.

(b) Smallpox vaccine development

(1) In general

The Secretary shall award contracts, enter into cooperative agreements, or carry out such other activities as may reasonably be required in order to ensure that the stockpile under subsection (a) of this section 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) of this section.

(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 under paragraph (10).

(B) Security countermeasure

For purposes of this subsection, the term ''security countermeasure'' means a drug (as that term is defined by section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1))), biological product (as that term is defined by section 262(i) of this title), 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 182(2) and 184(a) of title 6) 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 [21 U.S.C. 351 et seq.] or licensed under section 262 of this title; or

(bb) is a countermeasure for which the Secretary determines that sufficient and satisfactory clinical experience or research data (including data, if available, from pre-clinical and clinical trials) support a reasonable conclusion that the countermeasure will qualify for approval or licensing within eight years after the date of a determination under paragraph (5); or

(ii) is authorized for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360bbb–3].

(2) Determination of material threats

(A) Material threat

The Homeland Security Secretary, in consultation with the Secretary and the heads of other agencies as appropriate, shall on an ongoing basis—

(i) assess current and emerging threats of chemical, biological, radiological, and nuclear agents; and

(ii) determine which of such agents present a material threat against the United States population sufficient to affect national security.

(B) Public health impact; necessary countermeasures

The Secretary shall on an ongoing basis—

(i) assess the potential public health consequences for the United States population of exposure to agents identified under subparagraph (A)(ii); and

(ii) determine, on the basis of such assessment, the agents identified under subparagraph (A)(ii) for which countermeasures are necessary to protect the public health.

(C) Notice to Congress

The Secretary and the Homeland Security Secretary shall promptly notify the designated congressional committees (as defined in paragraph (10)) that a determination

has been made pursuant to subparagraph (A) or (B).

(D) Assuring access to threat information

In making the assessment and determination required under subparagraph (A), the Homeland Security Secretary shall use all relevant information to which such Secretary is entitled under section 122 of title 6, 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.

(4) Call for development of countermeasures; commitment for recommendation for procurement

(A) Proposal to the President

If, pursuant to an assessment under paragraph (3), the Homeland Security Secretary and the Secretary make a determination that a countermeasure would be appropriate but is either currently not developed or unavailable for procurement as a security countermeasure or is approved, licensed, or cleared only for alternative uses, such Secretaries may jointly submit to the President a proposal to—

(i) issue a call for the development of such countermeasure; and

(ii) make a commitment that, upon the first development of such countermeasure that meets the conditions for procurement under paragraph (5), the Secretaries will, based in part on information obtained pursuant to such call, make a recommendation under paragraph (6) that the special reserve fund under paragraph (10) be made available for the procurement of such countermeasure.

(B) Countermeasure specifications

The Homeland Security Secretary and the Secretary shall, to the extent practicable, include in the proposal under subparagraph (A)—

(i) estimated quantity of purchase (in the form of number of doses or number of effective courses of treatments regardless of dosage form);

(ii) necessary measures of minimum safety and effectiveness;

(iii) estimated price for each dose or effective course of treatment regardless of dosage form; and

(iv) other information that may be necessary to encourage and facilitate research, development, and manufacture of the countermeasure or to provide specifications for the countermeasure.

(C) Presidential approval

If the President approves a proposal under subparagraph (A), the Homeland Security Secretary and the Secretary shall make known to persons who may respond to a call for the countermeasure involved—

(i) the call for the countermeasure;

(ii) specifications for the countermeasure under subparagraph (B); and

(iii) the commitment described in subparagraph (A)(ii).

(5) Secretary's determination of countermeasures appropriate for funding from special reserve fund

(A) In general

The Secretary, in accordance with the provisions of this paragraph, shall identify specific security countermeasures that the Secretary determines, in consultation with the Homeland Security Secretary, to be appropriate for inclusion in the stockpile under subsection (a) of this section pursuant to procurements made with amounts in the special reserve fund under paragraph (10) (referred to in this subsection individually as a ''procurement under this subsection'').

(B) Requirements

In making a determination under subparagraph (A) with respect to a security countermeasure, the Secretary shall determine and consider the following:

(i) The quantities of the product that will be needed to meet the stockpile needs.

(ii) The feasibility of production and delivery within eight years of sufficient quantities of the product.

(iii) Whether there is a lack of a significant commercial market for the product at the time of procurement, other than as a security countermeasure.

(6) Recommendation for President's approval

(A) Recommendation for procurement

In the case of a security countermeasure that the Secretary has, in accordance with paragraphs (3) and (5), determined to be appropriate for procurement under this subsection, the Homeland Security Secretary and the Secretary shall jointly submit to the President, in coordination with the Director of the Office of Management and Budget, a recommendation that the special reserve fund under paragraph (10) be made available for the procurement of such countermeasure.

(B) Presidential approval

The special reserve fund under paragraph (10) is available for a procurement of a secu-

rity countermeasure only if the President has approved a recommendation under subparagraph (A) regarding the countermeasure.

(C) Notice to designated congressional committees

The Secretary and the Homeland Security Secretary shall notify the designated congressional committees of each decision of the President to approve a recommendation under subparagraph (A). Such notice shall include an explanation of the decision to make available the special reserve fund under paragraph (10) for procurement of such a countermeasure, including, where available, the number of, nature of, and other information concerning potential suppliers of such countermeasure, and whether other potential suppliers of the same or similar countermeasures were considered and rejected for procurement under this section and the reasons therefor.

(D) Subsequent specific countermeasures

Procurement under this subsection of a security countermeasure for a particular purpose does not preclude the subsequent procurement under this subsection of any other security countermeasure for such purpose if the Secretary has determined under paragraph (5)(A) that such countermeasure is appropriate for inclusion in the stockpile and if, as determined by the Secretary, such countermeasure provides improved safety or effectiveness, or for other reasons enhances preparedness to respond to threats of use of a biological, chemical, radiological, or nuclear agent. Such a determination by the Secretary is committed to agency discretion.

(E) Rule of construction

Recommendations and approvals under this paragraph apply solely to determinations that the special reserve fund under paragraph (10) will be made available for a procurement of a security countermeasure, and not to the substance of contracts for such procurement or other matters relating to awards of such contracts.

(7) Procurement

(A) In general

For purposes of a procurement under this subsection that is approved by the President under paragraph (6), the Homeland Security Secretary and the Secretary shall have responsibilities in accordance with subparagraphs (B) and (C).

(B) Interagency agreement; cost

The Homeland Security Secretary shall enter into an agreement with the Secretary for procurement of a security countermeasure in accordance with the provisions of this paragraph. The special reserve fund under paragraph (10) shall be available for payments made by the Secretary to a vendor for such procurement.

(C) Procurement

(i) In general

The Secretary shall be responsible for—

(I) arranging for procurement of a security countermeasure, including negotiating terms (including quantity, production schedule, and price) of, and entering into, contracts and cooperative agreements, and for carrying out such other activities as may reasonably be required, 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 eight years, if the Secretary determines that complexities or other difficulties in performance under the contract justify such a period. The contract shall be renewable for additional periods, none of which shall exceed five years.

(IV) Storage by vendor

The contract may provide that the vendor will provide storage for stocks of a product delivered to the ownership of the Federal Government under the contract, for such period and under such terms and conditions as the Secretary may specify, and in such case amounts from the special reserve fund under paragraph (10) shall be available for costs of shipping, handling, storage, and related costs for such product.

(V) Product approval

The contract shall provide that the vendor seek approval, clearance, or licensing of the product from the Secretary; for a timetable for the development of data and other information to support such approval, clearance, or licensing; and that the Secretary may waive part or all of this contract term on request of the vendor or on the initiative of the Secretary.

(VI) Non-stockpile transfers of security countermeasures

The contract shall provide that the vendor will comply with all applicable export-related controls with respect to such countermeasure.

(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 253(c)(1) of title 41.

(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, may specify—

(aa) the dosing and administration requirements for countermeasures to be developed and procured;

(bb) the amount of funding that will be dedicated by the Secretary for development and acquisition of the countermeasure; and

(cc) the specifications the countermeasure must meet to qualify for procurement under a contract under this section.

(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 403(11) of title 41, for purposes of application to such procurement, pursuant to section 252a(a) of title 41, of—

(aa) section 253(g)(1)(A) of title 41 and its implementing regulations; and

(bb) section 252a(b) of title 41 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 (relating to contract work hours and safety standards).

(bb) Subsections (a) and (b) of section 57 of title 41.

(cc) Section 254d of title 41 (relating to the examination of contractor records).

(dd) Section 3131 of title 40 (relating to bonds of contractors of public buildings or works).

(ee) Subsection (a) of section 254 of title 41 (relating to contingent fees to middlemen).

(ff) Section 6962 of this title.

(gg) Section 1354 of title 31 (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 253(c)(1) of title 41 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 253(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 253(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 253a(a)(1)(B) of title 41 if such request has given notice that the Secretary may so exclude such a source.

(8) Interagency cooperation

(A) In general

In carrying out activities under this section, the Homeland Security Secretary and the Secretary are authorized, subject to subparagraph (B), to enter into interagency agreements and other collaborative undertakings with other agencies of the United States Government. 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, 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.

(9) Restrictions on use of funds

Amounts in the special reserve fund under paragraph (10) shall not be used to pay—

(A) costs for the purchase of vaccines under procurement contracts entered into before July 21, 2004; or

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

(10) Definitions

(A) Special reserve fund

For purposes of this subsection, the term ''special reserve fund'' has the meaning given such term in section 510[1] of the Homeland Security Act of 2002.

(B) Designated congressional committees

For purposes of this section, the term ''designated congressional committees'' means the following committees of the Congress:

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

(ii) In the Senate: the appropriate committees.

(d) Disclosures

No Federal agency shall disclose under section 552 of title 5 any information identifying the location at which materials in the stockpile under subsection (a) of this section are stored.

(e) Definition

For purposes of subsection (a) of this section, the term ''stockpile'' includes—

(1) a physical accumulation (at one or more locations) of the supplies described in subsection (a) of this section; 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) of this section.

(f) Authorization of appropriations

(1) Strategic National Stockpile

For the purpose of carrying out subsection (a) of this section, there are authorized to be appropriated $640,000,000 for fiscal year 2002, and such sums as may be necessary for each of fiscal years 2003 through 2006. Such authorization is in addition to amounts in the special reserve fund referred to in subsection (c)(10)(A) of this section.

(2) Smallpox vaccine development

For the purpose of carrying out subsection (b) of this section, there are authorized to be appropriated $509,000,000 for fiscal year 2002, and such sums as may be necessary for each of fiscal years 2003 through 2006.

(July 1, 1944, ch. 373, title III, § 319F–2, formerly Pub. L. 107–188, title I, § 121, June 12, 2002, 116 Stat. 611; Pub. L. 107–296, title XVII, § 1705(a), Nov. 25, 2002, 116 Stat. 2316; renumbered § 319F–2 of act July 1, 1944, and amended Pub. L. 108–276, § 3(a), July 21, 2004, 118 Stat. 842; Pub. L. 109–417, title I, § 102(c), title IV, §§ 403(b), 406, Dec. 19, 2006, 120 Stat. 2834, 2874, 2879.)

[1] See References in Text note below.

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (c)(1)(B)(i)(III)(aa), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended. Chapter V of the Act is classified generally to subchapter V (§ 351 et seq.) of chapter 9 of Title 21, Food and Drugs. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

The Project BioShield Act of 2004, referred to in subsec. (c)(7)(C)(iii)(IV), is Pub. L. 108–276, July 21, 2004, 118 Stat. 835. For complete classification of this Act to the Code, see Short Title of 2004 Amendments note set out under section 201 of this title and Tables.

Section 510 of the Homeland Security Act of 2002, referred to in subsec. (c)(10)(A), probably means section 510 of Pub. L. 107–296 as added by Pub. L. 108–276, which defines ''special reserve fund'', and which was renumbered section 521 of that Act by Pub. L. 109–295, title VI, § 611(7), Oct. 4, 2006, 120 Stat. 1395, and is classified to section 321j of Title 6, Domestic Security. Another section 510 of Pub. L. 107–296, relating to urban and other high risk area communications capabilities, was classified to section 321 of Title 6, prior to repeal by Pub. L. 109–295, title VI, § 611(5), Oct. 4, 2006, 120 Stat. 1395. Another section 510 of Pub. L. 107–296, relating to credentialing and typing, is classified to section 320 of Title 6.

CODIFICATION

Section was formerly classified to section 300hh–12 of this title prior to renumbering by Pub. L. 108–276.

AMENDMENTS

2006—Pub. L. 109–417, § 406(1), inserted ''and security countermeasure procurements'' after ''Stockpile'' in section catchline.

Subsec. (a)(1). Pub. L. 109–417, § 102(c), inserted ''in collaboration with the Director of the Centers for Disease Control and Prevention, and'' after ''The Secretary,'' and inserted at end ''The Secretary shall conduct an annual review (taking into account at-risk individuals) of the contents of the stockpile, including non-pharmaceutical supplies, and make necessary additions or modifications to the contents based on such review.''

Subsec. (c). Pub. L. 109–417, § 406(2)(A), struck out ''biomedical'' before ''countermeasures'' in heading.

Subsec. (c)(1)(B)(i)(I). Pub. L. 109–417, § 403(b), which directed amendment of section 319F–2(c)(1)(B) by substituting ''diagnose, mitigate, prevent, or treat'' for ''treat, identify, or prevent'' wherever appearing, was executed by making the substitution in two places in subsec. (c)(1)(B)(i)(I) of this section, which is section 319F–2 of the Public Health Service Act, to reflect the probable intent of Congress.

Subsec. (c)(3). Pub. L. 109–417, § 406(2)(B), designated existing provisions as subpar. (A), inserted heading, and added subpar. (B).

Subsec. (c)(4)(A). Pub. L. 109–417, § 406(2)(C), inserted ''not developed or'' after ''currently'' in introductory provisions.

Subsec. (c)(5)(B)(i). Pub. L. 109–417, § 406(2)(D), substituted ''to meet the stockpile needs'' for ''to meet the needs of the stockpile''.

Subsec. (c)(7)(B). Pub. L. 109–417, § 406(2)(E), substituted ''cost'' for ''costs'' in subpar. heading, struck out cl. (i) designation and heading before ''The Homeland'', and struck out heading and text of cl. (ii). Text read as follows: ''The actual costs to the Secretary under this section, other than the costs described in clause (i), shall be paid from the appropriation provided for under subsection (f)(1) of this section.''

Subsec. (c)(7)(C)(ii)(I). Pub. L. 109–417, § 406(2)(F)(i), amended heading and text of subcl. (I) generally. Prior to amendment, text read as follows: ''The contract shall provide that no payment may be made until delivery has been made of a portion, acceptable to the Secretary, of the total number of units contracted for, except that, notwithstanding any other provision of law,

the contract may provide that, if the Secretary determines (in the Secretary's discretion) that an advance payment is necessary to ensure success of a project, the Secretary may pay an amount, not to exceed 10 percent of the contract amount, in advance of delivery. The contract shall provide that such advance payment is required to be repaid if there is a failure to perform by the vendor under the contract. Nothing in this subclause may be construed as affecting rights of vendors under provisions of law or regulation (including the Federal Acquisition Regulation) relating to termination of contracts for the convenience of the Government.''

Subsec. (c)(7)(C)(ii)(VII) to (IX). Pub. L. 109–417, §406(2)(F)(ii), added subcls. (VII) to (IX).

Subsec. (c)(8)(A). Pub. L. 109–417, §406(2)(G), inserted at end ''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, except that all such orders shall be processed under the terms established under this subsection for the procurement of countermeasures.''

2004—Pub. L. 108–276, §3(a)(2), amended section generally. Prior to amendment, text related in subsec. (a) to Strategic National Stockpile, in subsec. (b) to smallpox vaccine development, in subsec. (c) to disclosures, in subsec. (d) to definition of ''stockpile'', and in subsec. (e) to authorization of appropriations.

2002—Subsec. (a)(1). Pub. L. 107–296, §1705(a)(1), substituted ''The Secretary of Homeland Security'' for ''The Secretary of Health and Human Services'' and inserted ''the Secretary of Health and Human Services and'' after ''in coordination with'' and ''of Health and Human Services'' after ''as are determined by the Secretary''.

Subsecs. (a)(2), (b)(1). Pub. L. 107–296, §1705(a)(2), inserted ''of Health and Human Services'' after ''Secretary'' wherever appearing.

CHANGE OF NAME

Committee on Government Reform of House of Representatives changed to Committee on Oversight and Government Reform of House of Representatives by House Resolution No. 6, One Hundred Tenth Congress, Jan. 5, 2007.

EFFECTIVE DATE OF 2002 AMENDMENT

Pub. L. 107–296, title XVII, §1705(b), Nov. 25, 2002, 116 Stat. 2316, provided that: ''The amendments made by this section [amending this section] shall take effect on the date of transfer of the Strategic National Stockpile of the Department of Health and Human Services to the Department [of Homeland Security].''

STOCKPILE FUNCTIONS TRANSFERRED

Pub. L. 108–276, §3(c)(1),(2), July 21, 2004, 118 Stat. 853, provided that:

''(1) IN GENERAL.—Except as provided in paragraph (2), there shall be transferred to the Secretary of Health and Human Services the functions, personnel, assets, unexpended balances, and liabilities of the Strategic National Stockpile, including the functions of the Secretary of Homeland Security relating thereto.

''(2) EXCEPTIONS.—

''(A) FUNCTIONS.—The transfer of functions pursuant to paragraph (1) shall not include such functions as are explicitly assigned to the Secretary of Homeland Security by this Act [see Short Title of 2004 Amendments note set out under section 201 of this title] (including the amendments made by this Act).

''(B) ASSETS AND UNEXPENDED BALANCES.—The transfer of assets and unexpended balances pursuant to paragraph (1) shall not include the funds appropriated under the heading 'BIODEFENSE COUNTERMEASURES' in the Department of Homeland Security Appropriations Act, 2004 (Public Law 108–90 [117 Stat. 1148]).''

POTASSIUM IODIDE

Pub. L. 107–188, title I, §127, June 12, 2002, 116 Stat. 615, provided that:

''(a) IN GENERAL.—Through the national stockpile under section 121 [now section 319F–2 of act July 1, 1944, this section], the President, subject to subsections (b) and (c), shall make available to State and local governments potassium iodide tablets for stockpiling and for distribution as appropriate to public facilities, such as schools and hospitals, in quantities sufficient to provide adequate protection for the population within 20 miles of a nuclear power plant.

''(b) STATE AND LOCAL PLANS.—

''(1) IN GENERAL.—Subsection (a) applies with respect to a State or local government, subject to paragraph (2), if the government involved meets the following conditions:

''(A) Such government submits to the President a plan for the stockpiling of potassium iodide tablets, and for the distribution and utilization of potassium iodide tablets in the event of a nuclear incident.

''(B) The plan is accompanied by certifications by such government that the government has not already received sufficient quantities of potassium iodide tablets from the Federal Government.

''(2) LOCAL GOVERNMENTS.—Subsection (a) applies with respect to a local government only if, in addition to the conditions described in paragraph (1), the following conditions are met:

''(A) The State in which the locality involved is located—

''(i) does not have a plan described in paragraph (1)(A); or

''(ii) has a plan described in such paragraph, but the plan does not address populations at a distance greater than 10 miles from the nuclear power plant involved.

''(B) The local government has petitioned the State to modify the State plan to address such populations, not exceeding 20 miles from such plant, and 60 days have elapsed without the State modifying the State plan to address populations at the full distance sought by the local government through the petition.

''(C) The local government has submitted its local plan under paragraph (1)(A) to the State, and the State has approved the plan and certified that the plan is not inconsistent with the State emergency plan.

''(c) GUIDELINES.—Not later than one year after the date of the enactment of this Act [June 12, 2002], the President, in consultation with individuals representing appropriate Federal, State, and local agencies, shall establish guidelines for the stockpiling of potassium iodide tablets, and for the distribution and utilization of potassium iodide tablets in the event of a nuclear incident. Such tablets may not be made available under subsection (a) until such guidelines have been established.

''(d) INFORMATION.—The President shall carry out activities to inform State and local governments of the program under this section.

''(e) REPORTS.—

''(1) PRESIDENT.—Not later than six months after the date on which the guidelines under subsection (c) are issued, the President shall submit to the Congress a report—

''(A) on whether potassium iodide tablets have been made available under subsection (a) or other Federal, State, or local programs, and the extent to which State and local governments have established stockpiles of such tablets; and

''(B) the measures taken by the President to implement this section.

''(2) NATIONAL ACADEMY OF SCIENCES.—

''(A) IN GENERAL.—The President shall request the National Academy of Sciences to enter into an agreement with the President under which the Academy conducts a study to determine what is the most effective and safe way to distribute and administer potassium iodide tablets on a mass scale. If the Academy declines to conduct the study, the President shall enter into an agreement with another appropriate public or nonprofit private entity to conduct the study.

''(B) REPORT.—The President shall ensure that, not later than six months after the date of the enactment of this Act [June 12, 2002], the study required in subparagraph (A) is completed and a report describing the findings made in the study is submitted to the Congress.

''(f) APPLICABILITY.—Subsections (a) and (d) cease to apply as requirements if the President determines that there is an alternative and more effective prophylaxis or preventive measures for adverse thyroid conditions that may result from the release of radionuclides from nuclear power plants.''

[Memorandum of President of the United States, July 3, 2007, 72 F.R. 37627, provided:

[Memorandum for the Secretary of Health and Human Services[,] the Secretary of Energy[,] the Secretary of Homeland Security[,] the Chairman of the Nuclear Regulatory Commission[, and] the Director of the Office of Science and Technology Policy

[By the authority vested in me as President by the Constitution and the laws of the United States, including section 301 of title 3, United States Code, and section 204(b) of the National Science and Technology Policy, Organization, and Priorities Act of 1976, as amended (42 U.S.C. 6613(b)), the functions of the President under section 127 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107–188) (42 U.S.C. 247d–6b note) are assigned as follows:

[(1) the function of making a determination under subsection 127(f) of Public Law 107–188 is assigned to the Director of the Office of Science and Technology Policy; and

[(2) the functions of the President under section 127 of Public Law 107–188 other than that assigned under subsection 127(f) are assigned to the Chairman of the Nuclear Regulatory Commission.

[In the performance of such functions the Chairman and the Director should consult each other and the Secretaries of Health and Human Services, Energy, and Homeland Security, as appropriate.

[The Director is authorized and directed to publish this memorandum in the Federal Register.]

DESIGNATION AND AUTHORIZATION TO PERFORM FUNCTIONS UNDER SECTION 319F–2 OF THE PUBLIC HEALTH SERVICE ACT

Memorandum of President of the United States, Oct. 21, 2004, 69 F.R. 70349, provided:

Memorandum for the Director of the Office of Management and Budget

By the authority vested in me by the Constitution and the laws of the United States of America, including section 301 of title 3, United States Code, I hereby direct you to perform the functions vested in the President under section 319F–2(c)(6) of the Public Health Service Act, 42 U.S.C. 247d–6b(c)(6).

Any reference in this memorandum to the provision of any Act shall be deemed to include references to any hereafter-enacted provision of law that is the same or substantially the same as such provision.

You are authorized and directed to publish this memorandum in the Federal Register.

GEORGE W. BUSH.

§ 247d–6c. Reports regarding authorities under this Act

(a) Secretary of Health and Human Services

(1) Annual reports on particular exercises of authority

(A) Relevant authorities

The Secretary of Health and Human Services (referred to in this subsection as the ''Secretary'') shall submit reports in accordance with subparagraph (B) regarding the exercise of authority under the following provisions of law:

(i) With respect to section 247d–6a of this title:

(I) Subsection (b)(1) (relating to increased simplified acquisition threshold).

(II) Subsection (b)(2) (relating to procedures other than full and open competition).

(III) Subsection (c) (relating to expedited peer review procedures).

(ii) With respect to section 247d–6b of this title:

(I) Subsection (c)(7)(C)(iii) (relating to simplified acquisition procedures).

(II) Subsection (c)(7)(C)(iv) (relating to procedures other than full and open competition).

(III) Subsection (c)(7)(C)(v) (relating to premium provision in multiple-award contracts).

(iii) With respect to section 360bbb–3 of title 21:

(I) Subsection (a)(1) (relating to emergency uses of certain drugs and devices).

(II) Subsection (b)(1) (relating to a declaration of an emergency).

(III) Subsection (e) (relating to conditions on authorization).

(B) Contents of reports

The Secretary shall annually submit to the designated congressional committees a report that summarizes—

(i) the particular actions that were taken under the authorities specified in subparagraph (A), including, as applicable, the identification of the threat agent, emergency, or the biomedical countermeasure with respect to which the authority was used;

(ii) the reasons underlying the decision to use such authorities, including, as applicable, the options that were considered and rejected with respect to the use of such authorities;

(iii) the number of, nature of, and other information concerning the persons and entities that received a grant, cooperative agreement, or contract pursuant to the use of such authorities, and the persons and entities that were considered and rejected for such a grant, cooperative agreement, or contract, except that the report need not disclose the identity of any such person or entity; and

(iv) whether, with respect to each procurement that is approved by the President under section 247d–6b(c)(6) of this

title, a contract was entered into within one year after such approval by the President.

(2) Annual summaries regarding certain activity

The Secretary shall annually submit to the designated congressional committees a report that summarizes the activity undertaken pursuant to the following authorities under section 247d–6a of this title:

(A) Subsection (b)(3) (relating to increased micropurchase threshold).

(B) Subsection (d) (relating to authority for personal services contracts).

(C) Subsection (e) (relating to streamlined personnel authority).

With respect to subparagraph (B), the report shall include a provision specifying, for the one-year period for which the report is submitted, the number of persons who were paid amounts greater than $100,000 and the number of persons who were paid amounts between $50,000 and $100,000.

(3) Report on additional barriers to procurement of security countermeasures

Not later than one year after July 21, 2004, the Secretary, in consultation with the Secretary of Homeland Security, shall report to the designated congressional committees any potential barriers to the procurement of security countermeasures that have not been addressed by this Act.

(b) Government Accountability Office review

(1) In general

Four years after July 21, 2004, the Comptroller General of the United States shall initiate a study—

(A)(i) to review the Secretary of Health and Human Services' utilization of the authorities granted under this Act with respect to simplified acquisition procedures, procedures other than full and open competition, increased micropurchase thresholds, personal services contracts, streamlined personnel authority, and the purchase of security countermeasures under the special reserve fund; and

(ii) to make recommendations to improve the utilization or effectiveness of such authorities in the future;

(B)(i) to review and assess the adequacy of the internal controls instituted by such Secretary with respect to such authorities, where required by this Act; and

(ii) to make recommendations to improve the effectiveness of such controls;

(C)(i) to review such Secretary's utilization of the authority granted under this Act to authorize an emergency use of a biomedical countermeasure, including the means by which the Secretary determines whether and under what conditions any such authorizations should be granted and the benefits and adverse impacts, if any, resulting from the use of such authority; and

(ii) to make recommendations to improve the utilization or effectiveness of such authority and to enhance protection of the public health;

(D) to identify any purchases or procurements that would not have been made or would have been significantly delayed except for the authorities described in subparagraph (A)(i); and

(E)(i) to determine whether and to what extent activities undertaken pursuant to the biomedical countermeasure research and development authorities established in this Act have enhanced the development of biomedical countermeasures affecting national security; and

(ii) to make recommendations to improve the ability of the Secretary to carry out these activities in the future.

(2) Additional provisions regarding determination on development of biomedical countermeasures affecting national security

In the report under paragraph (1), the determination under subparagraph (E) of such paragraph shall include—

(A) the Comptroller General's assessment of the current availability of countermeasures to address threats identified by the Secretary of Homeland Security;

(B) the Comptroller General's assessment of the extent to which programs and activities under this Act will reduce any gap between the threat and the availability of countermeasures to an acceptable level of risk; and

(C)(i) the Comptroller General's assessment of threats to national security that are posed by technology that will enable, during the 10-year period beginning on July 21, 2004, the development of antibiotic resistant, mutated, or bioengineered strains of biological agents; and

(ii) recommendations on short-term and long-term governmental strategies for addressing such threats, including recommendations for Federal policies regarding research priorities, the development of countermeasures, and investments in technology.

(3) Report

A report providing the results of the study under paragraph (1) shall be submitted to the designated congressional committees not later than five years after July 21, 2004.

(c) Report regarding biocontainment facilities

Not later than 120 days after July 21, 2004, the Secretary of Homeland Security and the Secretary of Health and Human Services shall jointly report to the designated congressional committees whether there is a lack of adequate large-scale biocontainment facilities necessary for the testing of security countermeasures in accordance with Food and Drug Administration requirements.

(d) Designated congressional committees

For purposes of this section, the term ''designated congressional committees'' means the following committees of the Congress:

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

(2) In the Senate: the appropriate committees.

(Pub. L. 108–276, § 5, July 21, 2004, 118 Stat. 860.)

REFERENCES IN TEXT

This Act, referred to in subsecs. (a)(3) and (b)(1), (2)(B), is Pub. L. 108–276, July 21, 2004, 118 Stat. 835, known as the Project BioShield Act of 2004. For complete classification of this Act to the Code, see Short Title of 2004 Amendments note set out under section 201 of this title and Tables.

CODIFICATION

Section was enacted as part of the Project BioShield Act of 2004, and not as part of the Public Health Service Act which comprises this chapter.

CHANGE OF NAME

Committee on Government Reform of House of Representatives changed to Committee on Oversight and Government Reform of House of Representatives by House Resolution No. 6, One Hundred Tenth Congress, Jan. 5, 2007.

§ 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) of this section has been issued with respect to such countermeasure.

(2) Scope of claims for loss

(A) Loss

For purposes of this section, the term ''loss'' means any type of loss, including—

(i) death;

(ii) physical, mental, or emotional injury, illness, disability, or condition;

(iii) fear of physical, mental, or emotional injury, illness, disability, or condition, including any need for medical monitoring; and

(iv) loss of or damage to property, including business interruption loss.

Each of clauses (i) through (iv) applies without regard to the date of the occurrence, presentation, or discovery of the loss described in the clause.

(B) Scope

The immunity under paragraph (1) applies to any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure, including a causal relationship with the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use of such countermeasure.

(3) Certain conditions

Subject to the other provisions of this section, immunity under paragraph (1) with respect to a covered countermeasure applies only if—

(A) the countermeasure was administered or used during the effective period of the declaration that was issued under subsection (b) of this section 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) of this section, the declaration under such subsection provides that subsection (a) of this section 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 this section, 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) of this section 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) of this section 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) of this section 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) of this section 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) of this section is effective only to a particular means of distribution as provided in subsection (a)(5) of this section 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 247d–6b of this title, 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) of this section 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.

(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) of this section, or at any time with respect to conduct undertaken in accordance with such declaration, no State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that—

(A) is different from, or is in conflict with, any requirement applicable under this section; and

(B) relates to the design, development, clinical testing or investigation, formulation, manufacture, distribution, sale, donation, purchase, marketing, promotion, packaging, labeling, licensing, use, any other aspect of safety or efficacy, or the prescribing, dispensing, or administration by qualified persons of the covered countermeasure, or to any matter included in a requirement applicable to the covered countermeasure under this section or any other provision of this chapter, or under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.].

(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) of this section, 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) of this section.

(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) of this section 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) of this section.

(D) Initial rulemaking

Within 180 days after December 30, 2005, 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) of this section, 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) of this section, 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) of this section to constitute willful misconduct, is subject to regulation by this chapter or by the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], such act or omission shall not constitute ''willful misconduct'' for purposes of subsection (d) of this section 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) of this section 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 [21 U.S.C. 355(i), 360j(g)], 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 [21 U.S.C. 360bbb–3], or a suspension or withdrawal, based on willful misconduct, of an approval or clearance under chapter V of such Act [21 U.S.C. 351 et seq.] or of a licensure under section 262 of this title.

(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 [21 U.S.C. 355(i), 360j(g)], a debarment, an investigator disqualification, a revocation of an authorization under section 564 of such Act [21 U.S.C. 360bbb–3], or a suspension or withdrawal of an approval or clearance under chapter 5[1] of such Act or of a licensure under section 262 of this title; 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 [21 U.S.C. 301 et seq.], of this chapter, 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 chapter, under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], under title 18, 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) of this section, the sole exception to the immunity from suit and liability of covered persons set forth in subsection (a) of this section 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) of this section, by such covered person. For purposes of section 2679(b)(2)(B) of title 28, 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) of this section 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) of this section 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) of this section, 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.

[1] So in original. Probably should be chapter ''V''.

(4) Verification, certification, and medical records

(A) In general

In an action under subsection (d) of this section, 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) of this section, 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) of this section 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 and paragraph (3) of subsection (b) of section 2284 of title 28 shall not apply to actions under subsection (d) of this section.

(6) Civil discovery

(A) Timing

In an action under subsection (d) of this section, 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) of this section 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) of this section, 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) of this section.

(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) of this section, 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) of this section, 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) of this section or based on an assertion of the exclusion under subsection (c)(5) of this section.

(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 (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 subchapter XIX of this chapter.

(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 247d–6b(c)(1)(B) of this title); or

(C) a drug (as such term is defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)), biological product (as such term is defined by section 262(i) of this title), 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 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360bbb–3].

(2) Covered person

The term ''covered person'', when used with respect to the administration or use of a covered countermeasure, means—

(A) the United States; or

(B) a person or entity that is—

(i) a manufacturer of such countermeasure;

(ii) a distributor of such countermeasure;

(iii) a program planner of such countermeasure;

(iv) a qualified person who prescribed, administered, or dispensed such countermeasure; or

(v) an official, agent, or employee of a person or entity described in clause (i), (ii), (iii), or (iv).

(3) Distributor

The term ''distributor'' means a person or entity engaged in the distribution of drugs, biologics, or devices, including but not limited to manufacturers; repackers; common carriers; contract carriers; air carriers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies.

(4) Manufacturer

The term ''manufacturer'' includes—

(A) a contractor or subcontractor of a manufacturer;

(B) a supplier or licenser of any product, intellectual property, service, research tool, or component or other article used in the design, development, clinical testing, investigation, or manufacturing of a covered countermeasure; and

(C) any or all of the parents, subsidiaries, affiliates, successors, and assigns of a manufacturer.

(5) Person

The term ''person'' includes an individual, partnership, corporation, association, entity, or public or private corporation, including a

Federal, State, or local government agency or department.

(6) Program planner

The term ''program planner'' means a State or local government, including an Indian tribe, a person employed by the State or local government, or other person who supervised or administered a program with respect to the administration, dispensing, distribution, provision, or use of a security countermeasure or a qualified pandemic or epidemic product, including a person who has established requirements, provided policy guidance, or supplied technical or scientific advice or assistance or provides a facility to administer or use a covered countermeasure in accordance with a declaration under subsection (b) of this section.

(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)),[2] biological product (as such term is defined by section 262(i) of this title), 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))[2] 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; or

(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); and

(B)(i) approved or cleared under chapter V of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 351 et seq.] or licensed under section 262 of this title;

(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 [21 U.S.C. 355(i), 360j(g)]; or

(iii) authorized for emergency use in accordance with section 564 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360bbb–3].

(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) of this section.

[2] So in original. A third closing parenthesis probably should appear.

(9) Security countermeasure

The term ''security countermeasure'' has the meaning given such term in section 247d–6b(c)(1)(B) of this title.

(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.

(July 1, 1944, ch. 373, title III, § 319F–3, as added Pub. L. 109–148, div. C, § 2, Dec. 30, 2005, 119 Stat. 2818.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsecs. (b)(8)(B), (c)(5)(A), (B)(i), (ii)(I), (C)(i), and (i)(7)(B)(i), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§ 301 et seq.) of Title 21, Food and Drugs. Chapter V of the Act is classified generally to subchapter V (§ 351 et seq.) of chapter 9 of Title 21. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

The Federal Rules of Civil Procedure, referred to in subsec. (e)(6)(B), (9), are set out in the Appendix to Title 28, Judiciary and Judicial Procedure.

The Public Readiness and Emergency Preparedness Act, referred to in subsec. (h), is div. C of Pub. L. 109–148, Dec. 30, 2005, 119 Stat. 2818, which enacted this section, section 247d–6e of this title, and provisions set out as a note under section 201 of this title. For complete classification of this Act to the Code, see Short Title of 2005 Amendment note set out under section 201 of this title and Tables.

§ 247d–6e. Covered countermeasure process

(a) Establishment of Fund

Upon the issuance by the Secretary of a declaration under section 247d–6d(b) of this title, 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 247d–6d(b) of this title, the Secretary shall, after amounts have by law been provided for the Fund under subsection (a) of this section, 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 239c, 239d, and 239e of this title in the case of certain individuals injured as a result of administration of certain countermeasures against smallpox, except that section 239e(a)(2)(B) of this title 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 239e of this title.

(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 239a of this title (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 239b of this title (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 239a, 239b, 239c, 239d, and 239e of this title 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 239b of this title'' 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 247d–6d of this title 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 247d–6d(d) of this title against a covered person (as such term is defined in section 247d–6d(i)(2) of this title) unless such individual has exhausted such remedies as are available under subsection (a) of this section, except that if amounts have not by law been provided for the Fund under subsection (a) of this section, 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 247d–6d(d) of this title.

(2) Tolling of statute of limitations

The time limit for filing a civil action under section 247d–6d(d) of this title for an injury or death shall be tolled during the pendency of a claim for compensation under subsection (a) of this section.

(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, to exhaust administrative remedies.

(4) Exclusivity

The remedy provided by subsection (a) of this section shall be exclusive of any other civil action or proceeding for any claim or suit this section encompasses, except for a proceeding under section 247d–6d of this title.

(5) Election

If under subsection (a) of this section 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 247d–6d(d) of this title. 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 247d–6d of this title.

(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 247d–6d(b) of this title.

(5) Eligible individual

The term ''eligible individual'' means an individual who is determined, in accordance with subsection (b) of this section, to be a covered individual who sustains a covered injury.

(July 1, 1944, ch. 373, title III, § 319F–4, as added Pub. L. 109–148, div. C, § 3, Dec. 30, 2005, 119 Stat. 2829.)

REFERENCES IN TEXT

H. Con. Res. 95 of the 109th Congress, referred to in subsec. (a), is H. Con. Res. 95, Apr. 28, 2005, 119 Stat. 3633, which is not classified to the Code.

§ 247d–7. Demonstration program to enhance bioterrorism training, coordination, and readiness

(a) In general

The Secretary shall make grants to not more than three eligible entities to carry out demonstration programs to improve the detection of pathogens likely to be used in a bioterrorist attack, the development of plans and measures to respond to bioterrorist attacks, and the training of personnel involved with the various responsibilities and capabilities needed to respond to acts of bioterrorism upon the civilian population. Such awards shall be made on a competitive basis and pursuant to scientific and technical review.

(b) Eligible entities

Eligible entities for grants under subsection (a) of this section are States, political subdivisions of States, and public or private non-profit organizations.

(c) Specific criteria

In making grants under subsection (a) of this section, the Secretary shall take into account the following factors:

(1) Whether the eligible entity involved is proximate to, and collaborates with, a major research university with expertise in scientific training, identification of biological agents, medicine, and life sciences.

(2) Whether the entity is proximate to, and collaborates with, a laboratory that has expertise in the identification of biological agents.

(3) Whether the entity demonstrates, in the application for the program, support and participation of State and local governments and research institutions in the conduct of the program.

(4) Whether the entity is proximate to, and collaborates with, or is, an academic medical center that has the capacity to serve an uninsured or underserved population, and is equipped to educate medical personnel.

(5) Such other factors as the Secretary determines to be appropriate.

(d) Duration of award

The period during which payments are made under a grant under subsection (a) of this section may not exceed 5 years. The provision of such payments shall be subject to annual approval by the Secretary of the payments and subject to the availability of appropriations for the fiscal year involved to make the payments.

(e) Supplement not supplant

Grants under subsection (a) of this section shall be used to supplement, and not supplant, other Federal, State, or local public funds provided for the activities described in such subsection.

(f) Government Accountability Office report

Not later than 180 days after the conclusion of the demonstration programs carried out under subsection (a) of this section, the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate, and the Committee on Commerce and the Committee on Appropriations of the House of Representatives, a report that describes the ability of grantees under such subsection to detect pathogens likely to be used in a bioterrorist attack, develop plans and measures for dealing with such threats, and train personnel involved with the various responsibilities and capabilities needed to deal with bioterrorist threats.

(g) Authorization of appropriations

There is authorized to be appropriated to carry out this section $6,000,000 for fiscal year 2001, and such sums as may be necessary through fiscal year 2006.

(July 1, 1944, ch. 373, title III, § 319G, as added Pub. L. 106–505, title I, § 102, Nov. 13, 2000, 114 Stat. 2323; amended Pub. L. 108–271, § 8(b), July 7, 2004, 118 Stat. 814.)

AMENDMENTS

2004—Subsec. (f). Pub. L. 108–271 substituted ''Government Accountability Office'' for ''General Accounting Office'' in heading.

CHANGE OF NAME

Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of

House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

§ 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 295p of this title, 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) of this section 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.

(July 1, 1944, ch. 373, title III, § 319H, as added Pub. L. 107–188, title I, § 106, June 12, 2002, 116 Stat. 607.)

§ 247d–7b. Emergency system for advance registration of health professions volunteers

(a) In general

Not later than 12 months after December 19, 2006, the Secretary shall link existing State verification systems to maintain a single national interoperable network of systems, each system being maintained by a State or group of States, for the purpose of verifying the credentials and licenses of health care professionals who volunteer to provide health services during a public health emergency.

(b) Requirements

The interoperable network of systems established under subsection (a) (referred to in this section as the ''verification network'') shall include—

(1) with respect to each volunteer health professional included in the verification network—

(A) information necessary for the rapid identification of, and communication with, such professionals; and

(B) the credentials, certifications, licenses, and relevant training of such individuals; and

(2) the name of each member of the Medical Reserve Corps, the National Disaster Medical System, and any other relevant federally-sponsored or administered programs determined necessary by the Secretary.

(c) Other assistance

The Secretary may make grants and provide technical assistance to States and other public or nonprofit private entities for activities relating to the verification network developed under subsection (a) of this section.

(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 300hh–15 of this title.

(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 300hh–11(c) of this title or otherwise. Such appointment may only be made under section 300hh–11 or 300hh–15 of this title.

(i) Health care provider licenses

The Secretary shall encourage States to establish and implement mechanisms to waive the application of licensing requirements applicable to health professionals, who are seeking to provide medical services (within their scope of practice), during a national, State, local, or tribal public health emergency upon verification that such health professionals are licensed and in good standing in another State and have not been disciplined by any State health licensing or disciplinary board.

(j) Rule of construction

This section may not be construed as authorizing the Secretary to issue requirements regarding the provision by the States of credentials, licenses, accreditations, or hospital privileges.

(k) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated $2,000,000

for fiscal year 2002, and such sums as may be necessary for each of the fiscal years 2003 through 2011.

(July 1, 1944, ch. 373, title III, § 319I, as added Pub. L. 107–188, title I, § 107, June 12, 2002, 116 Stat. 608; amended Pub. L. 109–417, title III, § 303(b), Dec. 19, 2006, 120 Stat. 2857.)

AMENDMENTS

2006—Subsecs. (a), (b). Pub. L. 109–417, § 303(b)(2), added subsecs. (a) and (b) and struck out former subsecs. (a) and (b) which related to establishment of a verification system and provisions regarding its promptness and efficiency.

Subsec. (c). Pub. L. 109–417, § 303(b)(3), substituted ''network'' for ''system''.

Subsecs. (d) to (k). Pub. L. 109–417, § 303(b)(1), (4), (5), added subsecs. (d) to (i), redesignated former subsecs. (e) and (f) as (j) and (k), respectively, substituted ''2011'' for ''2006'' in subsec. (k), and struck out heading and text of former subsec. (d). Text read as follows: ''The Secretary may encourage each State to provide legal authority during a public health emergency for health professionals authorized in another State to provide certain health services to provide such health services in the State.''

§ 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 247d through 247d–7b of this title or section 247d–7d of this title, the Secretary may, subject to subsection (b) of this section, 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) of this section, 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.

(July 1, 1944, ch. 373, title III, § 319J, as added Pub. L. 107–188, title I, § 110, June 12, 2002, 116 Stat. 611.)

§ 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 247d–6(h)(4) of this title).

(b) Guidelines

The Secretary may develop guidelines to enable entities eligible to receive assistance under subsection (a) of this section to secure their facilities against potential terrorist attack.

(July 1, 1944, ch. 373, title III, § 319K, as added Pub. L. 107–188, title I, § 124, June 12, 2002, 116 Stat. 614.)

§ 247d–7e. Biomedical Advanced Research and Development Authority

(a) Definitions

In this section:

(1) BARDA

The term ''BARDA'' means the Biomedical Advanced Research and Development Authority.

(2) Fund

The term ''Fund'' means the Biodefense Medical Countermeasure Development Fund established under subsection (d).

(3) Other transactions

The term ''other transactions'' means transactions, other than procurement contracts, grants, and cooperative agreements, such as the Secretary of Defense may enter into under section 2371 of title 10.

(4) Qualified countermeasure

The term ''qualified countermeasure'' has the meaning given such term in section 247d–6a of this title.

(5) Qualified pandemic or epidemic product

The term ''qualified pandemic or epidemic product'' has the meaning given the term in section 247d–6d of this title.

(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 [21 U.S.C. 301 et seq.] or under section 262 of this title.

(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 [21 U.S.C. 301 et seq.] or under section 262 of this title 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 im-

prove and make available new technologies to increase manufacturing surge capacity;

(iv) activities to improve the shelf-life of the product or technologies for administering the product; and

(v) such other activities as are part of the advanced stages of testing, refinement, improvement, or preparation of the product for such use and as are specified by the Secretary.

(7) Security countermeasure

The term ''security countermeasure'' has the meaning given such term in section 247d–6b of this title.

(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 December 19, 2006, the Secretary shall develop and make public a strategic plan to integrate biodefense and emerging infectious disease requirements with the advanced research and development, strategic initiatives for innovation, and the procurement of qualified countermeasures and qualified pandemic or epidemic products. The Secretary shall carry out such activities as may be practicable to disseminate the information contained in such plan to persons who may have the capacity to substantially contribute to the activities described in such strategic plan. The Secretary shall update and incorporate such plan as part of the National Health Security Strategy described in section 300hh–1 of this title.

(2) Content

The strategic plan under paragraph (1) shall guide—

(A) research and development, conducted or supported by the Department of Health and Human Services, of qualified countermeasures and qualified pandemic or epidemic products against possible biological, chemical, radiological, and nuclear agents and to emerging infectious diseases;

(B) innovation in technologies that may assist advanced research and development of qualified countermeasures and qualified pandemic or epidemic products (such research and development referred to in this section as ''countermeasure and product advanced research and development''); and

(C) procurement of such qualified countermeasures and qualified pandemic or epidemic products by such Department.

(c) Biomedical Advanced Research and Development Authority

(1) Establishment

There is established within the Department of Health and Human Services the Biomedical Advanced Research and Development Authority.

(2) In general

Based upon the strategic plan described in subsection (b), the Secretary shall coordinate the acceleration of countermeasure and product advanced research and development by—

(A) facilitating collaboration between the Department of Health and Human Services and other Federal agencies, relevant industries, academia, and other persons, with respect to such advanced research and development;

(B) promoting countermeasure and product advanced research and development;

(C) facilitating contacts between interested persons and the offices or employees authorized by the Secretary to advise such persons regarding requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] and under section 262 of this title; and

(D) promoting innovation to reduce the time and cost of countermeasure and product advanced research and development.

(3) Director

The BARDA shall be headed by a Director (referred to in this section as the ''Director'') who shall be appointed by the Secretary and to whom the Secretary shall delegate such functions and authorities as necessary to implement this section.

(4) Duties

(A) Collaboration

To carry out the purpose described in paragraph (2)(A), the Secretary shall—

(i) facilitate and increase the expeditious and direct communication between the Department of Health and Human Services and relevant persons with respect to countermeasure and product advanced research and development, including by—

(I) facilitating such communication regarding the processes for procuring such advanced research and development with respect to qualified countermeasures and qualified pandemic or epidemic products of interest; and

(II) soliciting information about and data from research on potential qualified countermeasures and qualified pandemic or epidemic products and related technologies;

(ii) at least annually—

(I) convene meetings with representatives from relevant industries, academia, other Federal agencies, international agencies as appropriate, and other interested persons;

(II) sponsor opportunities to demonstrate the operation and effectiveness of relevant biodefense countermeasure technologies; and

(III) convene such working groups on countermeasure and product advanced research and development as the Secretary may determine are necessary to carry out this section; and

(iii) carry out the activities described in section 405 of the Pandemic and All-Hazards Preparedness Act.

(B) Support advanced research and development

To carry out the purpose described in paragraph (2)(B), the Secretary shall—

(i) conduct ongoing searches for, and support calls for, potential qualified countermeasures and qualified pandemic or epidemic products;

(ii) direct and coordinate the countermeasure and product advanced research and development activities of the Department of Health and Human Services;

(iii) establish strategic initiatives to accelerate countermeasure and product advanced research and development and innovation in such areas as the Secretary may identify as priority unmet need areas; and

(iv) award contracts, grants, cooperative agreements, and enter into other transactions, for countermeasure and product advanced research and development.

(C) Facilitating advice

To carry out the purpose described in paragraph (2)(C) the Secretary shall—

(i) connect interested persons with the offices or employees authorized by the Secretary to advise such persons regarding the regulatory requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] and under section 262 of this title related to the approval, clearance, or licensure of qualified countermeasures or qualified pandemic or epidemic products; and

(ii) with respect to persons performing countermeasure and product advanced research and development funded under this section, enable such offices or employees to provide to the extent practicable such advice in a manner that is ongoing and that is otherwise designed to facilitate expeditious development of qualified countermeasures and qualified pandemic or epidemic products that may achieve such approval, clearance, or licensure.

(D) Supporting innovation

To carry out the purpose described in paragraph (2)(D), the Secretary may award contracts, grants, and cooperative agreements, or enter into other transactions, such as prize payments, to promote—

(i) innovation in technologies that may assist countermeasure and product advanced research and development;

(ii) research on and development of research tools and other devices and technologies; and

(iii) research to promote strategic initiatives, such as rapid diagnostics, broad spectrum antimicrobials, and vaccine manufacturing technologies.

(5) Transaction authorities

(A) Other transactions

(i) In general

The Secretary shall have the authority to enter into other transactions under this subsection in the same manner as the Secretary of Defense enters into such transactions under section 2371 of title 10.

(ii) Limitations on authority

(I) In general

Subsections (b), (c), and (h) of section 845 of the National Defense Authorization Act for Fiscal Year 1994 (10 U.S.C. 2371 note) shall apply to other transactions under this subparagraph as if such transactions were for prototype projects described by subsection (a) of such section 845.

(II) Written determinations required

The authority of this subparagraph may be exercised for a project that is expected to cost the Department of Health and Human Services in excess of $20,000,000 only upon a written determination by the senior procurement executive for the Department (as designated for purpose of section 414(c) of title 41), that the use of such authority is essential to promoting the success of the project. The authority of the senior procurement executive under this subclause may not be delegated.

(iii) Guidelines

The Secretary shall establish guidelines regarding the use of the authority under clause (i). Such guidelines shall include auditing requirements.

(B) Expedited authorities

(i) In general

In awarding contracts, grants, and cooperative agreements, and in entering into other transactions under subparagraph (B) or (D) of paragraph (4), the Secretary shall have the expedited procurement authorities, the authority to expedite peer review, and the authority for personal services contracts, supplied by subsections (b), (c), and (d) of section 247d–6a of this title.

(ii) Application of provisions

Provisions in such section 247d–6a of this title 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 247d–6a(b)(1)(D) of this title 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 or section 5 of title 41 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 253(c)(3) of title 41.

(6) At-risk individuals

In carrying out the functions under this section, the Secretary may give priority to the advanced research and development of qualified countermeasures and qualified pandemic or epidemic products that are likely to be safe and effective with respect to children, pregnant women, elderly, and other at-risk individuals.

(7) Personnel authorities

(A) Specially qualified scientific and professional personnel

(i) In general

In addition to any other personnel authorities, the Secretary may—

(I) without regard to those provisions of title 5 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 247d–6a(e)(2) of this title.

(iii) Term of appointment

The term limitations described in section 9903(c) of title 5 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 209(f) of this title.

(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 are authorized to be appropriated to the Fund—

(A) $1,070,000,000 for fiscal years 2006 through 2008, the amounts to remain available until expended; and

(B) such sums as may be necessary for subsequent fiscal years, the amounts to remain available until expended.

(e) Inapplicability of certain provisions

(1) Disclosure

(A) In general

The Secretary shall withhold from disclosure under section 552 of title 5 specific technical data or scientific information that is created or obtained during the countermeasure and product advanced research and development carried out under subsection (c) that reveals significant and not otherwise publicly known vulnerabilities of existing medical or public health defenses against biological, chemical, nuclear, or radiological threats. Such information shall be deemed to be information described in section 552(b)(3) of title 5.

(B) Review

Information subject to nondisclosure under subparagraph (A) shall be reviewed by the Secretary every 5 years, or more frequently as determined necessary by the Secretary, to determine the relevance or necessity of continued nondisclosure.

(C) Sunset

This paragraph shall cease to have force or effect on the date that is 7 years after December 19, 2006.

(2) Review

Notwithstanding section 14 of the Federal Advisory Committee Act, a working group of BARDA under this section and the National Biodefense Science Board under section 247d–7f of this title 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.

(July 1, 1944, ch. 373, title III, § 319L, as added Pub. L. 109–417, title IV, § 401, Dec. 19, 2006, 120 Stat. 2865.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsecs. (a)(6)(A)(ii), (B)(i) and (c)(2)(C), (4)(C)(i), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§ 301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

Section 405 of the Pandemic and All-Hazards Preparedness Act, referred to in subsec. (c)(4)(A)(iii), is section 405 of Pub. L. 109–417, which is set out as a note under section 247d–6a of this title.

Section 845 of the National Defense Authorization Act for Fiscal Year 1994, referred to in subsec. (c)(5)(A)(ii)(I), is section 845 of Pub. L. 103–160, which is set out as a note under section 2371 of Title 10, Armed Forces.

The Federal Tort Claims Act, referred to in subsec. (c)(5)(B)(ii), is title IV of act Aug. 2, 1946, ch. 753, 60 Stat. 842, which was classified principally to chapter 20 (§§ 921, 922, 931–934, 941–946) of former Title 28, Judicial Code and Judiciary. Title IV of act Aug. 2, 1946, was substantially repealed and reenacted as sections 1346(b) and 2671 et seq. of Title 28, Judiciary and Judicial Procedure, by act June 25, 1948, ch. 646, 62 Stat. 992, the first section of which enacted Title 28. The Federal Tort Claims Act is also commonly used to refer to chapter 171 of Title 28, Judiciary and Judicial Procedure. For complete classification of title IV to the Code, see Tables. For distribution of former sections of Title 28 into the revised Title 28, see Table at the beginning of Title 28.

Section 14 of the Federal Advisory Committee Act, referred to in subsec. (e)(2), is section 14 of Pub. L. 92–463, which is set out in the Appendix to Title 5, Government Organization and Employees.

§ 247d–7f. 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; and

(ii) one such member shall be an individual from an organization representing healthcare consumers.

(3) Term of appointment

A member of the Board described in subparagraph (B), (C), or (D) of paragraph (2) shall serve for a term of 3 years, except that the Secretary may adjust the terms of the initial Board appointees in order to provide for a staggered term of appointment for all members.

(4) Consecutive appointments; maximum terms

A member may be appointed to serve not more than 3 terms on the Board and may serve not more than 2 consecutive terms.

(5) Duties

The Board shall—

(A) advise the Secretary on current and future trends, challenges, and opportunities presented by advances in biological and life sciences, biotechnology, and genetic engineering with respect to threats posed by naturally occurring infectious diseases and chemical, biological, radiological, and nuclear agents;

(B) at the request of the Secretary, review and consider any information and findings received from the working groups established under subsection (b); and

(C) at the request of the Secretary, provide recommendations and findings for expanded, intensified, and coordinated biodefense research and development activities.

(6) Meetings

(A) Initial meeting

Not later than one year after December 19, 2006, 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 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.

(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 247d–7e of this title and that is used in this section shall have the same meaning in this section as such term is given in section 247d–7e of this title.

(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.

(July 1, 1944, ch. 373, title III, § 319M, as added Pub. L. 109–417, title IV, § 402, Dec. 19, 2006, 120 Stat. 2872.)

§ 247d–8. Coordinated program to improve pediatric oral health

(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 [25 U.S.C. 1651 et seq.], and tribes that contract with the Indian Health Service pursuant to the Indian Self-De-

termination and Education Assistance Act [25 U.S.C. 450 et seq.]) to enable such schools, institutions, and programs to develop programs of oral health promotion, to increase training of oral health services providers in accordance with State practice laws, or to increase the utilization of dental services by eligible children.

(c) Distribution

In awarding grants under this section, the Secretary shall, to the extent practicable, ensure an equitable national geographic distribution of the grants, including areas of the United States where the incidence of early childhood caries is highest.

(d) Authorization of appropriations

There is authorized to be appropriated to carry out this section $10,000,000 for each[1] the fiscal years 2001 through 2005.

(July 1, 1944, ch. 373, title III, § 320A, as added Pub. L. 106–310, div. A, title XVI, § 1603, Oct. 17, 2000, 114 Stat. 1151.)

REFERENCES IN TEXT

The Indian Health Care Improvement Act, referred to in subsec. (b), is Pub. L. 94–437, Sept. 30, 1976, 90 Stat. 1400, as amended. Title V of the Act is classified generally to subchapter IV (§ 1651 et seq.) of chapter 18 of Title 25, Indians. For complete classification of this Act to the Code, see Short Title note set out under section 1601 of Title 25 and Tables.

The Indian Self-Determination and Education Assistance Act, referred to in subsec. (b), is Pub. L. 93–638, Jan. 4, 1975, 88 Stat. 2203, as amended, which is classified principally to subchapter II (§ 450 et seq.) of chapter 14 of Title 25, Indians. For complete classification of this Act to the Code, see Short Title note set out under section 450 of Title 25 and Tables.

CODIFICATION

Section 1603 of Pub. L. 106–310, which directed that section 320A (this section) be added at the end of part B of the Public Health Service Act, was executed by adding section 320A at the end of part B of title III of the Public Health Service Act, to reflect the probable intent of Congress, notwithstanding that section 320 of the Public Health Service Act (section 247e of this title) appears in part C of title III of the Public Health Service Act.

PART C—HOSPITALS, MEDICAL EXAMINATIONS, AND MEDICAL CARE

AMENDMENTS

1978—Pub. L. 95–626, title I, § 113(a)(1), Nov. 10, 1978, 92 Stat. 3562, struck out heading ''Subpart I—General Provisions''.

1976—Pub. L. 94–484, title IV, § 407(a), Oct. 12, 1976, 90 Stat. 2268, added heading ''Subpart I—General Provisions''.

§ 247e. National Hansen's Disease Programs Center

(a) Care and treatment

(1) At or through the National Hansen's Disease Programs Center (located in the State of Louisiana), the Secretary shall without charge provide short-term care and treatment, including outpatient care, for Hansen's disease and related complications to any person determined by the Secretary to be in need of such care and treatment. The Secretary may not at or through such Center provide long-term care for any such disease or complication.

(2) The Center referred to in paragraph (1) shall conduct training in the diagnosis and management of Hansen's disease and related complications, and shall conduct and promote the coordination of research (including clinical research), investigations, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of Hansen's disease and other mycobacterial diseases and complications related to such diseases.

(3) Paragraph (1) is subject to section 211 of the Department of Health and Human Services Appropriations Act, 1998.

(b) Additional sites authorized

In addition to the Center referred to in subsection (a) of this section, 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) Agency designated by Secretary

The Secretary shall carry out subsections (a) and (b) of this section 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) Payments to Board of Health of Hawaii

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) of this section. Payments under this subsection are subject to the availability of appropriations for such purpose.

(July 1, 1944, ch. 373, title III, § 320, formerly § 331, 58 Stat. 698; June 25, 1948, ch. 654, § 4, 62 Stat. 1018; June 25, 1952, ch. 460, 66 Stat. 157; Pub. L. 86–624, § 29(b), July 12, 1960, 74 Stat. 419; renumbered § 339, Pub. L. 94–484, title IV, § 407(b)(2), Oct. 12, 1976, 90 Stat. 2268; renumbered § 320, and amended Pub. L. 95–626, title I, § 105(a), Nov. 10, 1978, 92 Stat. 3560; Pub. L. 96–32, § 7(b), July 10, 1979, 93 Stat. 84; Pub. L. 99–117, § 2(a), Oct. 7, 1985, 99 Stat. 491; Pub. L. 105–78, title II, § 211(h), Nov. 13, 1997, 111 Stat. 1494; Pub. L. 107–220, § 1(a), Aug. 21, 2002, 116 Stat. 1332.)

REFERENCES IN TEXT

Section 211 of the Department of Health and Human Services Appropriations Act, 1998, referred to in subsec. (a)(3), is section 211 of Pub. L. 105–78, which enacted this section and provisions set out as notes below.

CODIFICATION

Section was classified to section 255 of this title prior to its renumbering by Pub. L. 95–626.

[1] So in original. Probably should be followed by ''of''.